

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360382-1

<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>
28.0	F	10-Oct-2009	10-Oct-2009	0	12-Oct-2009	16-Oct-2009	DE		16-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	500760P	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Oropharyngeal pain, Paraesthesia, Paraesthesia oral, Respiratory rate increased

**Symptom Text:** tingling in left lip - progressed to sore throat by 8:45, by 9pm increased resp rate, pain upon i nspiration, tingling in face, and sore throat continued - went to ED by 10pm, given benadryl 25mg, placed on O2 chest xray, lab work. Sent home from ED at 5am - decreased resp rate and tingling subsided

**Other Meds:** yasmin

**Lab Data:** CBC (WBC elevated), Chem7 and D-dimer (elevated), chest xray, urinalysis, nuclear med study.

**History:** Allergic to penicillin, biacin, and latex - no other issues

**Prex Illness:** No illness

**Prex Vax Illns:** none~ ()~~0.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360634-1

<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>
11.0	M	07-Oct-2009	09-Oct-2009	2	13-Oct-2009	16-Oct-2009	CA		16-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Confusional state, Dizziness, Headache, Oropharyngeal pain, Pyrexia

**Symptom Text:** Fecer 100, dizziness, sore throat, confusion, headache.

**Other Meds:** NA

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360731-1

<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>
4.0	F	07-Oct-2009	07-Oct-2009	0	13-Oct-2009	23-Oct-2009	FL		23-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	UT3178BA	2	Left arm	Intramuscular	DTAP IPV MMR

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest pain

**Symptom Text:** Chest pain left side oppressive ( persistent for 2 hours) within 4 hours of getting the flu shot. No associated signs or symptoms.

**Other Meds:**

**Lab Data:** EKG Normal

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360875-1

<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>
11.0	M	09-Oct-2009	09-Oct-2009	0	14-Oct-2009	15-Oct-2009	IA		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)	UNKNOWN MANUFACTURER	500759P	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia, Upper respiratory tract congestion

**Symptom Text:** Patient received H1N1 as flu mist at clinic on October 9, 2009 at 8 AM. Patient developed fever at 101.5F Friday night. Then developed headache and congestion on Saturday, October 10, 2009. Presented to clinic 10/12/09.

**Other Meds:** None

**Lab Data:** Pt seen 10/12/09 no influenza sxs and + rapid influenza A test \*which has had many children ill with influenza sxs - suspect community acquired illness.

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360903-1

<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>
42.0	F	14-Oct-2009	14-Oct-2009	0	14-Oct-2009	15-Oct-2009	LA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP001AA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysgeusia

**Symptom Text:** metallic taste in mouth

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360953-1

<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>
36.0	F	14-Oct-2009	14-Oct-2009	0	15-Oct-2009	29-Oct-2009	FL		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>
	FLU(H1N1)	SANOFI PASTEUR	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Heart rate increased, Hypoaesthesia, Immediate post-injection reaction, Nausea

**Symptom Text:** Client c/o nausea immediately following the shot, headache 2 1/2 hrs after and dizziness 3 1/2 hrs after, felt fast heart rate which lasted for 15 mins, numbness (L) breast, had on 3 pillows last night. Did not take any meds. Is still c/o slight dizziness today. Patient recovering still c/o slight nausea and dizziness.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360954-1

<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>
36.0	F	15-Oct-2009	15-Oct-2009	0	15-Oct-2009	29-Oct-2009	PA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP002AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pruritus generalised

**Symptom Text:** Five minutes after receiving injectable H1N1 vaccine, developed dry cough & generalized itching.

**Other Meds:** Birthcontrol pill; Retin-A

**Lab Data:**

**History:** GERD; Acne

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360965-1

<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>
43.0	M	13-Oct-2009	13-Oct-2009	0	15-Oct-2009	15-Oct-2009	KS		15-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	0	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthma, Condition aggravated, Headache, Immediate post-injection reaction

**Symptom Text:** Had slight headache right after receiving nasal mist for h1n1.It lasted for about 3 hours. Had a asthma attach at 10:30 pm and used Maxair inhaler to stop episode.

**Other Meds:**

**Lab Data:**

**History:** Seasonal, exercise induced asthma & allergies,Macrodantin allergy

**Prex Illness:** NO

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 360990-1

<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>
2.0	F	14-Oct-2009	14-Oct-2009	0	15-Oct-2009	16-Oct-2009	VA		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Developed hives covering stomach & chest, knees, back of knees, some on back as well. Spoke with her Dr immediately and gave Benadryl upon Dr's recommendation. Hives subsided. However, next morning (10/15) some new hives had developed on face & knees. Not nearly as severe, though. Administered Benadryl again.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361003-1

<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>
39.0	F	14-Oct-2009	14-Oct-2009	0	15-Oct-2009	15-Oct-2009	CO		16-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	UP006AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Feeling abnormal, Feeling hot, Nausea, Pyrexia

**Symptom Text:** Face felt hot. Area lateral to injection site was pink. No rash or urticaria. Nausea and a "funny feeling" through anterior neck region. Described symptoms as similar to those she experienced when she had a reaction that caused her to be flown to a larger hospital. Initial S/S began about 3pm. Patient had low grade fever then. Took tylenol and benadryl 25mg, then another 25mg about a 1/2 hour later. At approximately 4:15, patient stated that she felt no better and felt like she did when she was flown out for an allergic reaction. Arrangements were made for patient to be seen in attached clinic. Patient was evaluated by physician and sent to the ER in the attached hospital. Presented to the ER at 4:45pm and treated with IV SoluMedrol 125mg and Zantac 300mg. She was admitted as an Extended ER and treated with singulair 10mg po, benadryl 50mg po every 6 hours and Prednisone 40mg at 8pm. Monitored overnight. No further complications and a resolution of S/S. Discharged to home at 9:25am on 10/15/2009. Patient is to take Prednisone 50mg Daily for 4 days and Benadryl 50mg three times a day for 4 days. She is to see her PCP in one week.

**Other Meds:** Gatifloxacin 0.3% Eye Drops every 2 hours to right eye for 2 days then every 4 hours for right eye for 5 days Phentermine 30mg PO Daily

**Lab Data:** None

**History:** Allergy: Sulfa Previous reaction to sulfa resulted in patient having anaphylaxis type reaction.

**Prex Illness:** Patient had a right eye infection. Treated with gatifloxacin 0.3% eye drops. No fever.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361004-1

<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>
17.0	F	15-Oct-2009	15-Oct-2009	0	15-Oct-2009	16-Oct-2009	PA		16-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>
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	2	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	500756P	0	Unknown	Unknown	
	FLU	SANOFI PASTEUR	U3210AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Child c/o itchiness of b/l arms. No rash present. Child was otherwise well. VSS. Lungs CTA. MD was notified. Benadryl given. CHild stayed in office x 30 min. Itching resolved. No further intervention required.

**Other Meds:** None

**Lab Data:** n/a

**History:** Hx of headaches and anemia

**Prex Illness:** n/a

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361019-1

<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>
27.0	F	14-Oct-2009	14-Oct-2009	0	15-Oct-2009	16-Oct-2009	IL		16-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007392P	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** Late evening of day vaccinated began to see rash on scalp & face with urticaria. Hives spread across neck, shoulders, extremities

**Other Meds:** Zyrtec, Yaz, Mucinex-D, Cefzil (completed 7 day course 2 days prior)

**Lab Data:** Observation in employee health office, no testing

**History:** Had just completed antibiotics for ear infection and has seasonal allergies

**Prex Illness:** none stated

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361020-1      **Related reports:** 361020-2

<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>
39.0	F	15-Oct-2009	15-Oct-2009	0	15-Oct-2009	16-Oct-2009	DE		16-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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Feeling abnormal, Pruritus, Respiratory rate increased

**Symptom Text:** Redness amd itching below site of administration. Itching of both arms chest and neck. "head felt foggy". felt like she was breathing fast.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361020-2      **Related reports:** 361020-1

<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	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	19-Oct-2009	DE	1	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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dizziness, Dyspnoea, Headache, Heart rate increased, Malaise, Nausea, Pruritus, Tremor

**Symptom Text:** I started itching first on my arm of the vaccination about 1hr after the needle. Then I started to breath heavy along with a headache and became dizzy and my chest started tightening. I went to my employee health at the time and an epi pen was administered and Benadryl was given. Then i was taken to our ED that is when i started shaking all over and couldnt control it. Heart Rate was very fast and breathing was off. After being monitored of 4 hrs i was released with Steroids and a Epi pen for relaspe just in case. Now this is day two and i still dont feel that well I have a headache and nausea. Has to miss Work 10/16 to go to my family Doctor

**Other Meds:**

**Lab Data:**

**History:** Allergic to Keflex

**Prex Illness:** No Illness

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361028-1

<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>
69.0	M	14-Oct-2009	15-Oct-2009	1	15-Oct-2009	16-Oct-2009	NY		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)	SANOFI PASTEUR	UP001AA	0	Unknown	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Areflexia, Blood product transfusion, Guillain-Barre syndrome, Muscular weakness, Paraesthesia, Sensory disturbance, Tremor

**Symptom Text:** Pt. to primary care Md with weakness in arms and legs. LP done. Being treated for possible Guillain-Barre per Dr (time above onset unknown) 10/16/09: the neurologist-who is treating this patient. gave me the following info: This case is Level 1 confirmed GBS. The pt was given IVIG dose 1 as an outpatient and is improving. Onset of symptoms was about 12 hours after receipt of H1N1. Pt had no URI or diarrhea symptoms in the last month. The pt has not been hospitalized. 10/16/09-neurology records received for date of service 10/16/09-felt weak, progressively worse with hip, knee and other joints hurting, trouble climbing stairs, tingling of left middle three fingers. Presented with new and progressive onset of bilateral upper and lower body weakness, arms greater than legs with absent upper extremity reflexes. Neuro exam:strength 4/5 both deltoids, finger range of motion limited in upward direction. Sensory evaluation reduced distally bilaterally. Mild tremor left greater than right with protracted extension of arms.

**Other Meds:** unknown

**Lab Data:** As per Dr. pt had a LP done. 10/16/09-information received-The CSF protein was 50 and this is within normal limits for the lab doing the testing.

**History:** not known 10/16/09-records received-PMH: hypertension, hyperlipidemia, acid reflex, asthma and allergies. Nasal polyps removed, coronary artery disease, arthritis of left thumb, treated for possible Lyme disease. Long history of tingling and numbness in both lower extremities. Allegies to animal dander, seasonal allergies.

**Prex Illness:** none known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361033-1

<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>
51.0	M	14-Oct-2009	15-Oct-2009	1	15-Oct-2009	16-Oct-2009	MO		16-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	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hive spots on neck, went away, then hive spots appeared underarms and bottome off feet and have not disappeared

**Other Meds:** Anti hypertensive

**Lab Data:** None

**History:** Hypertension, swollen prostate

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361036-1

<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>
29.0	F	14-Oct-2009	15-Oct-2009	1	15-Oct-2009	16-Oct-2009	VA		16-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	UP003AA	0	Right arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion

**Symptom Text:** Seizure

**Other Meds:** anti seizure medications

**Lab Data:** ER visit Neurologist follow up

**History:** previous history of brain tumor

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361048-1

<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	M	13-Oct-2009	14-Oct-2009	1	15-Oct-2009	16-Oct-2009	MN		20-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	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Fatigue, Headache, Myalgia, Rhinorrhoea

**Symptom Text:** Cough, runny nose, chills, myalgias, headache, fatigue.

**Other Meds:**

**Lab Data:** None.

**History:** None.

**Prex Illness:** No.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361050-1

<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>
28.0	F	14-Oct-2009	14-Oct-2009	0	15-Oct-2009	16-Oct-2009	TN		16-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	MED500757P	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dyspnoea

**Symptom Text:** shortness of breath along with feeling of pressure in my chest after Flumist H1N1 virus.

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361052-1

<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>
62.0	F	13-Oct-2009	14-Oct-2009	1	15-Oct-2009	16-Oct-2009	WV		16-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	UP001AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** Headache x 2 days. Treated with Nsaids. Did not seek/need medical attention.

**Other Meds:**

**Lab Data:**

**History:** hypertension

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361100-1

<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>
27.0	F	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	19-Oct-2009	NC		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	UPOO9AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Heart rate increased, Palpitations

**Symptom Text:** 10/16/09 8:20am: Patient reports rapid heart rate, palpitations, severe dizziness since receiving H1N1 vaccination 10/15/09. Patient sent to ER for monitoring. 10/22/2009 records from ED visit 10/16/2009. Patient with c/o's dizziness, SOB, palpitations post vaccine. PE was normal, EKG noted NSR. Tx: none DC DX: none noted

**Other Meds:**

**Lab Data:** Lab none noted No xrays, EKG normal

**History:** 17 weeks pregnancy PMH: Clotting disorder, patient is 17 weeks pregnant Allergies: NKDA

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361114-1 (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>
89.0	M	30-Sep-2009	30-Sep-2009	0	16-Oct-2009	19-Oct-2009	FR	2009020908	20-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	09201701		Unknown	Intramuscular			

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Asthenia, Femur fracture, Surgery, Syncope

**Symptom Text:** Report received from a foreign regulator on 14-OCT-2009. A 89-year-old male patient (initials: unknown, date of birth: 06/02/1920) received PANVAX H1N1 (batch number 09201701) on 30-SEP-2009 intramuscularly. It was reported that the patient felt well on the day of vaccination. Concomitant medications included ACTONEL (35 microgram weekly (? mg) and LOSEC (20 microgram daily (? mg). Two hours after vaccination, the patient went shopping and collapsed. The patient was transferred via ambulance to hospital. The patient suffered from a fractured femur which was surgically repaired the next day. The patient reported feeling weak prior to the collapse, but the treating nurse indicated that there was no pathology identified as a cause of the fall. The patient was transferred to a Health Service to treat the suspected fractures. The patient outcome is unknown. The regulator assessed the causality as possible.

**Other Meds:** ACTONEL, dosage was 35 ug 1x/week; LOSEC, dosage was 20 ug QD

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361117-1

<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>
41.0	F	20-Sep-2009	01-Oct-2009	11	16-Oct-2009	19-Oct-2009	FR	2009020907	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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Oxygen saturation decreased, Respiratory distress

**Symptom Text:** Report received from the Foreign regulator on 14-OCT-2009. A female patient (age 41 years, date of birth unknown) received PANVAX H1N1 vaccine (batch unknown) on 30-SEP-2009. Medical history was not provided. The patient's weight was 200 kg. On 01-OCT-2009, within 20 hours of receipt of the vaccine, the patient developed sudden onset respiratory distress. The patient desaturated to 50% on room air. Treatment was received with oxygen, CLEXANE subcutaneously, arterial blood gases were monitored and the patient was transferred to another hospital. Patient outcome is unknown. The regulator assessed the causality as possible.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361118-1 (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	Unknown	01-Oct-2009		16-Oct-2009	19-Oct-2009	FR	2009020906	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	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy

**Symptom Text:** Report received from a foreign regulator on 14-OCT-2009. A female patient (age unknown, date of birth: 01/05/1979) received PANVAX H1N1 vaccine (batch unknown) on unknown date. Medical history was not provided. On 01-OCT-2009, within 24 hours of receipt of the vaccine, the patient miscarried. The patient was sent to hospital. Patient outcome is unknown. The regulator assessed the causality as possible.

**Other Meds:**

**Lab Data:**

**History:** Pregnant; Spontaneous abortion

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361122-1

<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>
45.0	F	13-Oct-2009	14-Oct-2009	1	16-Oct-2009	19-Oct-2009	WI		23-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		Unknown	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA476AA		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Injection site rash, Rash pruritic

**Symptom Text:** Torso red, itchy rash. Rash also noted around administration area. Took Benadryl.

**Other Meds:** Celebrex

**Lab Data:** none

**History:** allergy to piperacillin

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361125-1

<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>
37.0	F	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	16-Oct-2009	IL		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)	SANOFI PASTEUR	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Chest pain, Dizziness, Pain in extremity, Palpitations, Vision blurred

**Symptom Text:** Arm pain radiating to chest, weakness, dizziness, blurred vision, heart pounding and racing.

**Other Meds:** Lamictal 400mg, Paxil 15mg, OrthoTricyclin, MVI

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361127-1

<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>
44.0	F	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	19-Oct-2009	MD	MD	23-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	UP009AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3188AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Eye swelling, Oropharyngeal pain, Swelling face

**Symptom Text:** Developed rapid onset sore throat and cough, went to bed and woke up with swollen face, especially around the mouth and eyes.

**Other Meds:** Wellbutrin XL 150mg daily Zoloft 150mg daily

**Lab Data:**

**History:** None.

**Prex Illness:** No.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361201-1

<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>
47.0	M	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	16-Oct-2009	IA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP001AA	0	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Chest discomfort, Condition aggravated, Cough, Headache, Pollakiuria, Rhinorrhoea, Sinus headache

**Symptom Text:** Headache, sinus pressure, runny nose, cough, slight chest discomfort associated with cough, questionable chills (unknown if fever), low back pain, increased urination

**Other Meds:**

**Lab Data:**

**History:** Seasonal allergies

**Prex Illness:** Stated that he had a headache and sinus pressure prior to receiving the vaccination.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361258-1

<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>
31.0	F	16-Oct-2009	16-Oct-2009	0	16-Oct-2009	19-Oct-2009	IN		23-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	UP001AA	0	Right arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Flushing, Headache, Heart rate increased, Hyperhidrosis

**Symptom Text:** Severe headache, fast heartbeat, flushed, light headed, sweating,

**Other Meds:** Asacol

**Lab Data:** EKG

**History:** Crohns Disease

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361267-1

<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>
52.0	F	16-Oct-2009	16-Oct-2009	0	16-Oct-2009	19-Oct-2009	WI		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)	SANOFI PASTEUR	UP006AA	0	Right arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA448BA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Dry mouth, Headache, Hypertension, Tachycardia

**Symptom Text:** hypertension- 166/85 tachycardic-106 Profound HA- 8 out of 10 pain scale weak, dizzy mouth very dry

**Other Meds:** unknown

**Lab Data:** BP- 166/85 HR- 106

**History:** allergies- iodine, epinephrine

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361269-1

<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>
35.0	F	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	30-Oct-2009	AZ		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	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Feeling hot, Hyperventilation, Injection site swelling, Paraesthesia

**Symptom Text:** Arm became swollen at injection site - cl stated she was hot & tingling of fingers, hyperventilating - given 25 mg Benadryl B/P elevated 2 preeclampsia per report. Called her at 8pm - stated she felt fine & swelling down.

**Other Meds:**

**Lab Data:**

**History:** S/P C Sect 10/3/09

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361271-1

<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>
9.0	M	16-Oct-2009	16-Oct-2009	0	16-Oct-2009	30-Oct-2009	IL		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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007392P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Syncope; recovered after brief period of time w/min

**Other Meds:**

**Lab Data:** Glucose WNL

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361278-1

<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>
43.0	M	13-Oct-2009	13-Oct-2009	0	16-Oct-2009	19-Oct-2009	VA		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)	SANOFI PASTEUR	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Headache, Oropharyngeal pain, Productive cough, Respiratory tract congestion, Rhinorrhoea, Sinus congestion, Sinus headache

**Symptom Text:** Started with Runny Nose. By evening, I had a slight sore throat from drainage. Sinus pressure behind eyes that night (10-13-09) and next day. On 10-14-09, I had a headache similar to head cold and felt tired from blowing my nose all night long. Night of 10-14-09, drainage is trying to work its way in to my chest with slight coughing up of drainage. On 10-15-09, sinus drainage slowed up and almost stopped, but still have some chest congestion. Over the past days, I have taken Theraflu for symptoms.

**Other Meds:**

**Lab Data:** none

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361298-1

<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>
7.0	M	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	19-Oct-2009	IA		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Choking, Headache, Pyrexia

**Symptom Text:** Developed HA and fever and choking episode that lasted 30 seconds.

**Other Meds:**

**Lab Data:**

**History:** Unknown

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361301-1

<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>
4.0	F	15-Oct-2009	16-Oct-2009	1	16-Oct-2009	19-Oct-2009	MN	10/15/2009	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)	UNKNOWN MANUFACTURER		NULL	1	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Activities of daily living impaired, Diet refusal, Gait disturbance, Hypersomnia, Pyrexia

**Symptom Text:** Fever,wont eat, can barely walk,cant get out of bed, slept for 14hrs!

**Other Meds:**

**Lab Data:**

**History:** NO

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361307-1

<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>
23.0	F	14-Oct-2009	14-Oct-2009	0	17-Oct-2009	19-Oct-2009	UT		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Hyperhidrosis, Pyrexia

**Symptom Text:** Severe headache, all over head. Headache lasted until next morning. Also, low-grade fever and sweats.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361314-1

<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>
57.0	F	16-Oct-2009	16-Oct-2009	0	17-Oct-2009	19-Oct-2009	OR		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)	SANOFI PASTEUR	NULL		Unknown	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest pain, Injection site pain, Musculoskeletal pain, Pain, Pain in extremity

**Symptom Text:** Shooting pains from injection site left arm across my chest to the right arm shoulder bone.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361315-1

<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>
32.0	F	16-Oct-2009	17-Oct-2009	1	17-Oct-2009	19-Oct-2009	NM		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)	SANOFI PASTEUR	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Dyspnoea, Musculoskeletal chest pain

**Symptom Text:** CRUSHING RIB AND BACK pain,mild shortness of breath

**Other Meds:**

**Lab Data:**

**History:** ALLERGIES-SULFA

**Prex Illness:** NO

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361324-1

<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>
13.0	M	16-Oct-2009	17-Oct-2009	1	17-Oct-2009	19-Oct-2009	MD		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)	SANOFI PASTEUR	UP0091AA		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia, Somnolence

**Symptom Text:** Fever 102 and complaint of headache Fever about 104 at 11 pm and complaint of being very sleepy

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361341-1

<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>
34.0	F	15-Oct-2009	15-Oct-2009	0	18-Oct-2009	19-Oct-2009	OH		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)	SANOFI PASTEUR	UP002AA	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Balance disorder, Eye pruritus, Eye swelling, Headache, Oropharyngeal pain, Palpitations, Throat irritation, Wheezing

**Symptom Text:** MILD WHEEZING, "OFF BALANCE" Equilibrium OFF, HEADACHE AND EYES STARTED ITCHING AROUND 11:00PM, EYES WHERE SWOLLEN BY 05:15AM THE NEXT MORNING, LATER ON 10/16/09-HEART STARTED RACING. SWOLLEN EYES OVER THE NEXT 2 DAYS WITH A MILD SORE THROAT. TOOK BENADRYL TO KEEP REACTION DOWN.I STILL HAVE MILD SWELLING TO MY EYES BUT CAN'T TAKE ANY BENADRYL WHILE ON DUTY..TODAY IS 10/18/2009. THROAT IS STILL SCRATCHY, MILD WHEEZES INTERMITTENTLY. I DIDN'T GO TO THE DOCTOR'S TO PAY FOR SOMETHING I ALREADY KNOW HOW TO TREAT..IF I CAN'T MAINTAIN ON MY OWN, THEN I WILL GO.

**Other Meds:** NAPROSYN, NAPROXEN, RELEFEN-ITCHY, SOB,HIVES/ LATEX-SWELLING, REDNESS

**Lab Data:**

**History:** latex, NSAIDS excluding ibuprophen allergy, alkolosing spondilitis

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361344-1

<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>
43.0	M	15-Oct-2009	15-Oct-2009	0	18-Oct-2009	19-Oct-2009	TN		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)	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pain, Pyrexia

**Symptom Text:** Aches, Headache, slight fever on 10/15/2009. By 10/16/2009, all symptoms worse, fever 103.2, visited walk in clinic - diagnosis - more than likely - H1N1 as a result of the live virus vaccine. Said no treatment available except medicine to control fever, rest and lots of fluids.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361346-1

<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>
25.0	M	15-Oct-2009	16-Oct-2009	1	18-Oct-2009	19-Oct-2009	IA		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Dizziness, Exposure to communicable disease, Headache, Oropharyngeal pain, Pain, Pyrexia

**Symptom Text:** 10/16 afternoon started to develop sore throat, 10/17 am started to develop fever which has ranged from ~100-103 on 10/17-10/18, aches, headache, mild dizziness, cough. Did not visit physician. Of note I am a pharmacist and have been exposed to many people with flu-like illnesses over the last week or two. Symptoms are beginning to improve pm of 10/18 though I still have a fever over 100F.

**Other Meds:** none

**Lab Data:** Have not visited physician.

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361349-1

<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>
11.0	M	17-Oct-2009	18-Oct-2009	1	18-Oct-2009	19-Oct-2009	PA		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Decreased appetite, Headache, Pain, Pyrexia

**Symptom Text:** Fever, Body Aches, Headache, Loss of Appetite

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361418-1

<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>
6.0	F	14-Oct-2009	15-Oct-2009	1	19-Oct-2009	28-Oct-2009	NE		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Body temperature increased, Joint swelling, Pain, Pyrexia, Rash, Tonic convulsion

**Symptom Text:** 17 hours post administration - Pt presented w / 105 temperature, B knee edematous, rash, tonic seizure, body aches, fever 101-103 and body aches lasted 3 days. 10/20/2009 received VAERS report , lab done 10/17/2009 and note from MD office stating that mother called MD office on 10/15/2009 to report that daughter, 1 day post vaccine, had sx of bilateral knee edema, fever of 105, rash, tonic seizure activity and arthralgias.

**Other Meds:** Enbrel; Depakote; Prevacid; Prednisone; Atterax; Xyzal; Elavil

**Lab Data:** Lab: CBC, MCV 91.6 high, ESR normal, Glucose 165 high, K-3.5 low, BUN 23 high, AlkPh 141 high, CRP 2.40 high

**History:** Still's disease; Gerd; Migraines; Seizure disorder PMH: Stills disease, Seizure disorder, GERD, Migraines Allergies: NKDA

**Prex Illness:** Chronic disease only

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361449-1

<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>
27.0	F	15-Oct-2009	16-Oct-2009	1	19-Oct-2009	20-Oct-2009	KS		20-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	CSL LIMITED	06449111A	5	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP001AA		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Burning sensation, Herpes zoster, Pain, Paraesthesia, Rash erythematous

**Symptom Text:** large red areas of rash rt. side with pain, burning, tingling. Started on Lt side at 6:00pm 10/17/09. To physician on 10/18/09, diagnosed with bilateral shingles due to H1N1 Vaccine. Given Samvir 500mg 1 q 8 hours.

**Other Meds:** Pentasa 500mg 2 tabs 4x day Imiprimine 25 mg 1 tab daily Ortho tricycline 1 daily

**Lab Data:**

**History:** Crohn's Disease, allergic to Cipro and Flagyl

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361455-1

<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>
10.0	F	14-Oct-2009	15-Oct-2009	1	19-Oct-2009	20-Oct-2009	PA		20-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	0	Unknown	Unknown	FLU VARCEL

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Headache, Nausea

**Symptom Text:** Stomach ache, headache, nausea. Child sent home from school. Rest, soup and crackers for a day and was feeling better.

**Other Meds:**

**Lab Data:** none done.

**History:** Asthma

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361496-1

<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>
35.0	F	14-Oct-2009	14-Oct-2009	0	19-Oct-2009	20-Oct-2009	WI		20-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	UP006AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dysphagia, Ear discomfort, Erythema, Injection site erythema, Injection site swelling, Injection site urticaria, Oedema peripheral, Pruritus, Rash macular

**Symptom Text:** Within 15 minutes of getting the vaccine, I started having red blotchy marks all over my neck front and back, chest, and face. Constant itching. My ears were a fire red and burning feeling. The palms of my hands were red and swollen and even in between my fingers. The site of injection was a welt the size of a dime, with my arm red and swollen down to my elbow. It was difficult for me to swallow and my chest felt tight.

**Other Meds:**

**Lab Data:** Went to the local ER where they administered injections of EPI and Benadryl.

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361498-1

<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>
11.0	F	16-Oct-2009	16-Oct-2009	0	19-Oct-2009	20-Oct-2009	MA		20-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	U3265JA		Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP009AA		Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fall, Head injury, Nausea, Presyncope, Retching, Vomiting

**Symptom Text:** Pt had a vasovagal episode in waiting room. Notes that she did not eat much lunch and had no snack before coming to the office. Has never passed out in the past. Pt fell onto carpet floor, hit her head. Pt with some nausea, but no vomiting and no visual changes. Pt was placed in supine position with knees flexed. Ice to forehead and post neck. Pt was given water to drink once nausea resolved. Pt was transferred to exam table. Dizziness resolved on its own. Pt was able to stand and walk with no dizziness. The next morning, 10/17/09, pt felt nauseous when she stood up out of bed and vomited twice- dry heaves. Felt nauseous from 8-10 am. Mom gave her mint tea, 11:15 felt nauseous again. Pt was cautioned on signs and symptoms of dehydration and advised BRAT diet as well as small, frequent sips of electrolyte-rich fluids.

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361512-1

<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>
3.0	F	15-Oct-2009	17-Oct-2009	2	19-Oct-2009	20-Oct-2009	MT		20-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	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Lethargy, Pyrexia, Rhinorrhoea, Vomiting

**Symptom Text:** Fever initially, developed cough and higher fever at 12:00am and was given motrin. Continued to have fever, cough, rhinorrhea and lethargy throughout the next day. Vomited the follow night (10/19/09)and continues to have fevers to 102 with coarse cough.

**Other Meds:** multi vitamin with fluoride

**Lab Data:** I was told that rapid influenza and PCR would be affected by the LAIV, so these were not performed.

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361513-1

<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>
55.0	F	15-Oct-2009	15-Oct-2009	0	19-Oct-2009	20-Oct-2009	WI		20-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	UP007AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** overall body rash

**Other Meds:** none known

**Lab Data:** none at this time

**History:** no

**Prex Illness:** none known or reported

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361516-1

<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>
39.0	F	15-Oct-2009	16-Oct-2009	1	19-Oct-2009	20-Oct-2009	OH		20-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	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus generalised, Rash, Urticaria

**Symptom Text:** The reaction starts out as a rash and within hours it was hives all over my body. For the next 2 1/2 days, it continued to produce hives and continual itching all over my body (including my scalp). Benedryl would relieve the intching temporarily, but not completely.

**Other Meds:** I take 175 mcg of Synthroid.

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361519-1

<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>
52.0	M	16-Oct-2009	16-Oct-2009	0	19-Oct-2009	20-Oct-2009	MT		20-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)	NOVARTIS VACCINES AND DIAGNOSTICS	100739IP	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Migraine, Visual impairment

**Symptom Text:** vision changes, acute onset migrane for 3 hours then headache for 3 hours

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361520-1

<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	16-Oct-2009	1	19-Oct-2009	29-Oct-2009	UT		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Pain, Pyrexia

**Symptom Text:** Fever increased 104.9 on Friday Oct 16, 2009. Body aches, cough.

**Other Meds:** None

**Lab Data:** Urine culture (negative); Strep test, negative

**History:** Asthma

**Prex Illness:** Healthy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361539-1

<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>
30.0	F	15-Oct-2009	Unknown		19-Oct-2009	20-Oct-2009	--		20-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	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paraesthesia oral

**Symptom Text:** Patient received vaccination in L arm, then developed tingling on right cheek and side of tongue. Seen in ED and told to followup with Primary Care Provider

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361551-1

<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>
44.0	F	19-Oct-2009	19-Oct-2009	0	19-Oct-2009	20-Oct-2009	MI		20-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	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Condition aggravated, Dyspnoea, Wheezing

**Symptom Text:** Shortness of breath, audible wheezing-client took asthma inhaler without relief and at our direction family member drove her to urgent care.

**Other Meds:** unknown

**Lab Data:**

**History:** Asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361557-1

<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>
48.0	M	18-Oct-2009	19-Oct-2009	1	19-Oct-2009	20-Oct-2009	HI		20-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	NOVARTIS VACCINES AND DIAGNOSTICS	97849PI		Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP002AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Headache, Pyrexia

**Symptom Text:** FEVER, CHILLS, HEADACHE SUGGESTED TREATING WITH MOTRIN

**Other Meds:**

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** EAR PAIN

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361561-1

<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>
25.0	F	19-Oct-2009	19-Oct-2009	0	19-Oct-2009	20-Oct-2009	KY		20-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	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal discomfort, Asthenia, Dizziness, Fatigue, Loss of consciousness, Nausea, Paraesthesia

**Symptom Text:** Dizziness and feeling sick to my stomach and feeling like I was going to pass out. Slight blacking out. Lasted around 5 minutes. Followed by general weakness and fatigue and some tingling in extremities. Lasted for about 2 hours.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361562-1

<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>
36.0	F	19-Oct-2009	19-Oct-2009	0	19-Oct-2009	20-Oct-2009	WV		20-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		UP001AA	0	Right arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Condition aggravated, Dizziness, Epistaxis, Hypertension

**Symptom Text:** DIZZINESS, HTN EPISODE, NOSE BLEED

**Other Meds:** K+, SINGULAIR, ALBUTEROL, PROTONIX, WELBUTRIN,

**Lab Data:**

**History:** HTN, ASTHMA, GERD, MTHFR,

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361567-1

<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>
4.0	F	15-Oct-2009	19-Oct-2009	4	19-Oct-2009	20-Oct-2009	MO		20-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	NULL	0	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	NULL	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Ear pain, Headache, Pyrexia, Vomiting

**Symptom Text:** FEVER, HEADACHE, STOMACHACHE, VOMITING EAR ACHE

**Other Meds:** ZYRTEC

**Lab Data:**

**History:** asthma

**Prex Illness:** none known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361572-1

<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>
47.0	M	19-Oct-2009	19-Oct-2009	0	19-Oct-2009	20-Oct-2009	IL		20-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	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal distension, Flatulence, Flushing, Hiccups, Hyperhidrosis

**Symptom Text:** i hour post vaccination describes feeling distended, gassy, hiccups for 15 minutes followed by flush and sweats. To OHS where placed on O2 with rebreather bag; BP 140/90, O2 Sats continued at 93 and removed from o2. Observed for 1 hour 30 minutes. breath sounds clear, respirations 1, Temp 98.1. Released to home per Taxi. Referred to PMD.

**Other Meds:** Zyrtec, Audifex, Verimune, Truvada

**Lab Data:** No testing in OHS. Referred to PMD for additional care

**History:** Asthma, HIV pos, smoker

**Prex Illness:** questionable, states was sick this past weekend. afebrile at time of injection

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361574-1

<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>
63.0	F	19-Oct-2009	19-Oct-2009	0	19-Oct-2009	20-Oct-2009	NC		20-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	UP009AA	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Flushing, Hypoaesthesia, Pain in extremity, Syncope

**Symptom Text:** Onset of severe pain in left (injection) arm (from above elbow to hand) and numbness in fingers; followed by difficulty breathing; severe flushing (head and upper thorax); fainting.

**Other Meds:** Immodium multi symptom (OTC)

**Lab Data:** Blood work, X-ray, and EKG.

**History:** Irritable Bowel Syndrome

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361587-1

<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>
0.5	F	19-Oct-2009	Unknown		19-Oct-2009	20-Oct-2009	MO		20-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007932P	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, No adverse event

**Symptom Text:** No vaccine related effects noted. Client given Novartis, preservative-free vaccine, cleared for 4 y/o and older.

**Other Meds:**

**Lab Data:**

**History:** None known

**Prex Illness:** None known

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361592-1

<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>
14.0	M	15-Oct-2009	18-Oct-2009	3	19-Oct-2009	20-Oct-2009	NC		20-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	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Eye swelling, Hypersensitivity, Rash, Swelling face

**Symptom Text:** my son woke up sunday morning after having the swine flu shot on thursday with the left side of his face red and a little swollen. By 5 o'clock sunday night it had got progressively worse now it was the whole side of his face his eye was swollen shut the redness,bumps and swelling had went all the way down his face to his neck,up in his hair line and back to his ear.I took him to the hospital I explained to them that he was not allergic to anything and that since when he woke up that morning it was like that so I didn't think it was anything he was exposed to. I told them that the only thing that was differant was that he had the swine flu shot.They did not see3m to think that was the problem,they said it was a definate allergic reaction but to what they didnt know,so they told me to give him benadryle and sent him home. Well by this morning 10/19/2009 at 7:00 AM it had got alot worse. I took him to the doctors again because it did not seem to me that the benadryle was enough. I took him to our local doctor; Dr. James Owens told him the same thing I had told the hospital the night before,he examined him and said yes knowing what I had told him and my sons history that it was a allergic reaction to the swine flu vaccination that he has got on thursday. Dr. Owens put him on prednizone and told me to keep giving him benadryle every four hours.Some of the swelling has went done but his eye is still almost shut from the swelling and his face is still red.I would like to know if anyone can tell me how long is this reaction gonna last. I am realy concerned since it was a vaccine.

**Other Meds:**

**Lab Data:** none done

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361619-1

<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>
39.0	F	19-Oct-2009	20-Oct-2009	1	20-Oct-2009	21-Oct-2009	OH		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysphonia, Throat tightness

**Symptom Text:** hoarseness and tightness in the throat

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361637-1

<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>
18.0	F	16-Oct-2009	17-Oct-2009	1	20-Oct-2009	21-Oct-2009	PA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP006A	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Hypoaesthesia

**Symptom Text:** Headache, pinching frontal, severe. Right arm numbness and hand numbness.

**Other Meds:**

**Lab Data:** CT of head -> normal

**History:** ADHD; Depression

**Prex Illness:** ADHD; Depression; None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361651-1

<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	U	05-Oct-2009	06-Oct-2009	1	20-Oct-2009	21-Oct-2009	OR		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	ANTH	UNKNOWN MANUFACTURER	NULL	2	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Blister, Haemorrhage, Headache, Rash

**Symptom Text:** Headache, stomach ache, rash 2in diameter. Rash got blisters and bleed.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361656-1

<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>
9.0	F	15-Oct-2009	15-Oct-2009	0	20-Oct-2009	21-Oct-2009	MA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP009AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness

**Symptom Text:** Child passed out. Elevated legs, blood pressure taken. O2 sat 99%, pulse 118, HR 110/60.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361667-1

<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>
4.0	M	17-Oct-2005	18-Oct-2009	1462	20-Oct-2009	21-Oct-2009	CT		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Swelling face, Urticaria

**Symptom Text:** My son woke up with one side of his face swollen, and his face and parts of his body (arm, back, groin area, legs) in hives. We administered Benadryl (as per the pediatrician's order) and also put calamine lotion on the rash. During the remainder of the day and onto yesterday morning the hives would sporadically appear and disappear.

**Other Meds:** None.

**Lab Data:** N/A. We called the pediatrician on Sunday and he told us that he did not believe that the hives were related to the Seasonal flu shot or H1N1 nasal spray that had been administered the day before. Nonetheless, there was nothing unusual that

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361682-1

<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>
14.0	M	15-Oct-2009	18-Oct-2009	3	20-Oct-2009	21-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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP009AA	0	Right arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	9721602	2	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Eye swelling, Face oedema, Ocular hyperaemia, Swelling face

**Symptom Text:** Awoke 10/18/09 AM with redness & slight swelling to right side of face & right eye. By same PM right-sided facial edema had increased to scalp area & right eye swollen closed. Taken to ER at Outer Bank Hospital & treated with Benadryl. 10/19/09 AM facial edema worsened & seen by local MD(Dr. Owens), treated with steroids & Benadryl. Per phone consult 10/20/09 with Dr. Owens: reaction may not be from H1N1 injection due to time delay from injection until s/s. Denied any local reaction or any other adverse s/s, NO respiratory distress involved.

**Other Meds:** None per parent report

**Lab Data:**

**History:** None Known

**Prex Illness:** None Known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361694-1

<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>
3.0	M	15-Oct-2009	17-Oct-2009	2	20-Oct-2009	21-Oct-2009	MT		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia, Vomiting

**Symptom Text:** Received nasal mist on 10/15/09. Developed fever on 10/17, vomited, has not had cough. Fevers up to 103.9, currently day 4 of fevers.

**Other Meds:** POLYVIFLOR

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361704-1

<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>
2.0	F	15-Oct-2009	16-Oct-2009	1	20-Oct-2009	21-Oct-2009	MT		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Condition aggravated, Diarrhoea, Pyrexia

**Symptom Text:** Received nasal mist on 10/15/09. Developed fever on 10/16/09. Has had diarrhea. Fevers present to 104 over 4 days.

**Other Meds:** Multivitamins with fluoride IMG

**Lab Data:**

**History:** None

**Prex Illness:** Low grade fever, ? teething

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361726-1

<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>
36.0	F	16-Oct-2009	17-Oct-2009	1	20-Oct-2009	22-Oct-2009	LA		22-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007391P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Condition aggravated, Migraine, Nausea

**Symptom Text:** Developed Migraine and Nausea. Nausea lasted for 4 hours. Has hx. of migraines and has prescription for Imitrex. Took Imitrex with onset of migraine

**Other Meds:**

**Lab Data:**

**History:** Migraines Hypertension Hx. of palpitations Vaginal infection (?)

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361764-1

<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>
52.0	F	19-Oct-2009	19-Oct-2009	0	20-Oct-2009	31-Oct-2009	WI		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)	SANOFI PASTEUR	UPOO6AA		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Itching, hives all over body. While at clinic was treated with 50 mg BENADRYL. Took 2 more BENADRYL doses 50 mg at home on same date, 10-20-09.

**Other Meds:** Aspirin 1 tablet daily; LISINOPRIL 20 mg 1 time daily; SYNTHROID 0.112 mg 1 time daily; NEURONTIN 300 mg 1 time daily; Insulin 10 unit 2 times daily; NPH 60 units taken at night.

**Lab Data:** No

**History:** Hypothroid; Diabetes; heart disease; Allergies: CODINE; MORPHINE; IVP; Dye.

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361780-1

<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>
4.0	M	17-Oct-2009	17-Oct-2009	0	20-Oct-2009	22-Oct-2009	MA		22-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	0	Unknown	Unknown	FLU	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Chills, Gait disturbance, Lip swelling, Oedema peripheral, Pyrexia, Rash macular, Urticaria

**Symptom Text:** Chills, aching joints and low grade fever at 7pm; hives covering body by 11pm; doctor visit 10/18/09 with suggestion of benadryl; Benadryl administered at 12:30pm and 6pm 10/18/09 - 8pm, hives still prominent, benadryl no effect, lips began to swell rapidly; ER visit 9pm 10/18/09 - received prescription of rotinidine for 2x/day for 4 days; 10/19/09 hives 50% better, 5pm fever of 102; 7pm temp at 98.6 after a 5pm does of Motrin; 10/20/09 hives more blotchy, bottom of feet swollen from hives, hard to walk, no fever, patient much more comfortable

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361784-1

<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>
24.0	F	18-Oct-2009	18-Oct-2009	0	20-Oct-2009	22-Oct-2009	IL		22-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	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Immediate post-injection reaction, Induration, Pruritus, Skin warm

**Symptom Text:** itching and redness immediately after administration; induration developed following day; 40mmx40mm induration remains, itching, redness, warmth also. Provided with cold pack. offered antihistamine.

**Other Meds:** multivitamin Nuvaring

**Lab Data:** No testing

**History:** Ragweed allergy

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361785-1

<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>
3.0	F	19-Oct-2009	20-Oct-2009	1	20-Oct-2009	22-Oct-2009	ND	Lot # UP010AA	22-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		UP010AA	0	Left arm	Unknown	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypersomnia, Rash erythematous, Rash pruritic

**Symptom Text:** Claire slept from 4:30 PM on October 19 until 7:00 AM on October 20th. When she woke up this morning, we noticed a rash on her face and stomach. It is not on her arms and a little bit on her legs. It seems to be itchy. It is a red spotty rash.

**Other Meds:**

**Lab Data:**

**History:** In the past, Claire has had problems with excema. At the time of the vaccination, she had some patches on her legs.

**Prex Illness:** Claire had finished antibiotics about 5 days prior to the vaccination. She had some infected skin in her belly button.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361796-1

<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>
24.0	F	15-Oct-2009	15-Oct-2009	0	20-Oct-2009	22-Oct-2009	IN		22-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	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Pain, Sensation of foreign body, Swollen tongue

**Symptom Text:** h/a; swollen tongue - felt like a marble at back of tongue; body aches

**Other Meds:**

**Lab Data:**

**History:** Asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361831-1

<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>
32.0	M	19-Oct-2009	20-Oct-2009	1	20-Oct-2009	30-Oct-2009	NY		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)	UNKNOWN MANUFACTURER	UP006AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Pt developed Diffuse Hives on anterior/posterior chest, neck and forehead.

**Other Meds:** None

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361835-1

<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	F	18-Oct-2009	18-Oct-2009	0	20-Oct-2009	22-Oct-2009	NV		22-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	SPL UP002AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Oropharyngeal pain, Pain, Pyrexia

**Symptom Text:** High Fever, sore throat, body aches 24+ hours

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361853-1

<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>
66.0	F	15-Oct-2009	16-Oct-2009	1	20-Oct-2009	22-Oct-2009	MA		22-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	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Pneumonia, Productive cough

**Symptom Text:** Developed extreme SOB, difficulty breathing. Dx'd with pneumonia about 12 hours after administration of vaccine. Afebrile, productive cough.

**Other Meds:** DIOVAN-daily; Atenolol-daily; Levothyroxin-daily

**Lab Data:** Unknown

**History:** None known

**Prex Illness:** None known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361856-1

<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>
51.0	F	18-Oct-2009	19-Oct-2009	1	20-Oct-2009	23-Oct-2009	TN		23-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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Diarrhoea, Eye pruritus, Headache, Oropharyngeal pain, Pain, Pyrexia

**Symptom Text:** sore throat, itchy eyes, GI distress (diarrhea) chills were the onset. Today 10/20 I have fever (100.8) chills, body aches, sore throat, headache. taking tylenol flu medication

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361861-1

<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>
2.0	M	20-Oct-2009	20-Oct-2009	0	20-Oct-2009	22-Oct-2009	TX		22-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		500756P	0	Unknown	Unknown	FLUN	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, No adverse event

**Symptom Text:** NO signs and symptoms of any distress. H1N1 flu mist given 22 days after seasonal flu mist.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361863-1

<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>
49.0	F	19-Oct-2009	19-Oct-2009	0	20-Oct-2009	22-Oct-2009	IN		22-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		Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Headache, Nausea, Pain, Pain in extremity, Sleep disorder

**Symptom Text:** complete exhaustion, went to bed woke up 2 hours later with severe HA and nausea. slept fitfully despite Tylenol and awoke hurting all over and with HA which has continued all day. Arm was sore as expected. 28 hours after the vaccine finally starting to feel better

**Other Meds:**

**Lab Data:** none

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361864-1

<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>
25.0	F	19-Oct-2009	19-Oct-2009	0	20-Oct-2009	22-Oct-2009	WA		22-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	UP00ZAA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Small bumps on both arms, chest, back and head. Progressed for about 10hrs. Treated with benadryl.

**Other Meds:**

**Lab Data:**

**History:** iodine, sulfa, polysporin

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361865-1

<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	F	19-Oct-2009	20-Oct-2009	1	20-Oct-2009	22-Oct-2009	GA		22-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	UP004AA	0	Right leg	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthma, Condition aggravated, Cough, Dyspnoea, Rash, Rash erythematous, Wheezing

**Symptom Text:** Acute Asthma attack, wheezing and difficulty breathing, significant cough. Red rash on face around eyes and forehead.

**Other Meds:**

**Lab Data:**

**History:** Asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361866-1

<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>
3.0	M	17-Oct-2009	18-Oct-2009	1	20-Oct-2009	22-Oct-2009	NV		22-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	0	Right arm	Unknown	VARCEL	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Fever above 103 and has not come down 2 days later. I have been giving tylenol and motrin in order to keep the fever down.

**Other Meds:**

**Lab Data:**

**History:** asthma

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361867-1

<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>
25.0	F	18-Oct-2009	19-Oct-2009	1	20-Oct-2009	22-Oct-2009	NH		22-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	0	Left arm	Intramuscular	FLU HPV4	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Myalgia

**Symptom Text:** Dizziness, muscle aches, headache. Continued through until present time (10/20/2009 6pm).

**Other Meds:** Necon 1/35, Multivitamin, Allegra prn

**Lab Data:** None

**History:** Hx of Asthma, allergy to Amoxicillin

**Prex Illness:** No active illnesses at time of vaccination.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361868-1

<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>
54.0	F	20-Oct-2009	20-Oct-2009	0	20-Oct-2009	22-Oct-2009	MA		22-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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Flushing, Hot flush

**Symptom Text:** Hot flash, flushed skin, "feels dizzy" BP 160/106 PM Cold pack and cold water given. 6:20 PM BP 171/100 P 82. Reviewed with MD. Lying down feet elevated. 6:44PM 140/90. 6:50 PM 130/84. Pt up and ambulating with no issues.

**Other Meds:** Vitamins

**Lab Data:**

**History:** History of documented elevated BP one year ago. No meds

**Prex Illness:** Healthy

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361869-1

<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>
40.0	F	20-Oct-2009	20-Oct-2009	0	20-Oct-2009	22-Oct-2009	OH		22-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	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysphagia, Hypoaesthesia oral, Nausea, Paraesthesia oral, Speech disorder

**Symptom Text:** driving to work began to have tingling in lips and around lips. Lips became numb and Benadryl taken in car. Continued driving and began having trouble swallowing, started to feel very nauseous and pulled into a parking lot. Difficulty speaking and called 911. Benadryl began kicking in and husband drove me to the ER and later to personal physician

**Other Meds:** Zyrtec 10 mg daily, Hydrochlorithiazide 12.5 mg daily, Vitamins daily

**Lab Data:**

**History:** Seasonal allergies, Hx of Meniere's Disease & Colitis

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361871-1

<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>
7.0	F	19-Oct-2009	19-Oct-2009	0	20-Oct-2009	22-Oct-2009	CO		22-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	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Muscle spasms, Muscle strain, Myalgia, Nausea, Pain

**Symptom Text:** Patient experience severe muscle pain, fatigue, and body ache. Followed by muscle spasms and strain (charlie horses) all over her body. Patient describes as "frozen muscle". No fever. No cough. No sore throat. Some nausea.

**Other Meds:**

**Lab Data:**

**History:** allergy-penicillin Reynon's disease chronic croop

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361873-1

<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	17-Oct-2009	18-Oct-2009	1	20-Oct-2009	22-Oct-2009	OH		22-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	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Activities of daily living impaired, Chills, Cough, Nasal congestion, Pain, Pyrexia, Wheezing

**Symptom Text:** Night fevers peaking at 101.4 degrees with chills; daytime fever of 99.3 while on Tylenol; incessant unproductive cough with wheezing that is worse at night; nasal congestion; body aches and stomach ache. Treated with Tylenol every 4-6 hours. Still sick as of this writing on 10/20. Missed at least 3 days kindergarten.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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 Catherization - 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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361878-1

<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>
4.0	M	16-Oct-2009	17-Oct-2009	1	20-Oct-2009	02-Nov-2009	WA		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>
	VARCEL	MERCK & CO. INC.	0847Y	1	Left leg	Subcutaneously	
	MMR	MERCK & CO. INC.	0564Y	1	Right leg	Subcutaneously	
	FLU(H1N1)	SANOFI PASTEUR	UP005AAL	0	Left leg	Intramuscular	
	FLU	SANOFI PASTEUR	U3210AA	3	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration, Injection site swelling

**Symptom Text:** Redness and swelling at injection site noted 10/17/09 and seen in office 10/19/09. Erythema induration 3 1/2cm with surrounding erythema 7x5cm

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361879-1

<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>
17.0	F	17-Oct-2009	18-Oct-2009	1	20-Oct-2009	02-Nov-2009	IA		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	UP001AA	0	Left arm	Unknown	FLUN

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Fatigue, Pain, Pyrexia

**Symptom Text:** Parent called me at the office on Oct 19, 2009 stating that her daughter was having symptoms. Fever, cough, body aches, chills and fatigue. Daughter was have these symptoms on Oct 18, 2009. Mom checking temp frequently and giving her TYLENOL for fever. Pt is responding to medication. Mom keeping her home from school.

**Other Meds:** TEGRTOL 4cc 3x day

**Lab Data:**

**History:** Seizure disorder 1997

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361921-1

<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>
4.0	M	16-Oct-2009	17-Oct-2009	1	20-Oct-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>
	MMR	MERCK & CO. INC.	0564Y	1	Right leg	Subcutaneously	
	FLU(H1N1)	SANOFI PASTEUR	UP005AA	0	Left leg	Intramuscular	
	VARCEL	MERCK & CO. INC.	0847Y	1	Left leg	Subcutaneously	
	FLU	SANOFI PASTEUR	U3210AA	3	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site induration, Injection site swelling

**Symptom Text:** Redness and swelling at injection site noted 10/17/09. Seen in office 10/19/09 erythema induration 3 1/2 cm with surrounding erythema 7x5cm.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361941-1

<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>
57.0	F	19-Oct-2009	19-Oct-2009	0	21-Oct-2009	03-Nov-2009	TN		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	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyspepsia, Pain in extremity, Pruritus, Rash erythematous, Swelling

**Symptom Text:** Onset wrist itching, then trunk. Gradually developed red, raised rash. Feet became painful with walking 10/19 and continued 10/20/09 with swelling. Severe indigestion-symptoms better 10/20 afternoon.

**Other Meds:**

**Lab Data:**

**History:** Mandelamine; streptomycin; ulcef

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361943-1

<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>
36.0	F	20-Oct-2009	20-Oct-2009	0	21-Oct-2009	22-Oct-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>
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	1	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** rash and itching 10/30/2009 MD records from 10/23/2009. Patient with c/o's rash and itching. Tx: benadryl.

**Other Meds:**

**Lab Data:** Benadryl for itch Labs none\Dx studies: none

**History:** 14 weeks pregnant insulin - dependent diabetes PMH: Insulin Dependent DM Allergies: NKDA

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361944-1

<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>
2.0	M	20-Oct-2009	20-Oct-2009	0	21-Oct-2009	22-Oct-2009	OH		22-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	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash papular

**Symptom Text:** pinpoint raised rash noted 1 hr after vaccine

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** raised, pinpoint rash on trunk and arms noted 1 hr after vaccine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361949-1

<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>
47.0	F	20-Oct-2009	20-Oct-2009	0	21-Oct-2009	22-Oct-2009	VA		22-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	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Heart rate increased

**Symptom Text:** Rapid Heart beat. Resting heart beat = 120

**Other Meds:** lexapro levothyroxine naproxine

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361950-1

<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>
6.0	F	19-Oct-2009	20-Oct-2009	1	21-Oct-2009	22-Oct-2009	PA		22-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	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** pretty sudden onset of a high fever Fever was 103.4 Called doctor's office and got on call office. Gave tyelenol. Fever still very high. Fever down to 100 by 8pm. Fever was 100.5 this morning

**Other Meds:** I don't know the vaccine info - the doctor would have that.

**Lab Data:**

**History:** none known

**Prex Illness:** Slight sniffle/cough but no fever

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361953-1

<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>
37.0	F	16-Oct-2009	20-Oct-2009	4	21-Oct-2009	22-Oct-2009	KY		22-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		UP009AA	0	Left arm	Intramuscular	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Chills, Malaise, Nausea

**Symptom Text:** Employee received H1N1 inactivated vaccine on 10/16/09. Reported feeling ill on 10/20/09 and temp was 100.2. Employee went home and temp at that time was 101.7; employee reported chills and nausea. Took Tylenol. Saw PCP at 2pm at which time temp was 99.2. Denied other symptoms. PCP advised that temp was probably due to vaccine received on 10/16/09. Temp has remained below 99 and no other symptoms.

**Other Meds:** Unknown

**Lab Data:** Employee reported that no testing/labs completed.

**History:** Employee denied pre-existing health conditions or allergies at time of vaccination.

**Prex Illness:** Employee denied illness at time of vaccination.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361960-1

<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>
63.0	F	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	22-Oct-2009	MI		22-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	UP006AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Head discomfort, Rash pruritic, Skin warm

**Symptom Text:** Ears got hot and red, then down back of neck and then the back of head felt funny, and then a rash broke out all over arms and back. Very itchy.

**Other Meds:**

**Lab Data:** BP 140/86 Pulse 66 Pulse ox 98

**History:** HTN, high cholestrol

**Prex Illness:** No illness at time of vaccine

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361981-1

<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>
55.0	F	20-Oct-2009	21-Oct-2009	1	21-Oct-2009	22-Oct-2009	NH		22-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	UP009AA	0	Unknown	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Fatigue, Headache, Hyperhidrosis, Lethargy, Vomiting

**Symptom Text:** Severe diarrhea, vomitting, severe headache, profuse sweating, real tired and lethargic

**Other Meds:**

**Lab Data:** None

**History:** NO

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361982-1

<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>
13.0	M	20-Oct-2009	20-Oct-2009	0	21-Oct-2009	22-Oct-2009	VA		22-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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Headache, Nasal congestion, Pain, Pyrexia

**Symptom Text:** Began with a headache at around 8 pm. Had chills, fever (101) and body aches by around 9:30 - 10 pm. Symptoms at 9 am the followind day include Low grade fever (100.9) chills, aches and nasal congestion.

**Other Meds:**

**Lab Data:**

**History:** Seasonal Allergies/ Occasional Seasonal Asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361986-1

<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>
39.0	F	19-Oct-2009	20-Oct-2009	1	21-Oct-2009	22-Oct-2009	NY		22-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	CSL LIMITED	07449111A		Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP006AA		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Nystagmus, Vertigo, Vomiting

**Symptom Text:** severe vertigo, nystagmus (BL), nausea, vomiting for 3 hours. no treatment, just rest the next day. My husband is a neurologist and we didn't go to the ER.

**Other Meds:** none

**Lab Data:** none...

**History:** None

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 361994-1

<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>
4.0	M	12-Oct-2009	20-Oct-2009	8	21-Oct-2009	22-Oct-2009	TN		22-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** HIGH FEVER ONSET ON 10/20/2009. MOM REPORTED TEMP OF 106

**Other Meds:** YOU WILL NEED TO CONTACT MOM FOR THE REST OF INFORMATION SINCE THE VACCINE WAS DONE ELSEWHERE. THANKS

**Lab Data:** POSITIVE FLU TEST FOR FLU A, NEGATIVE FOR STREP

**History:** PENICILLIM

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362003-1

<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>
45.0	F	20-Oct-2009	21-Oct-2009	1	21-Oct-2009	23-Oct-2009	TN		23-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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Paraesthesia

**Symptom Text:** When I awoke this am the fingers on my lf upper ext were numb and tingeling. This has not gone away. Called the Associate Health Nurse and she took report and contacted supervisor.

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362016-1

<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>
49.0	F	20-Oct-2009	20-Oct-2009	0	21-Oct-2009	03-Nov-2009	IN		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		VP001AA	0	Left arm	Unknown	FLUN	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Paraesthesia

**Symptom Text:** Numbness and tingling Left scapular area radiating to left mid axillary line in a linear fashion. Progressed from a pinpoint area to an area 2 inches x 8 inches.

**Other Meds:** fish oil; multivitamin; calcium; vitamin D

**Lab Data:**

**History:** Demerol; IVP dye

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362028-1

<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>
42.0	F	14-Oct-2009	21-Oct-2009	7	21-Oct-2009	23-Oct-2009	MI		27-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	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Facial palsy

**Symptom Text:** Bell's Palsey

**Other Meds:**

**Lab Data:** Seen by emergency room dr while on duty

**History:** allergy to PCN

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362030-1

<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>
43.0	M	19-Oct-2009	19-Oct-2009	0	21-Oct-2009	23-Oct-2009	NC		23-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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Condition aggravated, Feeling hot

**Symptom Text:** Client states feeling hot inside (hot patches) at various ares of body and face. Areas would move from spot to spot. Felt like sunburn. See past Hx. Felt worse during the night and early AM. States better now (10/20/2009 4:30 PM). States discussed with MD and was advised seek medical attention if cont. or worsens. States plans to see MD this week for seasonal flu vaccine as advised by MD. Client states he will call if any further px.

**Other Meds:**

**Lab Data:**

**History:** PAST HX. Client reports 02/06/2009 until 07/2009 illness. States specialist dx. unidentified virus after extensive testing. S/S began with "feeling hot inside (hot patches)like a sunburn that would move throughout different areas of the body." Also had various joint pain. Sores in mouth for several days and then bronchitis. S/S subsided sometime in July.

**Prex Illness:** NO

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362031-1

<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>
39.0	F	18-Oct-2009	18-Oct-2009	0	21-Oct-2009	23-Oct-2009	MO		23-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		Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Vomiting

**Symptom Text:** Started having slight headache with slight nausea while at work; Work in the Emergency Room, Left work at 0200, by 0600 woke up with severe vomiting which persisted until 1200. Took phenergan at home to calm vomiting. By 2200, 10/19/2009, severe vomiting subsided, still slightly nauseated but able to take fluids. No fever during this time. Moderate headache during this time persisted about the same time. 10/20/09 symptoms subsided.

**Other Meds:**

**Lab Data:**

**History:** Asthma Allergies: PCN, Claforan, Compazine

**Prex Illness:** No illness at time of vaccination

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362035-1

<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>
33.0	F	19-Oct-2009	19-Oct-2009	0	21-Oct-2009	23-Oct-2009	NH		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	NOVARTIS VACCINES AND DIAGNOSTICS	97840P2A		Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP009AA		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Facial palsy, Hypoaesthesia, Pain, Paraesthesia

**Symptom Text:** facial droop Left side 10/29/09 Medical Records received for office visit to primary care provider for date of service 10.21.09. Dx: Paresthesia, Acute Assessment: Presents with numbness of left jaw, tongue, eye and ear. Ear had improved, but experiencing pain in left ear, rest of L side of face numb, not increasing, no droop or drooling noted. Denies HA, gait disturbance, weakness, incoordination, lightheadedness. Pain 4/10. 10/30/09: Emergency Department Records received for date of service 10/19/09. Dx: Paresthesia, facial Assessment: Seen for L side facial numbness after flu shot. VSS. Denied pain. Discharged to home is stable condition.

**Other Meds:**

**Lab Data:** 10/29/09 Medical Records received for office visit to primary care provider for date of service 10.21.09. Labs and Diagnostics: None. 10/30/09: Emergency Department Records received for date of service 10/19/09. Labs and Diagnostics:

**History:** Latex allergy 10/29/09 Medical Records received for office visit to primary care provider for date of service 10.21.09. PMH: Allergic rhinitis, NEC, chronic variant asthma. 10/30/09: Emergency Department Records received for date of service 10/19/09. PMH: As above.

**Prex Illness:** Not known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362038-1

<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>
39.0	F	19-Oct-2009	20-Oct-2009	1	21-Oct-2009	23-Oct-2009	IN		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	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Nausea, Pyrexia

**Symptom Text:** Low grade Fever Nausea Fatigue Symptoms resolved by the next day 9/23/09 ED records received service date 9/23/09 to 10/21/09. Assessment: Sinus infection? Low grade fever, nausea, fatigue.

**Other Meds:**

**Lab Data:**

**History:** Pregnancy Gestational Diabetes

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362043-1 (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>
77.0	M	05-Oct-2009	05-Oct-2009	0	21-Oct-2009	22-Oct-2009	FR	2009020924	22-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	Unknown	
	FLU	UNKNOWN MANUFACTURER	25901		Unknown	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Nausea, Palpitations

**Symptom Text:** Report received from the regulator on 14-Oct-2009. Number is 257570. A 77 year-old male patient with unknown initials (Date of Birth 28-JUN-2006) received PANVAX H1N1 and vaccination on 5-Oct-2009. Seasonal influenza vaccine (batch number 25901) is a co-suspect drug. On 5-Oct-2009, 15 minutes after vaccination, the patient reported feeling a racing heart and nausea. Nil chest pain. Nil signs and symptoms of anaphylaxis. Treatment included sending the patient for monitoring. The outcome of the case is unknown. The reporter considered events to be possibly due to PANVAX H1N1.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362054-1

<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>
55.0	F	13-Oct-2009	13-Oct-2009	0	21-Oct-2009	23-Oct-2009	NE		23-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	Left leg	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Blood pressure increased, Dizziness, Erythema, Malaise, Myalgia, Nausea, Pruritus

**Symptom Text:** Lightheaded, dizzy, palms of hands red, elevated BP, scratchy scalp, intense all over muscle pain, nausea, feeling of impending doom, toxic feeling

**Other Meds:**

**Lab Data:** no tests, was given epinephrine 0.3ml IM with relief in 10 minutes

**History:** Fibromyalgia, drug allergy to Keflex and Lorabid

**Prex Illness:** Scratchy throat

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362063-1

<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>
50.0	F	20-Oct-2009	20-Oct-2009	0	21-Oct-2009	23-Oct-2009	LA		23-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	UP001AA	1	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Angioedema, Hypoaesthesia oral, Swollen tongue

**Symptom Text:** Patient developed swelling and numbness of tongue. Angioedema of menal area. Evaluated in ED. Patient received diphenhydramine and dexamethasone IM, befroe being released home.

**Other Meds:**

**Lab Data:**

**History:** Hypertension

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362074-1

<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>
36.0	M	20-Oct-2009	21-Oct-2009	1	21-Oct-2009	23-Oct-2009	DE		23-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	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Headache, Malaise, Oropharyngeal pain, Rhinorrhoea, Sinus congestion, Sneezing

**Symptom Text:** RUNNING NOSE, SORETHROAT,SINUS CONGESTION, RECURRENT SNEEZINGHEADACHE, MALAIZE,FATIGUE,

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362075-1

<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>
50.0	F	19-Oct-2009	19-Oct-2009	0	21-Oct-2009	23-Oct-2009	VA		23-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:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza

**Symptom Text:** All the h1n1 symptoms

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NO

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362083-1

<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>
37.0	F	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	23-Oct-2009	CT		23-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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysphagia, Swollen tongue

**Symptom Text:** Tongue Swelling and sensation that she could not swallow

**Other Meds:**

**Lab Data:**

**History:** None noted

**Prex Illness:** No illness at the time of vaccination

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362087-2      **Related reports:** 362087-1

<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>
Unknown	M	21-Oct-2009	Unknown		30-Oct-2009	02-Nov-2009	MI	200904440	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	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaphylactic shock, Immediate post-injection reaction

**Symptom Text:** Initial report received on 21 October 2009 from a consumer's son. A male patient (age and date of birth not reported) had received an injection of H1N1 2009 Monovalent Vaccine - Preservative (lot number, route and site not reported) on 21 October 2009 and immediately after vaccination, the patient went into anaphylactic shock. The patient was not allergic to eggs and he had previously received influenza vaccine annually with no complications. On 21 October 2009, immediately after receiving the vaccine, the patient went into anaphylactic shock. The patient, who was also a physician, had been in his clinic at the time of the event. The patient yelled for an EpiPen and asked his nurse to call 911. He was admitted to the emergency room and additional Epi-Pen doses were needed to fully recover after several hours. No additional information was provided at the time of the report. Documents held by sender: None.

**Other Meds:**

**Lab Data:** Not reported

**History:** The patient was not allergic to eggs. The patient also received influenza vaccine annually with no complications.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362092-1

<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>
69.0	F	20-Oct-2009	20-Oct-2009	0	21-Oct-2009	23-Oct-2009	NV		23-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	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea

**Symptom Text:** Violent attack of diarrhea lasting approximately 2-3 hours. Took 2 anti-diarrhea pills then 1 and sometime later another 1 which brought it under control.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362093-1

<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>
6.0	M	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	23-Oct-2009	PA		23-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		NULL		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nasal congestion, Nausea, Oropharyngeal pain, Pyrexia, Rhinorrhoea, Vomiting

**Symptom Text:** NAUSEA WITH FEVER 101 LEADING TO VOMITING. SPOKE WITH MD AND WAS TOLD IT MAY BE VIRAL. PT WAS COMPLAINING OF NAUSEA 1.5HR FROM TIME OF INJECTION. GAVE MOTRIN FOR FEVER. PT THEN DEVELOPED STUFFY/RUNNY NOSE AND PROCEEDED TO HAVE SORE THROAT.

**Other Meds:** PT ON ZITHROMAX FOR STREP 1 WEEK PRIOR TO H1N1 SHOT.

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362094-1

<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>
31.0	F	19-Oct-2009	20-Oct-2009	1	21-Oct-2009	22-Oct-2009	UT		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)	UNKNOWN MANUFACTURER	UP002AA	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abortion spontaneous, Drug exposure during pregnancy, Vaginal haemorrhage

**Symptom Text:** Bleeding/Spotting - eventual miscarriage of 6 week pregnancy 10/22/09 Medical records received for date 10/21/09. Pt. seen for c/o vaginal bleeding. Pt. states approx 5 weeks pregnant. Pt. received vax 10/19/09. Assessment: US performed which demonstrated normal endometrial stripe. No evidence of a gestational sac. No free fluid, no adnexal masses. DX:Early pregnancy, either a threatened miscarriage, continuing miscarriage, or ectopic pregnancy. Labs ordered

**Other Meds:**

**Lab Data:** Ultrasound to determine miscarriage

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362095-1

<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>
20.0	F	20-Oct-2009	21-Oct-2009	1	21-Oct-2009	23-Oct-2009	AZ		23-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	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Fatigue, Heart rate decreased, Sluggishness

**Symptom Text:** I began to feel a little dizzy and sluggish a few hours after the vaccine and the night of the day I received the vaccine I felt extremely tired. The next day, today 10/21 I am feeling very tired and breathing is tighter than normal. It is not necessarily hard to breathe but my pulse seems slower and breathing is tighter.

**Other Meds:** Nadolol

**Lab Data:**

**History:** Long QT syndrome- a heart irregularity, treated with the beta blocker, Nadolol

**Prex Illness:** headache

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362098-1

<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>
3.0	F	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	23-Oct-2009	KY		23-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	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous

**Symptom Text:** ERYTHEMATOUS RASH ON BACK

**Other Meds:**

**Lab Data:**

**History:** MONE

**Prex Illness:** DENIES

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362099-1

<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>
4.0	M	20-Oct-2009	21-Oct-2009	1	21-Oct-2009	23-Oct-2009	UT		23-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	0	Right arm	Unknown	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site swelling, Injection site warmth

**Symptom Text:** His arm became swollen from his shoulder to his elbow. Very red and very swollen. Visibly swollen from a distance. He would grimace with touch, although denied any pain. Hot to the touch as well.

**Other Meds:**

**Lab Data:**

**History:** Has a tube in one ear.

**Prex Illness:** Ear infection, not being treated. Possibly a common cold. He was not being treated at the time of the vaccination.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362100-1

<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	20-Oct-2009	21-Oct-2009	1	21-Oct-2009	23-Oct-2009	TN		23-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Rhinorrhoea

**Symptom Text:** Headache and nose running

**Other Meds:**

**Lab Data:**

**History:** Seasonal allergies - on Allegra D

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362101-1

<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>
7.0	F	20-Oct-2009	21-Oct-2009	1	21-Oct-2009	23-Oct-2009	TN		23-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** Complained of headache

**Other Meds:**

**Lab Data:**

**History:** Seasonal allergies - on Clarinex and Singular

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362102-1

<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>
30.0	F	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	23-Oct-2009	OH		23-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	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Hypoaesthesia, Paraesthesia

**Symptom Text:** had numbness and tingling bilaterally down arms to hands and fingers. also had tingling of face. presented with diarrhea around 9pm and then again at 9:30 pm. felt as if tongue was getting swollen but exam at 9:30 pm proved otherwise

**Other Meds:** mvi

**Lab Data:** na at this time, will follow up with pcp in am

**History:** previous anaphylactic reaction to overdose of allergy shot provided under physician supervision, allergies to shellfish, nuts, bananas, cucumbers, melons, seasonal dust, molds, mildew

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362106-1

<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>
11.0	M	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	23-Oct-2009	NJ		23-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	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives on face, rapidly spreading to neck.

**Other Meds:** No.

**Lab Data:**

**History:** Asthma

**Prex Illness:** No.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362132-1

<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>
37.0	M	14-Oct-2009	16-Oct-2009	2	22-Oct-2009	23-Oct-2009	OH		23-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	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Herpes zoster

**Symptom Text:** Herpeszoster outbreak at T10 on Right

**Other Meds:** None--correction on seasonal influenza immunization--it was given 21 hrs AFTER receiving the H1N1 vaccine (computer would not let me enter date AFTER 10/14/2009)

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362133-1

<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	F	21-Oct-2009	22-Oct-2009	1	22-Oct-2009	23-Oct-2009	WI		23-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	0	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia, Rhinorrhoea

**Symptom Text:** Fever, Headache, Runny Nose

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362134-1

<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>
31.0	F	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	PA		23-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	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Swelling face

**Symptom Text:** Patient presented to Employee Health with R-side facial swelling, VSS BP 120/80, HR 88, Resp 18, Temp 99.5. Speech clear, denied headache, dizziness, fever chills, no signs of respiratory distress. Referred to PCP for follow-up. Employee states today sytoms resolved within one hour after being seen. Reported to work today with no complaints.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362159-1      **Related reports:** 362159-2

<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>
36.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	PA		23-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	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Aphasia, Facial palsy, Hemiparesis

**Symptom Text:** At 4:47 PM a rapid response was called , the Team responded and the adult employee refused care. At 5:16 PM a code 99 was called and the Team responded to find an adult patient with left sided weakness and left facil droop. VS BP 151/96, HR 95, RR 26, O2Sat 99%, Galsco Coma Score 11; The patient was aphasic and unable to give a HX, co-workers related extensive history including lymphoma and TIA. Patient transported emergently with critical care transport team and physician to adult facility.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Patient aphasic at time of transport; co-workers related extensive medical history, including lymphoma and transient ischemic attacks (TIAs), cardiac cath.

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362159-1      **Related reports:** 362159-2

<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>
36.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	PA		23-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	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Aphasia, Facial palsy, Hemiparesis

**Symptom Text:** At 4:47 PM a rapid response was called , the Team responded and the adult employee refused care. At 5:16 PM a code 99 was called and the Team responded to find an adult patient with left sided weakness and left facil droop. VS BP 151/96, HR 95, RR 26, O2Sat 99%, Galsco Coma Score 11; The patient was aphasic and unable to give a HX, co-workers related extensive history including lymphoma and TIA. Patient transported emergently with critical care transport team and physician to adult facility.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Patient aphasic at time of transport; co-workers related extensive medical history, including lymphoma and transient ischemic attacks (TIAs), cardiac cath.

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362159-2 (S)    **Related reports:** 362159-1

<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>
36.0	F	20-Oct-2009	20-Oct-2009	0	23-Oct-2009	26-Oct-2009	PA		27-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	0	Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Cerebrovascular accident, Hemiparesis

**Symptom Text:** Pt is nurse at hospital. Got H1N1 vaccine, within "5 minutes" had acute L sided weakness and admitted to hospital with dx of CVA. But MRI 2 days later (-)= -> ?? (false (-)/ fectitious/other).

**Other Meds:** None

**Lab Data:** CT and MRI brain

**History:** Non-Hodgkins lymphoma- in remission, ? syncope

**Prex Illness:** Left sided weakness

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362159-2 (S)    **Related reports:** 362159-1

<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>
36.0	F	20-Oct-2009	20-Oct-2009	0	23-Oct-2009	26-Oct-2009	PA		27-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	0	Unknown	Intramuscular	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Cerebrovascular accident, Hemiparesis

**Symptom Text:** Pt is nurse at hospital. Got H1N1 vaccine, within "5 minutes" had acute L sided weakness and admitted to hospital with dx of CVA. But MRI 2 days later (-)= -> ?? (false (-)/ fectitious/other).

**Other Meds:** None

**Lab Data:** CT and MRI brain

**History:** Non-Hodgkins lymphoma- in remission, ? syncope

**Prex Illness:** Left sided weakness

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362160-1

<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>
13.0	F	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	WI		23-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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Heart rate increased

**Symptom Text:** Fast heart beat - 120 beats per minute - lasted until 7:30 p.m. Administered Benadryl as directed by Nurses on Call at Urgent Care.

**Other Meds:**

**Lab Data:**

**History:** allergic to penicillin and sulfa

**Prex Illness:** Cough

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362161-1

<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>
1.5	M	20-Oct-2009	21-Oct-2009	1	22-Oct-2009	23-Oct-2009	FL		23-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	0	Unknown	Unknown	DTAP FLU HIBV

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea

**Symptom Text:** loose stools & diarrhea

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362171-1

<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>
47.0	F	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	OH		23-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	UP006AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site anaesthesia, Injection site swelling, Pain, Paraesthesia

**Symptom Text:** Severe swelling at injection site (L arm). Extreme tingling and numbness in injection site extremity. Pain

**Other Meds:** Lopressor, Hormone Replacement and HCTZ

**Lab Data:**

**History:** Allergies to strawberries and codeine. History of hypertension

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362184-1

<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>
10.0	M	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	NY		23-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** hives and itching on face, neck, chest, back, and arms. Was at school - 3 tsp. benadryl liquid given. parents took home.

**Other Meds:**

**Lab Data:**

**History:** peanut allergy, lactose intolerance

**Prex Illness:** no

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362185-1

<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>
9.0	M	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	GA		23-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	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** Head ache started 1 hour after vaccine, concerned because mom got same vaccine and also had HA start about same time.

**Other Meds:**

**Lab Data:**

**History:** Nut allergy

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362189-1

<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>
43.0	F	20-Oct-2009	21-Oct-2009	1	22-Oct-2009	23-Oct-2009	GA		23-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		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** Headache 1 hour after vaccine. Concerned because son got vaccine at the same time and also developed headache.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362195-1

<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>
30.0	F	14-Oct-2009	15-Oct-2009	1	22-Oct-2009	23-Oct-2009	WI		23-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	GLAXOSMITHKLINE BIOLOGICALS	AFLUA476AA		Unknown	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP002AA		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eyelid oedema, Pruritus, Restlessness

**Symptom Text:** restlessness, facial itching and eyelid swelling

**Other Meds:** Employee taking clariton for itching and eyelid swelling. Takes effexor daily.

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362204-1

<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	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	VA		23-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		UP009AA	1	Right arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Cold sweat, Hypoaesthesia, Livedo reticularis, Pain in extremity

**Symptom Text:** Chest pain radiating to Left arm with left numbness. No SOB. Left arm cool to touch and mottled.

**Other Meds:**

**Lab Data:** EKG, Chest X-ray and Cardiac enzymes

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362207-1

<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>
36.0	F	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	TN		23-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		UP009AA	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Activities of daily living impaired, Asthenia, Chills, Confusional state, Hypersomnia, Mobility decreased, Nasopharyngitis, Pain, Tremor

**Symptom Text:** Started with aches, chills, and mild cold symptoms. By 9:00PM 10/21/2009, I was unable to care for my children. I was could barely move my arms or legs due to severe weakness. I was also acting as if I had been sedated. I was unable to stay awake and confused. As of morning of 10/22/2009, I was able to get dressed and come to work, but I am still weak and shaky, and still am experiencing minor cold symptoms. I reported these symptoms to my PCP. I have been taking Ibuprofen and Tylenol as needed.

**Other Meds:** DILT CD, 180 mg, once daily, for heart palpitations. Naproxen, PRN, for RA pain.

**Lab Data:**

**History:** Rheumatoid Arthritis

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362209-1

<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>
50.0	F	21-Oct-2009	22-Oct-2009	1	22-Oct-2009	23-Oct-2009	MI		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)	SANOFI PASTEUR		UP007AA	0	Left arm	Intramuscular	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye swelling, Hypersensitivity, Paraesthesia, Pruritus, Rash, Swelling face, Urticaria

**Symptom Text:** Awakened in am and noticed rash, swelling and itching right side of face. Urticaria rt eyelid, cheeks, neck and a few on center left side of face and neck. Skin tingely. Recommended antihistamine and cool compresses. No other adverse side effects. 10/26/09 ED records received from date 10/23/09. DX: Generalized allergic reaction. Presenting SX: pt. states received flu vax 10/21, face swelling, itching 10/22. ER 10/23 for continued swelling. Assessment: (+)facial swelling, right eye swelling. Pt. tx and d/c.

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362218-1

<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>
4.0	M	14-Oct-2009	15-Oct-2009	1	22-Oct-2009	23-Oct-2009	MA		23-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	MEDIMMUNE VACCINES, INC.	500705P	0	Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Induration, Skin warm

**Symptom Text:** Red induration 4 1/2 inches x 4 1/2 inches, warm to touch.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362223-1

<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>
47.0	F	15-Oct-2009	15-Oct-2009	0	22-Oct-2009	23-Oct-2009	WI		23-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	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Chest discomfort, Condition aggravated, Heart rate increased, Wheezing

**Symptom Text:** Pt received INFLUENZA A H1N1 shot at 14:20. At 14:40 pt c/o tightness in chest, pt was wheezing also. Her B/P was 146/80, P-108, R-16. Pt took 2 puffs of her ALBUTEROL inhaler at this time. At 14:50 her symptoms had resolved. B/P 120/70, P 80, R 16.

**Other Meds:**

**Lab Data:**

**History:** Asthma, hypothyroid, thyroiditis, allergic rhinitis

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362225-1

<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>
26.0	F	13-Oct-2009	13-Oct-2009	0	22-Oct-2009	23-Oct-2009	WY		23-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	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthma, Chest discomfort, Pruritus

**Symptom Text:** Patient received her H1N1 injection at approximately 3:15 on 10/13/09 and returned to work. At about 3:45 she began to experiencing itching, "felt like it was crawling under my skin" which began with her toes and moved upward to her face, where it was the most intense. She did not experience any rash or hives. At 4:15 she took 2 BENADRYL. At 5:00 she began to feel tightness in her chest, "asthma-like symptoms, which I have with my allergies". She finished her shift and went to the ER at 7:15, where she received a nebulizer treatment, breathing improved, itching improved. Also received a shot but is unsure what is. She was sent home, and was to continue with BENADRYL every 4 hours, and return in AM if not better. Itching improves, but then woke up about 2AM with intense itching. Returned to the ER and treated her with oral prednisone which she is continuing. States yesterday itching came and went, today itching gone and hasn't needed to take BENADRYL. Was only to return to Dr. if needed.

**Other Meds:** ZYRTEC; Atenolol; Amitriptyline

**Lab Data:** None

**History:** Seasonal - mold, pollen -> asthma like Rx

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362228-1

<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>
2.0	M	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	AZ		23-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	UP005AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Ocular hyperaemia, Vomiting

**Symptom Text:** Had H1N1 shot this morning. Mother called 6 hrs later reporting vomiting. Nurse stated he had red eyes this morning. Mother denied that he was sick. Said he had "allergies". Temp taken was normal.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** Red eyes-mother states "allergies"

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362263-1

<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>
26.0	F	16-Oct-2009	16-Oct-2009	0	22-Oct-2009	23-Oct-2009	OH		23-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	UP001AA		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Urticaria, Vomiting

**Symptom Text:** Hives - Right upper trunk, vomiting, diarrhea

**Other Meds:**

**Lab Data:**

**History:** Pregnant

**Prex Illness:** No

**Prex Vax Illns:** ~Hep B (no brand name)~~0.00~Patient|~Influenza (Seasonal) (no brand name)~~0.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362269-1

<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>
42.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	NC		23-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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Hypoaesthesia, Hypoaesthesia facial, Oedema peripheral, Pain in extremity, Paraesthesia

**Symptom Text:** Pain,redness,and swelling in right upper arm above the injection site.Tingling and numbness radiating up right side of neck and tingling and numbness in the right side of face.

**Other Meds:**

**Lab Data:** Sent to a neurologist today

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362270-1

<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>
54.0	F	19-Oct-2009	20-Oct-2009	1	22-Oct-2009	23-Oct-2009	PA		23-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		Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Tachycardia

**Symptom Text:** Tachycardia. Had to go to the emergency room.

**Other Meds:**

**Lab Data:**

**History:** Had history of tachycardia in the distant past. On toporol-xl for the condition. BUT have not had any problems with the tachycardia in 7-10 years.

**Prex Illness:** Not at the time. Had tachycardia the next morning. Had to go to the emergency room.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362272-1

<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>
14.0	F	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	MA		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	MEN

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Malaise, Nausea, Pallor, Presyncope

**Symptom Text:** Turned pale. Nausea,near fainting. Weak and sick.

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** cold

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362279-1

<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>
8.0	M	20-Oct-2009	22-Oct-2009	2	22-Oct-2009	23-Oct-2009	NY		23-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		UP007A	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Rash macular

**Symptom Text:** Increased temp of 102, macular rash, generalized exception back.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362280-1

<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>
37.0	F	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	MO		23-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	0	Right arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye pruritus, Eye swelling, Headache, Urticaria

**Symptom Text:** 10/21/09, 13:00, INFLUENZA H1N1 injection. 10/21/09, 17:30, left eye itchy-18:30-full blown hives on left eye, 18:45-antihistamine x 2 PO-headache. 10/22/09, 06:00, antihistamine x 2 PO-still swollen (eye), hives break out on hands/arms.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362288-1

<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>
66.0	M	21-Oct-2009	22-Oct-2009	1	22-Oct-2009	23-Oct-2009	AZ		23-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)	NOVARTIS VACCINES AND DIAGNOSTICS	?	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperhidrosis, Nausea

**Symptom Text:** sweating and nausea nausea persisted throughout the morning but has subsided mostly by 11:00AM

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362291-1

<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>
30.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	IL		23-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	UP005AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash erythematous, Urticaria

**Symptom Text:** Patient developed hives (raised red rash) on chest with intense itching reported. Diphenhydramine 25mg PO taken every 4 hours for approximately 4-5 doses.

**Other Meds:** Albuterol Oral Inhaler Ethinyl Estradiol/Drospirenone (Yaz) oral contraceptive.

**Lab Data:** N/A

**History:** Drug Allergy: Codeine Asthma

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362306-1

<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>
11.0	M	17-Oct-2009	21-Oct-2009	4	22-Oct-2009	23-Oct-2009	MA		23-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	UP009AA	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash papular

**Symptom Text:** Rash sm. pinpoint red bumps. Dr feels this is unlikely a reaction to H1N1 vaccine.

**Other Meds:** FLONASE; Loratadine

**Lab Data:** None

**History:** Allergic rhinitis; Nosebleeds; Heart murmur

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362311-1

<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>
1.9	M	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	OR		23-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	NULL	0	Left leg	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Diet refusal, Eye swelling, Hypersensitivity, Hypophagia, Injection site pain, Pallor, Pyrexia, Rash generalised, Urticaria, Wheezing

**Symptom Text:** Complaining of pain at injection site by 8pm on 10/20. Severe allergic reaction noticed next morning 8am on 10/21. Fever, severe hives and rashes all over body, swollen eyes, wheezing. Rash and fever got worse. Doctor gave Benadryl at 10am then Steroids that afternoon around 6pm. Rash and fever got worse, went to ER at 9:30pm. Rash then covered entire body, fever was 103. ER Dr. gave him IV of morphine, steroids, benadryl and tagamet (to ease stomach pain from steriods) Baby refused to eat or drink. ER DR. gave him fluids in IV. We were discharged at 2am after the rash was retreating and his fever was back to normal. Baby has new rash spots on 11/22 but no fever. He is very pale and still won't eat. He's on steroids, Tagamet, Benadryl and Tylenol w/ codeine to help him sleep and not itch the rash.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362314-1

<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>
35.0	F	19-Oct-2009	19-Oct-2009	0	22-Oct-2009	23-Oct-2009	DE		23-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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash, Pruritus generalised, Rash generalised, Skin warm

**Symptom Text:** Rash at injection site; very warm to touch. Rash noted on abdomen, chest, back of neck. Itching all over

**Other Meds:**

**Lab Data:**

**History:** No known pre existing conditions at time of vaccination

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362315-1

<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	M	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	MD		23-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	UP008AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Dizziness, Dyspnoea, Hyperhidrosis

**Symptom Text:** Pt became lightheaded, diaphoretic within 5 min of vaccination. Increase in anxiety. C/o SOB but able to move air without cyanosis, wheezing or stridor.

**Other Meds:**

**Lab Data:**

**History:** Asthma; ADHD

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362316-1

<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>
34.0	F	19-Oct-2009	19-Oct-2009	0	22-Oct-2009	23-Oct-2009	DE		23-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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Rash papular

**Symptom Text:** Face began to itch; raised rash on face/circumoral; No swelling at or around injection site.

**Other Meds:** Depakote, Insulin, Glucophage, Depoprovera (q 3 months)

**Lab Data:**

**History:** Diabetes; allergic to all nuts, sulfa drugs, PCN, ASA

**Prex Illness:** No known illness

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362319-1

<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>
46.0	M	14-Oct-2009	16-Oct-2009	2	22-Oct-2009	23-Oct-2009	--		23-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		Right arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Musculoskeletal discomfort, Myalgia, Pain in extremity, Restless legs syndrome

**Symptom Text:** EXTREME MUSCLE ACHES AND PAIN IN RIGHT ARM, JOINT PAIN IN HIPS, RESTLESS MUSCLES IN LEGS

**Other Meds:**

**Lab Data:**

**History:** ASTHMA, HYPERTENSION

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362322-1

<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>
21.0	F	22-Oct-2009	22-Oct-2009	0	22-Oct-2009	23-Oct-2009	AL		23-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	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Muscular weakness

**Symptom Text:** Patient complained of headache and weak legs

**Other Meds:**

**Lab Data:**

**History:** NKDA

**Prex Illness:** Patient reported an infected toe but denied any antibiotics

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362329-1

<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>
20.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	NY		23-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	UP006AA	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Nausea, Sensation of pressure

**Symptom Text:** upper anterior chest discomfort, internal poking/pressure sensation almost continuous, also has mild additional tightness across same area which is more intermittent, no SOB, cough, fever or palpitations, symptoms not affected by movement, breathing or exercise, injection given in left deltoid, injection site nontender, not red or swollen, has had mild nausea at bedtime but no vomiting or diarrhea, all symptoms gradually abating

**Other Meds:** none

**Lab Data:** EKG done 10/22/09 normal

**History:** none

**Prex Illness:** mild runny nose

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362344-1

<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>
35.0	F	21-Oct-2009	22-Oct-2009	1	22-Oct-2009	23-Oct-2009	VA		23-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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Headache, Hyperhidrosis, Pain, Presyncope

**Symptom Text:** near-syncopal episode. Weakness, dizziness, diaphoresis, headache, body aches.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362347-1

<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>
26.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	KS		23-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Bedridden, Headache, Oropharyngeal pain, Pyrexia, Tonsillar hypertrophy

**Symptom Text:** Swollen tonsils, sore throat, fever of 101 and higher throughout the night and next two days. Also, severe headache that prevent me from leaving the bed. I took Aleve and Tylenol alternating. Fever finally broke on 10/22/2009 around noon. However sore throat and swollen tonsils persist.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362349-1

<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>
7.0	M	22-Oct-2009	23-Oct-2009	1	23-Oct-2009	23-Oct-2009	IL		23-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	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives over trunk area, extending under armpits, on neck, and down legs to the knee area

**Other Meds:**

**Lab Data:** Administered 12.5 mg benadryl and applied cortisone cream to reduce itching. Called pediatrician. Based on on call doctor's advise administered and additional 12.5 mg of benadryl (weight aprox. 55 pounds). Told to monitor carefully for s

**History:** Asthma, grass, mold, dogs, cats,

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362352-1

<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>
20.0	F	22-Oct-2009	22-Oct-2009	0	22-Oct-2009	23-Oct-2009	IA		23-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	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Hypoaesthesia facial, Muscle twitching, Paraesthesia

**Symptom Text:** 2 hours after left deltoid injection, developed left lateral upper arm and left facial numbness/tingling along with left orbicularis muscular twitching/fasciculations.

**Other Meds:** Prenatal vits; SINGULAIR; ADVAIR DISKUS; Albuterol

**Lab Data:** Low normal Ca+, 8.5; slightly low Mg+, 1.6; and K+, 3.4

**History:** PCN-urticaria; Hx of asthma

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362353-1

<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>
36.0	F	22-Oct-2009	22-Oct-2009	0	22-Oct-2009	23-Oct-2009	AZ		23-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1008131P	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT:** Dysgeusia, Hot flush

**Symptom Text:** Hot flashes, unusual taste in her mouth.

**Other Meds:** Albuterol-LANTUS; Labetolol

**Lab Data:**

**History:** IDDM; Asthma; CHTN; Antibody S

**Prex Illness:** Pregnancy

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362356-1

<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>
50.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	AK		25-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	VP001AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Diarrhoea, Lip swelling, Migraine, Oedema peripheral

**Symptom Text:** Received vaccine 10.20.09 at 12:00. At 20:30 on 10.20.09 had swollen lips and fingers, a migraine, severe abdominal cramps, and diarrhea. Took an antihistamine and symptoms went away. No medical treatment.

**Other Meds:**

**Lab Data:**

**History:** Celiac sprue; Asthma

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362358-1

<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>
30.0	F	20-Oct-2009	20-Oct-2009	0	22-Oct-2009	23-Oct-2009	WA		25-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		UP008AA		Unknown	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Dizziness, Hot flush, Pruritus, Throat tightness

**Symptom Text:** 20 min. after injection, itchiness, tightness of throat, hot flashes, dizzy, increased BP 130/97. Taken to ED. PO BENADRYL, PREDNISONE, SOLUMEDROL.

**Other Meds:** None

**Lab Data:** Allergic reaction/not anaphylaxis

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362361-1

<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	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	23-Oct-2009	KS		27-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)	SANOPI PASTEUR	500763P	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Dizziness, Heart rate increased, Hypoaesthesia, Immediate post-injection reaction, Pain in extremity, Palpitations

**Symptom Text:** Immediately after she received H1N1 vaccine, she states her left arm went completely numb for 15-20 min and afterwards became very sore, and started becoming very dizzy and light headed with heart racing. Noted resting heart rate 122. 10/26/09 Medical records received for date 10/22/09. Presenting SX: Pt. is 34wks pregnant with c/o receiving H1N1 vaccine and immed had arm numbness lasting 20min. Then site of vax became sore, pt c/o dizziness. Assessment: increase BP, HR increased.

**Other Meds:**

**Lab Data:** 24 hour urine creatinine with total protein; Pih; Chem profile; CBC; BUN; Creatinine; Uric acid; ALT; AST Diagnostics/Labs: FHR(+), 24hr. urine creatinine clearance: creat cleared 166(H), total protein 132(H). Glucose 69 (L), BUN 6(L), INR

**History:** PMH: 34 weeks pregnant.

**Prex Illness:** Loss of sensation & numb arm

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362362-1

<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>
43.0	U	22-Oct-2009	22-Oct-2009	0	22-Oct-2009	23-Oct-2009	FL		25-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		UP009AA		Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Chills, Nausea

**Symptom Text:** 9:00am pt with vital signs (137/89), pt in complaining weakness, nausea, shivering. Keeping in observation. Pt denies any history of disease or current medication.

**Other Meds:** None

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362401-1

<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>
26.0	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	23-Oct-2009	KY		23-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	UP0048AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Diarrhoea, Dyspnoea, Feeling abnormal, Feeling hot, Heart rate increased, Impaired work ability, Local swelling, Muscle tightness, Rash, Urticaria

**Symptom Text:** Around 5:00 AM noticed a rash on neck and abdomen, felt hot. Left work at 6:30 AM, went home took Benadryl. Went to bed at 8:00 AM. Woke up at 9:30, jumping out of skin. Noted golf ball sized welps all over. Had swollen neck, tight, couldn't breathe; diarrhea. Went to ER at 9:45 AM. BP elevatetd, pulse rate elevated. At the ER, staff administered Epinephrine, Benadryl, Phenergan, zantac, prednisone and a dose of an antibiotic (possibly Keflex). Monitored her for about 2 hours and released home to be off work for 24 hours.

**Other Meds:** None

**Lab Data:** No

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362402-1

<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>
2.0	M	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	23-Oct-2009	TN		23-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	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Eye swelling, Hypersensitivity

**Symptom Text:** Allergic reaction causing severe swelling of right eye.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362413-1

<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>
51.0	F	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	23-Oct-2009	MA		23-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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye swelling, Myalgia, Nausea, Paraesthesia oral

**Symptom Text:** lips tingling, eyes swollen, severe nausea, muscles aches

**Other Meds:** Simvastatin

**Lab Data:**

**History:** allergic to cats; high cholesterol

**Prex Illness:** No illness at time of vaccination

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362415-1

<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>
21.0	M	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	23-Oct-2009	NY		25-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	UP007AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Diarrhoea, Pain, Pyrexia

**Symptom Text:** chills, fever, achiness approximately 2-3 hours following vaccination. Felt better by the next morning but then developed diarrhea which is persisting today (a day later)

**Other Meds:** None

**Lab Data:**

**History:** asthma

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362417-1

<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>
13.0	M	21-Oct-2009	23-Oct-2009	2	23-Oct-2009	23-Oct-2009	WI		25-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	UP007AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Loss of consciousness, Pyrexia

**Symptom Text:** The patient had a fever beginning within 6 hours after immunization. Peak measured temp of 103. On 10/23/2009 he passed out while voiding. Was unconscious for 3 or 4 minutes by the parent's estimation. No seizure like activity. Patient alert, oriented and feeling well within short time after the event.

**Other Meds:** Cyclosporin Lisinopril

**Lab Data:**

**History:** Nephrotic syndrome Focal Segmental Glomerulosclerosis Hypertension Immunosuppressive Therapy

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362419-1

<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>
50.0	F	16-Oct-2009	16-Oct-2009	0	23-Oct-2009	23-Oct-2009	FL		25-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	UP09AA		Unknown	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Myalgia, Rash

**Symptom Text:** Initial rash then onset of muscle aching & tired. Claritin taken

**Other Meds:** NOTE: Adverse reaction to H1NI Less than 4 weeks seasonal flu taken in same arm.

**Lab Data:** none

**History:** PCN, sulfa, codiene

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362421-1

<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>
10.0	F	20-Oct-2009	21-Oct-2009	1	23-Oct-2009	23-Oct-2009	NY		25-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	
	FLU	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Convulsion, Crying, Movement disorder, Paraesthesia, Tremor, Urinary incontinence

**Symptom Text:** Daughter awoke crying that she could not move, had lost controll of bladder and wet the bed. I tried to get her to move and she could not feel me touching her feet or moving her legs. I sat her on the toilet, and she could not sit there herself with out falling over. I took her to the ER, and there she started to move and started to get her feeling back in limbs. They tested her blood, and gave a CT scan which all of came back negative. Doctor at ER said that all of the signs she had where for a seizure, but was unsure if she had one or not because she could remember herself shaking in bed. Doctor was informed that child had day before seasonal flu, and H1N1 Live Attenuated vaccination. Being that all test came back negative, my daughter was discharged from ER. On 10-22-09 took daughter to family doctor, who did physical examination, and said that all neurological test where OK, but did order a EEG or EKG (not sure which one) for future, but did believe daughter did have seizure. Daughter is acting fine and normal now.

**Other Meds:** My daughter does not take any medication at all very health

**Lab Data:** CT scan, Blood work

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362424-1

<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>
58.0	M	14-Oct-2009	17-Oct-2009	3	23-Oct-2009	23-Oct-2009	MT		25-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	UP001AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Clumsiness, Gait disturbance, Muscular weakness, Peroneal nerve palsy

**Symptom Text:** Upon attempting to get out of bed, individual noticed that he had weakness in both lower extremities, and experienced "clumsiness" while attempting to dress, which required him to sit on the edge of the bed to be able to finish dressing. The weakness progressed until about 10:00 AM at which time the left was more involved than the right. Gait was mildly dysfunctional with foot drop noted on the left. Weakness was noted in the hip flexors, abductors, adductors and tibialis anterior muscles. Weakness began to resolve later on the afternoon of 10/17/2009 and was >90% resolved by 10:00 PM. By 10/18/2009, all weakness had resolved.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362425-1

<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>
11.0	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	23-Oct-2009	CA		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU
	HPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	MEN
							TD

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Nausea, Vomiting

**Symptom Text:** Severe abdominal pain & vomiting. 10/27/09 ED records received service date 10/22/09. Assessment: Possible reaction to immunization. Patient c/o periumbilical abdominal pain, nausea, vomiting.

**Other Meds:** none

**Lab Data:** Have call in to pediatric doctor

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362429-1

<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>
34.0	F	20-Oct-2009	20-Oct-2009	0	23-Oct-2009	23-Oct-2009	OH		25-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		UP006AA	0	Left arm	Intramuscular	FLU	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pain in extremity, Paraesthesia

**Symptom Text:** Tingling in feet, pain in calf muscles. Continued into next morning. Called family doctor who advised me to go to ER.

**Other Meds:** levothyroxine 200 mcg each morning fluoxetine 40 mg each day

**Lab Data:** CBC, urinalysis done at ER. CBC showed elevated white cells. Urinalysis showed possible urinary tract infection which is likely unrelated.

**History:** Thyroid Cancer/Thyroidectomy Oct 2005

**Prex Illness:** Recovering from strep throat. On day 5 of antibiotic treatment.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362437-1

<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>
45.0	F	20-Oct-2009	21-Oct-2009	1	23-Oct-2009	23-Oct-2009	FL		25-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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Feeling hot, Oropharyngeal pain, Pain

**Symptom Text:** sore throat, achiness, slight cough, feel feverish.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362440-1

<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>
35.0	F	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	23-Oct-2009	MI		25-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		UP007AA	0	Right arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Eye swelling, Lip swelling, Swelling face, Throat irritation

**Symptom Text:** Initial tickle in the throat. Took Benadryl approximately 1 1/2 hour later. By the next morning client noticed lips, nose, and eyes swollen and short of breath. Treated by EMTs shortly after.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362445-1

<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>
51.0	F	19-Oct-2009	19-Oct-2009	0	23-Oct-2009	23-Oct-2009	MI		25-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	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anxiety, Pruritus

**Symptom Text:** Feeling itchy and anxious for the next hour or so.

**Other Meds:**

**Lab Data:**

**History:** Latex allergy

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362519-1

<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>
3.0	F	21-Oct-2009	23-Oct-2009	2	23-Oct-2009	23-Oct-2009	WA		25-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Vomiting

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362523-1

<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>
50.0	F	23-Oct-2009	23-Oct-2009	0	23-Oct-2009	23-Oct-2009	SC		25-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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Reaction to preservatives

**Symptom Text:** Erythema of Hands and Feet, given steroids in ED. Infectious Disease doctor saw patient and thought it was a reaction to the thimerosal.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362526-1

<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>
11.0	M	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	23-Oct-2009	PA		25-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	MEDIMMUNE VACCINES, INC.	500705P		Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP007AA		Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Gait disturbance

**Symptom Text:** Bilateral knee pain and limp No swelling or redness Resolving but not completely gone on 10/23/09

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362528-1

<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>
40.0	F	14-Oct-2009	19-Oct-2009	5	23-Oct-2009	23-Oct-2009	MD		25-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1008131P	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Pain, Pyrexia, Rash generalised, Serum sickness

**Symptom Text:** Fever, chills, body aches, all over body rash/ serum sickness

**Other Meds:**

**Lab Data:** blood work, doctors visit

**History:** Asthma,environmental allergies

**Prex Illness:** no

**Prex Vax Illns:** none~ ()~~0.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362538-1

<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>
62.0	M	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	26-Oct-2009	NY		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	UP006AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Feeling cold, Feeling hot, Headache, Sensory disturbance, Throat tightness

**Symptom Text:** After receiving vaccine, 1 1/2 hours later, felt feverish, chilly and had sensation of fur over his body. Later, developed a headache and felt that his throat was closing.

**Other Meds:** None Known

**Lab Data:** None indicated

**History:** No known allergies

**Prex Illness:** No illness at time of vaccination

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362542-1

<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>
53.0	F	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	26-Oct-2009	VA		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	UP004AA		Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3211AA		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Diarrhoea, Vomiting

**Symptom Text:** stated: explosive vomiting, diarrhea, and chills

**Other Meds:**

**Lab Data:** unk

**History:** Arthritis - Plaquenil & Relafen

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362543-1

<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>
15.0	M	21-Oct-2009	22-Oct-2009	1	23-Oct-2009	26-Oct-2009	MA		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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Rash

**Symptom Text:** woke with rash on neck, no itch,pain,fever, erythema on back of neck from ear to ear and to shirt line. no bites/srctches/swelling. remaining skin within normal limits. treated with hydrocortisone cream 1%

**Other Meds:** does not take any medications daily is allergic to amoxicillin

**Lab Data:**

**History:** anemia

**Prex Illness:** upper respiratory symptoms, no fever

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362545-1

<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>
41.0	F	20-Oct-2009	Unknown		23-Oct-2009	26-Oct-2009	WV		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	UPO10AA	0	Right arm	Intramuscular	FLUN(H1N1)

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration, No adverse event

**Symptom Text:** EMPLOYEE CAME IN FOR THE H1N1 NASAL LIVE VACCINE ON 10/8/09, SHE CAME BACK ON 10/20 AND RECEIVED THE INJECTABLE H1N1. DID NOT UNDERSTAND THAT SHE WAS NOT TO GET THE SECOND VACCINE. NO ADVERSE REACTION REPORTED.

**Other Meds:**

**Lab Data:**

**History:** NO

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362546-1

<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>
61.0	F	22-Oct-2009	23-Oct-2009	1	23-Oct-2009	26-Oct-2009	MA		27-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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Grip strength decreased, Pain in extremity

**Symptom Text:** Pain in hand where vaccine was administered, unable to hold a pen. Also experiencing dizzy spells.

**Other Meds:**

**Lab Data:** None

**History:** Diabetes

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362556-1

<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>
29.0	F	20-Oct-2009	21-Oct-2009	1	23-Oct-2009	26-Oct-2009	KY		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dissociation, Pain in extremity, Paraesthesia

**Symptom Text:** Tingling in lower extremities from the knee down. Tingling in fingers. Pain in lower extremities. "Disconnected" feeling, did not feel like I usually do.

**Other Meds:**

**Lab Data:**

**History:** NO

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362561-1

<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>
13.0	M	21-Oct-2009	22-Oct-2009	1	23-Oct-2009	26-Oct-2009	MD	MD	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)	UNKNOWN MANUFACTURER		NULL		Unknown	Unknown	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Feeling of body temperature change, Headache, Hyperhidrosis, Hypokinesia, Malaise, Pain, Pyrexia

**Symptom Text:** Patient started feeling a bit ill at 9:15 PM so he went to bed. At 2:30 AM he came into our room with a throbbing headache and laid on the floor (hard for him to move). I took his temperature and he had 102.4 degree temperature and he was aching and said it was hard to move his head. I put him in a tepid bath for 30 minutes and gave him Tylenol to reduce the fever. Got him back in bed around 3:15 AM and now he was cold (put him in bed with blankets) and hour later (now 4:15 AM) burning hot and sweating, I got him out of bed (he had already kicked off all of the blankets and took his PJ's off) he laid on our foyer marble floor (with a t shirt on and boxer shorts) for about 15 minutes and then went back to bed. Woke up at 8:30 AM feeling fine and didn't have any more symptoms. He did not go to school just stayed home but was fine. My other 2 children (one 16 years old and the other 9 years old had no symptoms at all and were completely fine).

**Other Meds:** none

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362569-1

<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>
0.8	M	21-Oct-2009	22-Oct-2009	1	23-Oct-2009	26-Oct-2009	SD		27-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		UP001AA	0	Left leg	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash generalised

**Symptom Text:** Mom picked up child at 5:15 PM and noticed body rash shortly thereafter. Child has fine, red rash over entire body.

**Other Meds:** Giving benadryl for rash

**Lab Data:** None at this time

**History:** None

**Prex Illness:** Mild cold symptoms including cough and runny nose.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362572-1

<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>
37.0	F	23-Oct-2009	23-Oct-2009	0	23-Oct-2009	26-Oct-2009	TN		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	UP004AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Pruritus, Urticaria

**Symptom Text:** light headed, itching welps

**Other Meds:**

**Lab Data:**

**History:** DM type II htn copd asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362575-1

<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>
3.0	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	26-Oct-2009	AZ		27-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	500760P	0	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	U3201AA	3	Left leg	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Swelling face

**Symptom Text:** facial swelling

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362577-1

<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>
39.0	F	20-Oct-2009	20-Oct-2009	0	23-Oct-2009	26-Oct-2009	WI		27-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	UP006AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Axillary pain, Breast pain, Breast swelling, Joint swelling, Oedema peripheral, Sensation of heaviness

**Symptom Text:** In evening after receiving shot left breast felt sore when touched. Noticed swelling of L upper chest/arm/shoulder area. The following day the L breast was swollen, painful, heavy feeling. It was almost twice the size of the R breast. Pain the next day is primarily in L axilla and beneath the breast.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362578-1

<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>
23.0	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	26-Oct-2009	NV	up002aa	27-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	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Dyspnoea, Eye pruritus, Headache, Oropharyngeal pain, Pruritus generalised

**Symptom Text:** sever itching all over including eyes. Hoarse Cough (therefore sore throat), slight trouble breathing, headache

**Other Meds:**

**Lab Data:**

**History:** allergic to sulfa

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362586-1

<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>
44.0	F	16-Oct-2009	16-Oct-2009	0	23-Oct-2009	26-Oct-2009	NM		27-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	UP00A11	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest pain, Diarrhoea, Migraine, Pyrexia

**Symptom Text:** severe migraine, occasional stabbing chest pain, low grade fever, diarrhea x1

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362588-1

<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>
55.0	F	19-Oct-2009	19-Oct-2009	0	23-Oct-2009	26-Oct-2009	MA		27-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)	NOVARTIS VACCINES AND DIAGNOSTICS	100739 1P	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dizziness, Dysphonia, Fatigue, Generalised erythema, Influenza like illness, Lip swelling, Oral pruritus, Rhinorrhoea, Throat irritation, Throat tightness

**Symptom Text:** Pt c/o lips feeling swollen, dizziness and lightheadedness within 15 minutes of vaccination. Over the next 45 minutes the pt c/o throat feeling tight, voice husky, chest heaviness. Pt had intermittent episodes of redness of upper torso, upper arms, chest and face; and itchy palate and throat. Pt reported runny nose and flu-like symptoms for about 10-12 hours. All symptoms, except for mild fatigue, resolved within 12 hours without any medical intervention.

**Other Meds:** none

**Lab Data:** BP 130/74 P 76

**History:** History of similar symptoms in reaction to wasp stings, food allergies (including shell fish), and gadolinium contrast dye.

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362589-1

<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	M	20-Oct-2009	20-Oct-2009	0	23-Oct-2009	26-Oct-2009	FL		27-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		UP009AA		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Diarrhoea, Vomiting

**Symptom Text:** CLIENT STATED SHE HAD DIARRHEA, VOMITING, COUGHING AND A TEMP OF 99.9

**Other Meds:** UNKNOWN

**Lab Data:**

**History:** LUPUS

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:** Zoloft; 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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362607-1

<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>
9.0	F	21-Oct-2009	23-Oct-2009	2	23-Oct-2009	26-Oct-2009	IL		27-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		UP001AA	0	Left arm	Intramuscular	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia

**Symptom Text:** Fever 101 and under. Cough.

**Other Meds:** Singulair, Zyrtec

**Lab Data:**

**History:** Allergy to amoxicillin. Environmental allergies/asthma

**Prex Illness:**

**Prex Vax Illns:** Fever~ ()~~1.08~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362611-1

<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>
51.0	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	26-Oct-2009	TN		27-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	UP009AA	0	Right arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Headache

**Symptom Text:** Extreme chills, headache all through the night & into the next day. Took advil.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362612-1

<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>
6.0	F	23-Oct-2009	23-Oct-2009	0	23-Oct-2009	26-Oct-2009	MA		27-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		UP001AA		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hyperhidrosis, Pallor, Syncope, Tachycardia

**Symptom Text:** Child became pale, diaphoretic and tachycardic, had a syncopal episode

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** RECOVERING FROM PNEUMONIA

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362614-1

<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>
6.0	M	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	26-Oct-2009	WA		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)	SANOFI PASTEUR		UP008AA	0	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Capillary nail refill test abnormal, Cyanosis, Dizziness, Gaze palsy, Hypersensitivity, Pallor, Presyncope, Pruritus generalised, Urticaria, Vomiting

**Symptom Text:** vomitting, hives, dizziness. 10/28/09 ED records and ED DC summary received service date 10/22/09. Assessment: Allergy unspecified, not elsewhere classified. Patient vomited at school, hives, itchy all over, eyes rolled up, lips blue. While at PCP office was pale, vomited, and had near syncope. Presents pale, delayed capillary refill, alert. 10/30/09: Outpatient Clinic Records received for date of service 10/22/09. Dx: Urticaria, Anaphylaxis. Assessment: Supplemental oxygen given due to O2 sat of 92% on RA after near syncope event. Epi pen Jr. administered. Rash improved, color returned. Pt. to take Benadryl Q 6 hrs. until sx. free. Call if no improvement after 45 hours. Sent by personal vehicle to ED.

**Other Meds:**

**Lab Data:**

**History:** Asthma. Eczema. 10/30/09: Outpatient Clinic Records received for date of service 10/22/09. PMH: As above.

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362619-1

<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>
0.8	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	26-Oct-2009	IN		27-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		UP0014A	0	Left leg	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Condition aggravated, Cough, Decreased appetite, Immediate post-injection reaction, Insomnia, Lethargy, Rhinorrhoea, Skin warm

**Symptom Text:** After receiving the H1N1 shot, she almost immediately had a worse runny nose. She began to cough more. She had no appetite and barely slept that night. The next day(10/23), she went down for a nap at 11am. When she woke up, she was very warm. We used a temporal scanner to take her temperature repeatedly and it flucuated between 102-104. We gave Tylenol and it went down to around 100 or just below. She is still very lethargic and has a very runny nose and cough. We called doctor and were told to wait until the morning, and if her fever was still high, to call and try to get her in.

**Other Meds:**

**Lab Data:**

**History:** N/A

**Prex Illness:** A very slight cough and very slight runny nose.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362624-1

<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>
4.0	F	22-Oct-2009	23-Oct-2009	1	23-Oct-2009	26-Oct-2009	VA		27-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	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Oropharyngeal pain, Respiratory tract congestion, Vomiting, Wheezing

**Symptom Text:** sore throat (morning) congestion (throughout day) wheezing (evening) vomiting (evening -- 8:30PM continuing through time of this filing)

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362631-1

<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>
50.0	F	23-Oct-2009	23-Oct-2009	0	24-Oct-2009	26-Oct-2009	VA	UP004AA	27-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	Unknown	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Diarrhoea, Headache, Hyperhidrosis, Hypoaesthesia, Limb discomfort, Palpitations, Paraesthesia

**Symptom Text:** Sweats, pressure in lower right arm and hand keeps going to sleep. Lots of pressure. Heart palpitations, headache, diarrhea, back aching from 11:30pm 1/23/09 to now 10:55am 10/24/2009

**Other Meds:**

**Lab Data:**

**History:** none -

**Prex Illness:** Work up 10/23/09 at 11:30pm sweats pressure in lower right arm(shot arm) keeps going to sleep, 10/24/09 9:00am diarrhea headache

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362632-1

<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>
20.0	F	20-Oct-2009	20-Oct-2009	0	24-Oct-2009	26-Oct-2009	MA		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>
	FLU(H1N1)	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness postural, Fatigue, Flushing, Headache, Heart rate increased, Nausea, Tremor, Vertigo

**Symptom Text:** Feeling dizzy,nausea,shaking, fast pulse(220), light headed. 10/28/09 ER medical records received service date 10/20/09. Assessment: Acute vertigo. Consider reaction to influenza vaccine (H1N1). Patient presents with nausea and dizziness worsened by movement. Skin flushed. Headache and fatigue. Mildly orthostatic. 10/27/09 Clinic medical records received service date 10/22/09 - 10/23/09. Assessment: Vertigo. Reaction to H1N1 vaccine? Viral? Patient c/o she became dizzy, lightheaded, after H1N1 vaccine. Follow-up visit for vertigo. Feels better.

**Other Meds:**

**Lab Data:** no tests. LABS and DIAGNOSTICS: ECG - Abnormal, sinus arrhythmia, ST-T abnormalities.

**History:** none. Heart murmur. Reproductive surgery. Cecum resection.

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362632-1

<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>
20.0	F	20-Oct-2009	20-Oct-2009	0	24-Oct-2009	26-Oct-2009	MA		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>
	FLU(H1N1)	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Dizziness postural, Fatigue, Flushing, Headache, Heart rate increased, Nausea, Tremor, Vertigo

**Symptom Text:** Feeling dizzy,nausea,shaking, fast pulse(220), light headed. 10/28/09 ER medical records received service date 10/20/09. Assessment: Acute vertigo. Consider reaction to influenza vaccine (H1N1). Patient presents with nausea and dizziness worsened by movement. Skin flushed. Headache and fatigue. Mildly orthostatic. 10/27/09 Clinic medical records received service date 10/22/09 - 10/23/09. Assessment: Vertigo. Reaction to H1N1 vaccine? Viral? Patient c/o she became dizzy, lightheaded, after H1N1 vaccine. Follow-up visit for vertigo. Feels better.

**Other Meds:**

**Lab Data:** no tests. LABS and DIAGNOSTICS: ECG - Abnormal, sinus arrhythmia, ST-T abnormalities.

**History:** none. Heart murmur. Reproductive surgery. Cecum resection.

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362634-1

<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	22-Oct-2009	22-Oct-2009	0	24-Oct-2009	26-Oct-2009	TN		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)	UNKNOWN MANUFACTURER		UP003AA	0	Right arm	Unknown	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Chills, Dizziness, Lethargy, Nausea, Oropharyngeal pain, Pain, Pyrexia, Rhinorrhoea, Vomiting

**Symptom Text:** Within first half-hour, began to feel dizzy; symptom remained much of the day. First day: Felt faint often during day vaccine was given; nausea; low-grade (99.4) temp; body aches. Day two: 100F fever (waned with Advil); severe body aches; lethargy; unexplained and brief nasal drip; mild sore throat; nausea and late evening, vomited once. However, was able to go on with day (had to) with Advil. Day three: Lethargy; body ache; chills; 99.3 temp (reduced with tylenol); nausea. NO PAIN AT INJECTION SITE.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362636-1

<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>
47.0	F	14-Oct-2009	18-Oct-2009	4	24-Oct-2009	26-Oct-2009	WA		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Chills, Cough, Headache, Laryngitis, Nasal disorder, Oropharyngeal pain, Pain, Pyrexia, Sinus congestion, Skin warm, Vomiting

**Symptom Text:** 10/18- slight cough and soar throat 10/19- cough worsens, slight headache with developing body aches 10/20- fever in am (100.8 F), chills and body aches, severe headache and vomitting. Visit to ER. 10/21 and 10/22- improvement with headache, still coughing and body aches and weakness. still slight fever without medication. Developing nasal symptoms. 10/23- dry cough increases, slight soar throat and eventual complete laryngitis. 10/24- continued laryngitis,green mucousy sinus discharge That's where I am at today

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362637-1

<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>
43.0	M	19-Oct-2009	20-Oct-2009	1	24-Oct-2009	26-Oct-2009	MD		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	UP004AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache

**Symptom Text:** Headache on and off for 5 days located radiatingf from the back of the eyes to the base of the skull. Described as a naging dull ache.

**Other Meds:** Lipitor

**Lab Data:** none

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362640-1

<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>
61.0	F	20-Oct-2009	21-Oct-2009	1	24-Oct-2009	26-Oct-2009	GA		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	NOVARTIS VACCINES AND DIAGNOSTICS	97849P1		Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP003AA		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Dizziness, Fatigue, Lethargy, Nausea

**Symptom Text:** Diarrhea, Nausea, Dizziness, Lathargy, Was given regular flu and H1N1 at work. Became sick next day with diarrhea. Called family physician on 10/23/09 and they stated probably reaction to both flu shots at same time. Still feeling dizzy and fatigued 10/24/09.

**Other Meds:** Combivent Inhaler for Asthma, Toprolol XL for atrial fib, Celexa for Anxiety

**Lab Data:** No Tests as of 10/24/09. Resting at home taking tylenol, imodium and drinking plenty of liquids

**History:** Solumedrol, Demerol, Latex, IV Dye

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362642-1

<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>
48.0	F	23-Oct-2009	23-Oct-2009	0	24-Oct-2009	26-Oct-2009	VA		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea, Syncope, Vomiting

**Symptom Text:** Dizziness, nausea, syncope, vomiting

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:** syncope~ ()~3~31.25~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362643-1

<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>
45.0	M	23-Oct-2009	23-Oct-2009	0	24-Oct-2009	26-Oct-2009	MO		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Fatigue, Headache, Injection site pain, Nausea

**Symptom Text:** Headache, Nausea w/o vomiting, slight dizziness, fatigue. Resolved itself in approximately 6 hours. Injection site soreness remains.

**Other Meds:**

**Lab Data:**

**History:** Asthma, Hypertension

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362644-1

<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>
36.0	F	20-Oct-2009	21-Oct-2009	1	24-Oct-2009	26-Oct-2009	WA	WA	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)	UNKNOWN MANUFACTURER		NULL	0	Unknown	Unknown	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Fatigue, Nausea, Vomiting

**Symptom Text:** nausea, vomiting (profuse) x 2, fatigue. Once at 11pm on 10/21/09 (approximately 32 hours after receiving the LAIV against H1N1) and again on 10/22/09 at 9am. Continued to feel nauseated and weak for another day.

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362651-1

<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>
8.0	F	24-Oct-2009	24-Oct-2009	0	24-Oct-2009	26-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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** high fever (102.5 after dose of children's acetaminophen)

**Other Meds:** Prevacid Symbicort Singular Xopenex

**Lab Data:**

**History:** asthma

**Prex Illness:** cough due to asthma symptoms, no fever

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362652-1

<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>
8.0	M	24-Oct-2009	24-Oct-2009	0	24-Oct-2009	26-Oct-2009	IN		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	UP007AA	0	Left arm	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal discomfort, Dizziness, Nausea, Vomiting

**Symptom Text:** Patient felt light-headed after the injection. By about 2:00 PM he complained of having an upset-stomach and feeling like he may throw-up. He did not eat dinner, but finally threw-up at 8:15 PM.

**Other Meds:** No meds day of vaccine, but .25mg of risperidone and .5mg Prozac the previous evening.

**Lab Data:**

**History:** mild seasonal allergies

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362655-1

<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>
2.0	F	23-Oct-2009	24-Oct-2009	1	24-Oct-2009	26-Oct-2009	IL		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Insomnia, Rhinorrhoea, Vomiting

**Symptom Text:** Runny nose, cough, some sleep difficulties, progressing into more coughing and then vomiting at bedtime

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362658-1

<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	24-Oct-2009	24-Oct-2009	0	25-Oct-2009	26-Oct-2009	OH		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** DIZZY

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362661-1

<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>
33.0	F	24-Oct-2009	24-Oct-2009	0	25-Oct-2009	26-Oct-2009	CO		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)	UNKNOWN MANUFACTURER	NULL	1	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Axillary pain, Chest pain, Headache, Injection site pain, Lymph node pain, Musculoskeletal pain, Odynophagia, Oropharyngeal pain, Rhinalgia

**Symptom Text:** Headache, soariness of nasal and throat glands, pain while swallowing,soariness of glands of left arm pit (shot was given in left arm), achiness in left arm shoulder, chest and shoulder blade

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362662-1

<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>
13.0	F	21-Oct-2009	23-Oct-2009	2	25-Oct-2009	26-Oct-2009	CA		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Oropharyngeal pain, Rhinorrhoea

**Symptom Text:** Began with complaint of sore throat and progressed to runny nose and mild coughing. Currently giving DayQuil and/or NyQuil.

**Other Meds:** none

**Lab Data:**

**History:** no

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362668-1

<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>
56.0	F	22-Oct-2009	24-Oct-2009	2	25-Oct-2009	26-Oct-2009	FL		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Headache, Malaise, Musculoskeletal pain, Neck pain, Pain in extremity

**Symptom Text:** I woke up with a violent headache, which over the day into the next day, spread that pain to my neck shoulders and arms. The headache continues with powerful pain which is unresponsive to treatment with a combination of atthritis strength tylenol and 1 adult aspirin. I feel weak and not well. I was perfectly healthy and not a "headache person" prior to the immunization.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362670-1

<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>
31.0	F	22-Oct-2009	23-Oct-2009	1	25-Oct-2009	26-Oct-2009	ID		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)	UNKNOWN MANUFACTURER	500763	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Limb discomfort, Nausea

**Symptom Text:** Nausea, bad headache, dizziness, limbs falling asleep often.

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362671-1

<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	F	24-Oct-2009	24-Oct-2009	0	25-Oct-2009	26-Oct-2009	NC	NC	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	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Left leg	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Dehydration, Heart rate increased, Vomiting

**Symptom Text:** Stomach ache followed by severe vomiting (8 times between 8:00 PM and 4:00AM). Pulse rate increased to 130 beats/minute. Called Pediatrician office twice and then took daughter to ER because she could not keep anything down (even water) and was getting dehydrated.

**Other Meds:** None.

**Lab Data:** X ray of stomach, no finding. Some white blood cells found in urine. This was the first time she has ever had a flu vaccine, but has never reacted this way to any other vaccines. She was given the H1N1 shot and the seasonal flu mist at th

**History:** None.

**Prex Illness:** No.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362675-1

<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>
13.0	M	22-Oct-2009	23-Oct-2009	1	23-Oct-2009	26-Oct-2009	PA		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Depressed level of consciousness, Hypertension, Influenza like illness, Tremor

**Symptom Text:** Flu-like symptoms, shakes/chills, hypertension, slow to respond to questions.

**Other Meds:**

**Lab Data:** Influenza A +

**History:**

**Prex Illness:** Slight cough

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362676-1

<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>
1.2	M	24-Oct-2009	24-Oct-2009	0	26-Oct-2009	26-Oct-2009	CT		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	UP004AA	0	Left leg	Intramuscular	
	FLU	SANOFI PASTEUR	U3263DA	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Child received 0.25 FLUZONE and 0.25 H1N1 vaccines simultaneous B legs. 10 min. later developed hives-trunk, leg. Waning hive after BENADRYL 3/4 tsp. 12.5/5 given PO.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362677-1

<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>
46.0	F	23-Oct-2009	23-Oct-2009	0	23-Oct-2009	26-Oct-2009	MD		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	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Reports a latex glove sensitivity (ie. dentist uses latex gets welts). Received H1N1 2009 monovalent vaccine (multidose vial) at 8:30 AM, R deltoid. At 4:30 PM noted itchy, lacey rash at neck, arms, trunk and thighs. Denied difficulty breathing, shortness of breath, tongue thickness or swelling at time of reaction reporting at 7:30 PM. At 7:30 PM I noted light lace-like rash on neck, arms and abd. Associate denied treatment.

**Other Meds:**

**Lab Data:**

**History:** Not physician diagnosed latex sensitivity

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362678-1

<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>
22.0	F	24-Oct-2009	24-Oct-2009	0	25-Oct-2009	26-Oct-2009	IN		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Hypersomnia, Lethargy, Somnolence

**Symptom Text:** Lethargic, sleepy. Slept almost the entire day, had very little energy to do anything. Slept intermittently in the afternoon and then from ~5pm until 9am the next morning. These are very, very unusual sleeping patterns for me.

**Other Meds:**

**Lab Data:**

**History:** Allergic to codeine

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362681-1

<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>
33.0	F	19-Oct-2009	20-Oct-2009	1	25-Oct-2009	26-Oct-2009	NC		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)	UNKNOWN MANUFACTURER		UP009AA	0	Right arm	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Nausea, Oropharyngeal pain, Pharyngeal oedema, Pyrexia, Streptococcal identification test negative

**Symptom Text:** Felt nauseus. Sore throat. Next day throat was swollen. Went to doctor. Back of throat swollen. Possible bacterial. Strep test - neg. Followed by chills/fever and continued extremely sore throat. Doctor prescribed Antibiotics in case.

**Other Meds:** Seasonale Maxalt

**Lab Data:** On prescribed antibiotics, throat still very sore October 26th.

**History:** Asthma, respiratory issues.

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362682-1

<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>
3.0	F	24-Oct-2009	24-Oct-2009	0	25-Oct-2009	26-Oct-2009	MI		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>
	FLU(H1N1)	SANOFI PASTEUR	VP007AA	0	Left leg	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaphylactic reaction, Asthenia, Balance disorder, Cough, Hypotonia, Lymphadenopathy, Pallor, Stridor, Unresponsive to stimuli, Use of accessory respiratory muscles, Vomiting

**Symptom Text:** Approximately 2 to 3 minutes after my daughter received her vaccine (which was around 11 a.m. I don't know the exact time), after we had put on our coats preparing to leave I noticed my daughter was looking pale and swaying back and forth. I immediately took my daughter back to the nurse who gave the injection and told her my daughter was reacting to the vaccine. The nurse initially offered grape juice, thinking this was a drop in blood glucose. My daughter refused to drink something and was looking worse, she was very, very pale and began coughing along with (what sounded like to me) stridor. I asked the nurse what she had available for an allergic reaction which she stated, "Benadryl." I was becoming very concerned that Benadryl was not going to be sufficient to counteract what was taking place and stated this to the nurse. I had oral liquid Benadryl with me in my purse, I decided to give my daughter one teaspoon of Benadryl while the nurse seemed to be figuring out what was going on or what to do. After administering the Benadryl to my daughter I immediately picked her up in my arms, she was extremely weak and still very pale but not unconscious. I started following the nurse, who was now looking for an EMS person or physician, with my daughter and I began calling out for a physician or someone to help. I asked several times for someone to please get some epinephrine and administer it to my daughter. As I was directed to the EMS person the physician on duty came over to assess my daughter. For a brief moment my daughter was stood up on her feet again and she immediately vomited. I then sat down in a chair with my daughter in a supine position; she was limp and only occasionally opened her eyes to sound; she did not verbally respond when prompted. The doctor was trying to assess her and I was asking for epinephrine, which a second nurse (not the nurse who did the injection) brought over. After determining the appropriate dose for my daughters weight she was given .15 mg of epinephrine (based on 35

**Other Meds:** No other medications. Neither of my two children have ever reacted severely to a vaccine prior to 10/24/2009.

**Lab Data:** No laboratory tests were completed during time of treatment.

**History:** None known

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362683-1

<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>
43.0	F	22-Oct-2009	22-Oct-2009	0	25-Oct-2009	26-Oct-2009	OH		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Burning sensation, Dizziness, Dyspnoea, Feeling abnormal, Hyperhidrosis, Pallor, Palpitations, Tachycardia, Urticaria

**Symptom Text:** Feeling of impending doom, pale, diaphoretic,shaky, lightheaded, red raised welts on face and right arm. Burning sensation on right arm, and shortness of breath. Also racing heart rate(tachycardic)

**Other Meds:**

**Lab Data:** None. BP taken during event was 130/101

**History:** No

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362685-1

<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>
28.0	F	20-Oct-2009	23-Oct-2009	3	25-Oct-2009	26-Oct-2009	AZ		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		Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site haematoma, Pain, Pyrexia, Rash macular

**Symptom Text:** The afternoon after the H1N1 injection vaccine was given I had fever and body aches which improved a little 10/21 & 10/22, but then the fever came back on the am of 10/23. In the evening of 10/23 I broke out in macular red spots that blanch and are not itchy. The spots are located mainly on my back, chest and abdomen, but some spread to my arms and upper legs on 10/24. The fever resolved 10/24, but the spots persist at this time -10/25. The area where I received the injection is bruised about 2cm in diameter and has been since with day after the shot with no improvement in the bruise - worsened until 10/24. I work in a peds clinic so it is also possible that I picked up a weird virus the day before I got the shot.

**Other Meds:**

**Lab Data:** None

**History:** None pertinent to vaccination

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362686-1

<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	F	22-Oct-2009	23-Oct-2009	1	25-Oct-2009	26-Oct-2009	MD		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)	UNKNOWN MANUFACTURER	500754P	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia, Urinary tract infection, Urticaria

**Symptom Text:** Fever, hives on the stomach that spread to legs and arms Gave ibuprofen for fever and benadryl for hives as recommended by her pediatrician. She ran a fever through the night and on 10/24 the hives were worse. She was taken to an urgent care center where she was prescribed a steroid medication to treat the hives. Her fever was as high as 103 at some points. She was also diagnosed with a possible urinary tract infection and was given an antibiotic. She was given ibuprofen every six hours to control the fever. On 10/24 her fever returned to normal temperature and the hives seem to be improving.

**Other Meds:** none

**Lab Data:** Negative for strep and flu tests. Possible urinary tract infection. Ear infection

**History:** none

**Prex Illness:** Ear infection

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362691-1

<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>
42.0	F	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	26-Oct-2009	CA		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	UP006AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Pt. presented with hives on arms and legs approximately 2 hrs. after receiving H1N1 flu vaccine; denies SOB or difficulty swallowing. 10/27/09 occupational health clinic medical records received service date 10/21/09. Assessment: Urticaria associated with (H1N1) influenza vaccine. Patient presents with hives occurring 2 hours after receiving H1N1 flu vaccine. Streaks of urticaria on distal legs and on forearms.

**Other Meds:**

**Lab Data:** None

**History:** 10/27/09 occupational health clinic medical records received service date 10/21/09. Urticaria after prior seasonal influenza vaccines.

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362694-1

<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>
27.0	F	16-Oct-2009	19-Oct-2009	3	23-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>
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	98434P1		Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP001AA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Foetal heart rate abnormal, Foetal hypokinesia, Induced labour, Intra-uterine death

**Symptom Text:** A few days after the shot she experienced fetal demise at 30 weeks gestation. 10/26/09 Hospital records and discharge summary received. Service dates 10/21/09 to 10/22/09. Assessment: Status post delivery of intrauterine fetal demise, induced labor, stillborn infant. Estimated delivery date was 11/06/09. 10/26/09 PCP medical records received, includes vaccine records, service dates 6/8/09 to 10/21/09. Some duplication of hospital records. Revised estimated date of delivery 12/31/09. No fetal heart tones, no fetal movement for two days.

**Other Meds:**

**Lab Data:** None. 10/26/09 PCP medical records received service dates 6/8/09 to 10/21/09. LABS and DIAGNOSTICS: Ultrasound Limited OB - Fetal demise. CBC - WBC 10.7 K/uL (H) RBC 3.90 M/uL (L) Mono 0.94 K/UL (H).

**History:** None. PMH: Caffeine use. 10/26/09 PCP medical records received service dates 6/8/09 to 10/21/09. Previous hx of miscarriage.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362696-1

<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>
48.0	F	21-Oct-2009	21-Oct-2009	0	23-Oct-2009	26-Oct-2009	IL		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	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Throat irritation

**Symptom Text:** Approx. 1 hr. after vaccination this pt. presented to employee health RN with complaint of severe rash and itching on throat and chin. Dr. examined pt. at that time. Patient was given diphenhydramine 50 mg PO at that time and was sent home with diphenxydramine for prn use and instructed to go to ER if any breathing or swallowing problems developed.

**Other Meds:** Unknown

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362697-1

<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>
32.0	F	24-Oct-2009	25-Oct-2009	1	25-Oct-2009	26-Oct-2009	UT		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dysphonia, Dyspnoea, Ear pain, Eye swelling, Fatigue, Ocular hyperaemia, Oral pain, Oropharyngeal pain, Pain in jaw, Pyrexia, Respiratory tract congestion, Toothache

**Symptom Text:** Beginning with sore throat, then shortness of breath, hoarseness, fatigue, dizziness, mouth/ jaw pain/ tooth pain, earache, fever, congestion. First symptom was swelling of the membrane surrounding the eye and bloodshot eyes. Don't have health insurance to see physician.

**Other Meds:**

**Lab Data:** Have not yet sought medical attention

**History:** Asthma

**Prex Illness:** No

**Prex Vax Illns:** Severe Illness~Measles + Mumps + Rubella (no brand name)~1~30.25~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362699-1

<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>
21.0	F	23-Oct-2009	23-Oct-2009	0	25-Oct-2009	26-Oct-2009	KS		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	NULL	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus generalised, Rash, Rash erythematous

**Symptom Text:** Raised red rash on neck and face on the side of injection. Itching over entire body.

**Other Meds:** Junel Fe 1.5/28

**Lab Data:** NONE

**History:** History of exercise induced asthma. Allergies: penicillin, sulfa, doxycycline. No other birth defects of medical conditions

**Prex Illness:** No other acute illness present at time of vaccination.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362700-1

<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>
17.0	F	22-Oct-2009	23-Oct-2009	1	25-Oct-2009	26-Oct-2009	MD		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Allergy to vaccine, Headache, Rash generalised, Rash pruritic, Urticaria

**Symptom Text:** Diffuse hives. 10/27/09 ED records records received service date 10/25/09. Assessment: Allergic reaction to H1N1 Vaccine. Patient presents with generalized, diffuse, itching rash. Mild headache. Urticaria.

**Other Meds:**

**Lab Data:**

**History:** Asthma Allergy to Amoxicillin- rash

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362701-1

<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	23-Oct-2009	25-Oct-2009	2	25-Oct-2009	26-Oct-2009	WI		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Decreased appetite, Dizziness, Lethargy, Pyrexia

**Symptom Text:** Fever 102+, cough, dizziness, lethargy, loss of appetite

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362706-1

<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>
3.0	M	24-Oct-2009	24-Oct-2009	0	25-Oct-2009	26-Oct-2009	WA	unk	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)	UNKNOWN MANUFACTURER	UNKNOWN	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** fever

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362707-1

<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>
50.0	F	16-Oct-2009	19-Oct-2009	3	25-Oct-2009	26-Oct-2009	PA		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	NULL	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Rash pruritic

**Symptom Text:** itchy rash on hands & arms continues to spread x 1 week

**Other Meds:**

**Lab Data:**

**History:** Charcot-Marie-Tooth Dx Allergic to Flagyl

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362708-1

<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>
3.0	M	24-Oct-2009	25-Oct-2009	1	25-Oct-2009	26-Oct-2009	IL		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)	UNKNOWN MANUFACTURER		500763P	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Feeling abnormal, Pyrexia

**Symptom Text:** Fever of 102.1 10/25/2009 Toward the end of that night he was acting alittle spacey.

**Other Meds:** n/a

**Lab Data:**

**History:** n/a

**Prex Illness:** n/a

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362709-1

<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>
33.0	M	21-Oct-2009	25-Oct-2009	4	25-Oct-2009	26-Oct-2009	FL		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Urticaria

**Symptom Text:** While showering patient felt bumps all over his upper back. Red spots were present on the lower back and upper front chest. The bumps or hives are mostly raised. They do not itch or cause irritation.

**Other Meds:**

**Lab Data:**

**History:** Asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362711-1

<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	25-Oct-2009	25-Oct-2009	0	25-Oct-2009	26-Oct-2009	CA		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)	UNKNOWN MANUFACTURER	NULL		Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Headache

**Symptom Text:** Headache, fatigue

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** Common Cold

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362712-1

<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>
3.0	F	23-Oct-2006	24-Oct-2006	1	25-Oct-2009	26-Oct-2009	PA		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)	UNKNOWN MANUFACTURER		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Diarrhoea, Rash, Vomiting

**Symptom Text:** Patient has vomitted 3 times over the course of 24 hours (once during the day and twice in the middle of the night between 10/24/06 - 10/25/06), has had diarrhea, and has been complaining of stomache pains. Patient has also developed a rash on her lower stomach and left leg that looks like red pindots.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362754-1

<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>
49.0	F	23-Oct-2009	23-Oct-2009	0	26-Oct-2009	26-Oct-2009	NY		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	UP007AA		Gluteous maxima	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Heart rate increased, Hot flush, Paraesthesia, Throat tightness

**Symptom Text:** Tingling in extremities, surging hot flushing, rapid heart rate, tightening in chest and throat. Passed in about 10 mintues but returned mildly several times throughout the day. Went home and slept from 4:00 PM - 9:30 am the folling day. Then Felt better.

**Other Meds:** Nexium

**Lab Data:** N/A

**History:** NO

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362756-1 (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>
0.8	M	19-Oct-2009	21-Oct-2009	2	26-Oct-2009	03-Nov-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>	
	FLU(H1N1)	SANOFI PASTEUR		UP001AAA	0	Left leg	Unknown		

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Body temperature increased, Convulsion, Eyelid function disorder, Head titubation, Hypokinesia

**Symptom Text:** Pt received H1N1 vaccine 10/19 on Wed 10/21 pt experienced seizure activity of 10-15 total duration with 1 min seizure episodes and head shaking with eyes slightly opened with no associated full body mvmts with T. 103 deg rectally at ER admission. Admitted to hospital to rule out seizure etiology.

**Other Meds:** None

**Lab Data:** Lumbar puncture to rule out infection; Viral panel; Rapid flu A/B screen

**History:** Chronic otitis media infections

**Prex Illness:** Acute otitis media; URI

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362780-1

<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>
26.0	F	21-Oct-2009	21-Oct-2009	0	26-Oct-2009	26-Oct-2009	MO		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>
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	100739	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Client reported Abdominal itching to her on-call OB provider. Was instructed to take Benadryl, which she did. She awakened at 3:00 AM to more itching and noticed 12 welps on abdomen. By 12:00 Noon on 10/22/2009 she had itching and welps on her legs and lower back. Client had received and seasonal flu vaccine in early Sept. this year and one other time a few years ago. 10/27/09 OB/GYN records received sevice dates 6/25/09 to 10/23/09. Assessment: Hives. Patient reports hives, itching, took benadryl.

**Other Meds:**

**Lab Data:**

**History:** Client has multiple allergies has had allergy testing and has received allergy shots. Has had ill effects from this allergy testing and was aware of what to what for. Client has no allergies to eggs.

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362780-1

<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>
26.0	F	21-Oct-2009	21-Oct-2009	0	26-Oct-2009	26-Oct-2009	MO		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>
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	100739	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Client reported Abdominal itching to her on-call OB provider. Was instructed to take Benadryl, which she did. She awakened at 3:00 AM to more itching and noticed 12 welps on abdomen. By 12:00 Noon on 10/22/2009 she had itching and welps on her legs and lower back. Client had received and seasonal flu vaccine in early Sept. this year and one other time a few years ago. 10/27/09 OB/GYN records received sevice dates 6/25/09 to 10/23/09. Assessment: Hives. Patient reports hives, itching, took benadryl.

**Other Meds:**

**Lab Data:**

**History:** Client has multiple allergies has had allergy testing and has received allergy shots. Has had ill effects from this allergy testing and was aware of what to what for. Client has no allergies to eggs.

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362780-1

<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>
26.0	F	21-Oct-2009	21-Oct-2009	0	26-Oct-2009	26-Oct-2009	MO		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>
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	100739	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Client reported Abdominal itching to her on-call OB provider. Was instructed to take Benadryl, which she did. She awakened at 3:00 AM to more itching and noticed 12 welps on abdomen. By 12:00 Noon on 10/22/2009 she had itching and welps on her legs and lower back. Client had received and seasonal flu vaccine in early Sept. this year and one other time a few years ago. 10/27/09 OB/GYN records received sevice dates 6/25/09 to 10/23/09. Assessment: Hives. Patient reports hives, itching, took benadryl.

**Other Meds:**

**Lab Data:**

**History:** Client has multiple allergies has had allergy testing and has received allergy shots. Has had ill effects from this allergy testing and was aware of what to what for. Client has no allergies to eggs.

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362783-1

<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>
15.0	M	19-Oct-2009	19-Oct-2009	0	26-Oct-2009	26-Oct-2009	IL		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dizziness, Headache, Nausea

**Symptom Text:** felt lightheaded, had headache and nausea, 2 days later, chest pressure. Lasted 7 days, ER visit (10/21/09) doctor visit (10/22/09) No treatment

**Other Meds:** OTC allergy medication (claritin)

**Lab Data:** chest x-ray, nasal swab

**History:** Seasonal allergies Celiac artery compression syndrome

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362783-1

<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>
15.0	M	19-Oct-2009	19-Oct-2009	0	26-Oct-2009	26-Oct-2009	IL		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dizziness, Headache, Nausea

**Symptom Text:** felt lightheaded, had headache and nausea, 2 days later, chest pressure. Lasted 7 days, ER visit (10/21/09) doctor visit (10/22/09) No treatment

**Other Meds:** OTC allergy medication (claritin)

**Lab Data:** chest x-ray, nasal swab

**History:** Seasonal allergies Celiac artery compression syndrome

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362798-1

<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	23-Oct-2009	24-Oct-2009	1	26-Oct-2009	26-Oct-2009	FL		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		UP009AA	0	Left arm	Intramuscular	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Bronchitis, Pyrexia

**Symptom Text:** low grade fever, acute onset bronchitis. currently treating with Levaquin.

**Other Meds:** Lisinopril 10 mg Daily

**Lab Data:**

**History:** hypertension

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362798-1

<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	23-Oct-2009	24-Oct-2009	1	26-Oct-2009	26-Oct-2009	FL		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	UP009AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Bronchitis, Pyrexia

**Symptom Text:** low grade fever, acute onset bronchitis. currently treating with Levaquin.

**Other Meds:** Lisinopril 10 mg Daily

**Lab Data:**

**History:** hypertension

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362800-1

<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>
50.0	F	22-Oct-2009	22-Oct-2009	0	26-Oct-2009	26-Oct-2009	NV		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		UP006AA	0	Unknown	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Chest pain, Cough, Headache, Hypersensitivity, Oropharyngeal pain, Postnasal drip, Productive cough

**Symptom Text:** Client received H1N1 inactive influenza vaccine and within 3 minutes developed a headache that last about an hour. 20-30 minutes later she started having tightness, burning in her chest, sore throat, post nasal drainage and coughing. She took some Benadryl and went to bed. During the night she had a productive cough of yellow colored mucus. She denies fever, rash, swelling or tingling of lips. On Oct. 23, 2009 she went to her HCP and was told that she was having an allergic reaction. She was prescribed Augmentin, Singulair, Flovent, Albuterol and Ventolin.

**Other Meds:** Oxycodon Tylenol

**Lab Data:** Misc. Blood work

**History:** Fibromyalgia Alpha 1-antitrypsin

**Prex Illness:** Client went to the ER on Oct. 6, 2009 and was treated for influenza-like illness and a bladder infection. States she had been fu

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362800-1

<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>
50.0	F	22-Oct-2009	22-Oct-2009	0	26-Oct-2009	26-Oct-2009	NV		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	UP006AA	0	Unknown	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Chest pain, Cough, Headache, Hypersensitivity, Oropharyngeal pain, Postnasal drip, Productive cough

**Symptom Text:** Client received H1N1 inactive influenza vaccine and within 3 minutes developed a headache that last about an hour. 20-30 minutes later she started having tightness, burning in her chest, sore throat, post nasal drainage and coughing. She took some Benadryl and went to bed. During the night she had a productive cough of yellow colored mucus. She denies fever, rash, swelling or tingling of lips. On Oct. 23, 2009 she went to her HCP and was told that she was having an allergic reaction. She was prescribed Augmentin, Singulair, Flovent, Albuterol and Ventolin.

**Other Meds:** Oxycodon Tylenol

**Lab Data:** Misc. Blood work

**History:** Fibromyalgia Alpha 1-antitrypsin

**Prex Illness:** Client went to the ER on Oct. 6, 2009 and was treated for influenza-like illness and a bladder infection. States she had been fu

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362801-1

<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>
49.0	F	22-Oct-2009	22-Oct-2009	0	26-Oct-2009	26-Oct-2009	TN		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Dysphonia, Headache, Myalgia, Nausea, Pyrexia, Vomiting, Wheezing

**Symptom Text:** Wheezing, hoarsness, weakness, dizziness, headache, muscle aches, fever, nausea and vomiting

**Other Meds:** Prilosec, Vivelle hormone patch, Tranxene PRN

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362803-1

<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	22-Oct-2009	26-Oct-2009	4	26-Oct-2009	26-Oct-2009	FL		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>
	HPV4	MERCK & CO. INC.	MSD 0671Y	1	Left arm	Intramuscular	FLU
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	1	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Chest pain, Facial palsy, Headache, Hypoaesthesia facial, Paraesthesia, Tongue paralysis

**Symptom Text:** Bell's Palsy per ER doctor. Given Antibiotics and steroids. 10/27/09 ED records received service date 10/25/09. Assessment: Bell's Palsy Presented with right facial droop, numbness, and tingling. Left tongue deviation. Substernal chest pain. Headache, chest heaviness, and pressure in head.

**Other Meds:**

**Lab Data:** 10/27/09 ED records received service date 10/25/09. LABS AND DIAGNOSTICS: CT Scan Brain - WNL

**History:** None, per mother. 10/27/09 ED records received service date 10/25/09. Asthma.

**Prex Illness:** None, per mother.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362854-1

<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>
45.0	M	22-Oct-2009	22-Oct-2009	0	26-Oct-2009	27-Oct-2009	LA		27-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007391P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Rash macular, Rash papular

**Symptom Text:** Macular-papular rash to lt. arm mainly-with slight rash area to rt. arm. Taking Benadryl and rash subsiding

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362854-1

<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>
45.0	M	22-Oct-2009	22-Oct-2009	0	26-Oct-2009	27-Oct-2009	LA		27-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007391P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Rash macular, Rash papular

**Symptom Text:** Macular-papular rash to lt. arm mainly-with slight rash area to rt. arm. Taking Benadryl and rash subsiding

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362879-1

<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>
32.0	F	21-Oct-2009	22-Oct-2009	1	26-Oct-2009	27-Oct-2009	FL		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)	SANOFI PASTEUR	UP009AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Torticollis

**Symptom Text:** Severe torticollis. Treatment-warm compresses and MOTRIN.

**Other Meds:** TYLENOL

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362881-1

<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>
36.0	F	23-Oct-2009	24-Oct-2009	1	26-Oct-2009	27-Oct-2009	OR		27-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	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthma

**Symptom Text:** Asthma Flare Up used Albuterol with relief

**Other Meds:**

**Lab Data:**

**History:** Allergies and Asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362883-1

<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>
4.0	M	17-Oct-2009	18-Oct-2009	1	26-Oct-2009	27-Oct-2009	MO		27-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia

**Symptom Text:** Fever and cough. Fever began 1 day after receiving the H1n1 flu mist. it lasted 4 days. highest point being on day two, registering 103.6 under the arm (104.6 if you add a degree to that). Cough is still ongoing.

**Other Meds:** none

**Lab Data:** still has cough, although no fever

**History:** None

**Prex Illness:** No

**Prex Vax Illns:** fever~Varicella (no brand name)-1~1.00~Patient|possible fever~Measles + Mumps + Rubella (no brand name)-UN~0.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362883-1

<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>
4.0	M	17-Oct-2009	18-Oct-2009	1	26-Oct-2009	27-Oct-2009	MO		27-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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia

**Symptom Text:** Fever and cough. Fever began 1 day after receiving the H1n1 flu mist. it lasted 4 days. highest point being on day two, registering 103.6 under the arm (104.6 if you add a degree to that). Cough is still ongoing.

**Other Meds:** none

**Lab Data:** still has cough, although no fever

**History:** None

**Prex Illness:** No

**Prex Vax Illns:** fever~Varicella (no brand name)~1~1.00~Patient|possible fever~Measles + Mumps + Rubella (no brand name)~UN~0.00~Patient



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362885-1

<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>
76.0	U	Unknown	Unknown		26-Oct-2009	27-Oct-2009	IL		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)	SANOFI PASTEUR	UP005AA		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** None stated.

**Other Meds:**

**Lab Data:**

**History:** DM; HTN; HL; depression; colon resection; vit B12 deficiency

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362885-1

<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>
76.0	U	Unknown	Unknown		26-Oct-2009	27-Oct-2009	IL		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)	SANOFI PASTEUR	UP005AA		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** None stated.

**Other Meds:**

**Lab Data:**

**History:** DM; HTN; HL; depression; colon resection; vit B12 deficiency

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362886-1

<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>
66.0	U	Unknown	Unknown		26-Oct-2009	27-Oct-2009	IL		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)	SANOFI PASTEUR		UP005AA		Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** None stated

**Other Meds:**

**Lab Data:**

**History:** Mild-moderate asthma; DM

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362886-1

<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>
66.0	U	Unknown	Unknown		26-Oct-2009	27-Oct-2009	IL		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)	SANOFI PASTEUR	UP005AA		Left arm	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Unevaluable event

**Symptom Text:** None stated

**Other Meds:**

**Lab Data:**

**History:** Mild-moderate asthma; DM

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362897-1

<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>
48.0	M	24-Oct-2009	25-Oct-2009	1	26-Oct-2009	27-Oct-2009	NJ		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)	SANOFI PASTEUR	UP007AA		Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash macular, Rash pruritic

**Symptom Text:** 10-25-09-Wife noticed red rash on R side of neck, flat, occasionally itchy. Pt uses over the counter cortisone cream. No trouble breathing. No new detergent or soap used. No different foods. No allergies. Advised to check with PMD.

**Other Meds:** None

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362897-1

<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>
48.0	M	24-Oct-2009	25-Oct-2009	1	26-Oct-2009	27-Oct-2009	NJ		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)	SANOFI PASTEUR	UP007AA		Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash macular, Rash pruritic

**Symptom Text:** 10-25-09-Wife noticed red rash on R side of neck, flat, occasionally itchy. Pt uses over the counter cortisone cream. No trouble breathing. No new detergent or soap used. No different foods. No allergies. Advised to check with PMD.

**Other Meds:** None

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362904-1

<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>
30.0	F	23-Oct-2009	24-Oct-2009	1	26-Oct-2009	27-Oct-2009	NC		27-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	UP0003AA	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Rash generalised, Rash pruritic

**Symptom Text:** Itchy rash covering body when I woke up the morning of 10/24/09, I took 50mg Benadryl and it went away. At 08:00pm full body rash again, took 50mg Benadryl, 125mg methylprednisone and rash was gone by 02:00am 10/25/09. Woke 10/25/09 at 09:00am and rash started to come back and by noon it was all over my body again. Continued to take Benadryl every 4 hrs and rash never cleared. 10/26/09 went to internal medicine MD and prescribed Xyzal and Prednisone taper for 10 days. After taking 60mg prednisone and Xyzal rash is gone. With rash the only other symptom I experienced was left upper quadrant abdominal pain. No difficulty breathing, nausea, vomiting, diarrhea, fevers, sore throats, or upper respiratory sx. I have had flu vaccines in the past and have never been allergic to eggs.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362904-1

<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>
30.0	F	23-Oct-2009	24-Oct-2009	1	26-Oct-2009	27-Oct-2009	NC		27-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	UP0003AA	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Rash generalised, Rash pruritic

**Symptom Text:** Itchy rash covering body when I woke up the morning of 10/24/09, I took 50mg Benadryl and it went away. At 08:00pm full body rash again, took 50mg Benadryl, 125mg methylprednisone and rash was gone by 02:00am 10/25/09. Woke 10/25/09 at 09:00am and rash started to come back and by noon it was all over my body again. Continued to take Benadryl every 4 hrs and rash never cleared. 10/26/09 went to internal medicine MD and prescribed Xyzal and Prednisone taper for 10 days. After taking 60mg prednisone and Xyzal rash is gone. With rash the only other symptom I experienced was left upper quadrant abdominal pain. No difficulty breathing, nausea, vomiting, diarrhea, fevers, sore throats, or upper respiratory sx. I have had flu vaccines in the past and have never been allergic to eggs.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** NO

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362914-1

<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>
51.0	M	22-Oct-2009	22-Oct-2009	0	26-Oct-2009	27-Oct-2009	TN		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	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Asthenia, Blood glucose increased, Chills, Dysphonia, Dyspnoea, Embolism, Hypokalaemia, Hypotension, Hypoxia, Myalgia, Nausea, Oxygen saturation decreased, Pulmonary embolism, Pyrexia, Renal failure, Sinus tachycardia, Tachycardia, Vomiting

**Symptom Text:** hoarseness, weakness, fever, muscle aches 10/30/09 ICD9 codes and Medical records received for DOS 9/23. ED visit DX: acute hypoxia, sever dyspnea, sinus tachycardia, hypokalemia, renal insufficiency, elevated D-dimer, r/o PE. Patient developed weakness, nausea, vomiting x1, chills and joint pain s/p flu vaccine. Ibuprofen resolved. Later developed SOB and took nitro tab. BP dropped. 911 activated. Presented w/pulse 119, BP 114/55. O2 sat 94% on room air and dropped to high 80's. Increased to 90 and 96 on O2. Accucheck 163. Hypokalemia, renal insufficiency. Doppler results- thrombus L greater saphenous vein. ICD9 Codes: 276.51, 458.9, 278.8, 401.9, 272.4, 530.81, 250.0, 799.02, 427.89, 593.9.

**Other Meds:** Lisinopril, Prilosec, Zetia

**Lab Data:** Labs & Diags: EKG- sinus tachycardia, D-dimer 1200 (H), K 3.4 (L), BUN19 (L), Creat 1.8 (L), glucose 127 (H), UA neg. Doppler- thrombus visualized in the left greater saphenous vein. No evidence DVT LE bil. Lymphs 1.0 (L), PMN 96 (H). C

**History:** none. PMH: Essential hypertension, high cholesterol, GERD, Cholecystectomy, hives. Family h/o of CAD and MI. Allergies: None.

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362914-1

<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>
51.0	M	22-Oct-2009	22-Oct-2009	0	26-Oct-2009	27-Oct-2009	TN		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	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Asthenia, Blood glucose increased, Chills, Dysphonia, Dyspnoea, Embolism, Hypokalaemia, Hypotension, Hypoxia, Myalgia, Nausea, Oxygen saturation decreased, Pulmonary embolism, Pyrexia, Renal failure, Sinus tachycardia, Tachycardia, Vomiting

**Symptom Text:** hoarseness, weakness, fever, muscle aches 10/30/09 ICD9 codes and Medical records received for DOS 9/23. ED visit DX: acute hypoxia, sever dyspnea, sinus tachycardia, hypokalemia, renal insufficiency, elevated D-dimer, r/o PE. Patient developed weakness, nausea, vomiting x1, chills and joint pain s/p flu vaccine. Ibuprofen resolved. Later developed SOB and took nitro tab. BP dropped. 911 activated. Presented w/pulse 119, BP 114/55. O2 sat 94% on room air and dropped to high 80's. Increased to 90 and 96 on O2. Accucheck 163. Hypokalemia, renal insufficiency. Doppler results- thrombus L greater saphenous vein. ICD9 Codes: 276.51, 458.9, 278.8, 401.9, 272.4, 530.81, 250.0, 799.02, 427.89, 593.9.

**Other Meds:** Lisinopril, Prilosec, Zetia

**Lab Data:** Labs & Diags: EKG- sinus tachycardia, D-dimer 1200 (H), K 3.4 (L), BUN19 (L), Creat 1.8 (L), glucose 127 (H), UA neg. Doppler- thrombus visualized in the left greater saphenous vein. No evidence DVT LE bil. Lymphs 1.0 (L), PMN 96 (H). C

**History:** none. PMH: Essential hypertension, high cholesterol, GERD, Cholecystectomy, hives. Family h/o of CAD and MI. Allergies: None.

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362917-1

<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	F	24-Oct-2009	25-Oct-2009	1	26-Oct-2009	27-Oct-2009	CA		27-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	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia, Vomiting

**Symptom Text:** Fever 102 to highest 103.6, with cough on 10/25/09. On Monday 10/26/09 to daughter to MD at 10 am, had fever of 101. At 3 pm, began vomiting and fever to 102.

**Other Meds:** None

**Lab Data:** None, treat symptoms (Tylenol)

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362917-1

<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	F	24-Oct-2009	25-Oct-2009	1	26-Oct-2009	27-Oct-2009	CA		27-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	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia, Vomiting

**Symptom Text:** Fever 102 to highest 103.6, with cough on 10/25/09. On Monday 10/26/09 to daughter to MD at 10 am, had fever of 101. At 3 pm, began vomiting and fever to 102.

**Other Meds:** None

**Lab Data:** None, treat symptoms (Tylenol)

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362921-1

<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>
45.0	F	23-Oct-2009	23-Oct-2009	0	26-Oct-2009	27-Oct-2009	IL		27-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	0	Right arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Lethargy, Pain

**Symptom Text:** lethargic on 10/23/09 and 10/24/2009. Body aches that intensified until 10/25/2009. By 10/27/2009 the aches and lethargy had passed.

**Other Meds:** Levequin

**Lab Data:**

**History:** inflamatory lung disease, asthma

**Prex Illness:** Cough

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362922-1

<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>
40.0	M	20-Oct-2009	21-Oct-2009	1	26-Oct-2009	27-Oct-2009	MA		27-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	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Carpal tunnel syndrome, Condition aggravated, Erythema, Oedema peripheral, Pain

**Symptom Text:** swelling and aches in both hands without pre-existing trauma, joint aches in bilateral hips and knees, carpal tunnel symptoms in both hands, swelling and redness in right hand

**Other Meds:** motrin

**Lab Data:**

**History:** allergy to vancomycin (red man syndrome), rotator cuff tear right shoulder (oct09-ongoing), carpal tunnel syndrome right wrist (oct09-ongoing)

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362923-1

<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>
24.0	F	16-Oct-2009	16-Oct-2009	0	26-Oct-2009	27-Oct-2009	IN		27-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	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Hypersomnia

**Symptom Text:** EXTREME EXTREME EXTREME fatigue. No other cause. My routine, activity, and eating habits were the same as usual during these days. I slept 10/16/09 from 3pm--10am on 10/17/09. I continued to sleep on 10/17/09 from 12pm--7pm and then from 7pm--11am 10/18/09.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362923-1

<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>
24.0	F	16-Oct-2009	16-Oct-2009	0	26-Oct-2009	27-Oct-2009	IN		27-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	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Hypersomnia

**Symptom Text:** EXTREME EXTREME EXTREME fatigue. No other cause. My routine, activity, and eating habits were the same as usual during these days. I slept 10/16/09 from 3pm--10am on 10/17/09. I continued to sleep on 10/17/09 from 12pm--7pm and then from 7pm--11am 10/18/09.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362925-1

<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>
40.0	F	24-Oct-2009	24-Oct-2009	0	26-Oct-2009	27-Oct-2009	DC		27-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007392P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Blood glucose normal, Blood pressure increased, Dizziness, Feeling abnormal, Pregnancy, Visual impairment

**Symptom Text:** Lightheadedness. "Floaty feeling. Some weakness. Vision slightly skewed. Told nurse-they called EMT and paramedics took my blood pressure which was slightly elevated. Blood sugar was normal. They gave me the option since I am pregnant to go to the hospital, but I opted to take the doc's advice to eat a substantial meal, go home and rest, and stay hydrated. Slept and felt better. Feel better-may have just been that I didn't eat a lot of protein earlier that day. AM 6.5 months pregnant and they were just being cautious which I really appreciate. The follow up by DOH, and the EMT's was really impressive and I am really thankful.

**Other Meds:** Take Prilosec daily, Claritin, and a nasal spray for allergies.

**Lab Data:** n/a

**History:** chronic sinusitis, seasonal allergies. 6.5 months pregnant

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362925-1

<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>
40.0	F	24-Oct-2009	24-Oct-2009	0	26-Oct-2009	27-Oct-2009	DC		27-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1007392P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Blood glucose normal, Blood pressure increased, Dizziness, Feeling abnormal, Pregnancy, Visual impairment

**Symptom Text:** Lightheadedness. "Floaty feeling. Some weakness. Vision slightly skewed. Told nurse-they called EMT and paramedics took my blood pressure which was slightly elevated. Blood sugar was normal. They gave me the option since I am pregnant to go to the hospital, but I opted to take the doc's advice to eat a substantial meal, go home and rest, and stay hydrated. Slept and felt better. Feel better-may have just been that I didn't eat a lot of protein earlier that day. AM 6.5 months pregnant and they were just being cautious which I really appreciate. The follow up by DOH, and the EMT's was really impressive and I am really thankful.

**Other Meds:** Take Prilosec daily, Claritin, and a nasal spray for allergies.

**Lab Data:** n/a

**History:** chronic sinusitis, seasonal allergies. 6.5 months pregnant

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362927-1

<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>
36.0	F	23-Oct-2009	23-Oct-2009	0	26-Oct-2009	27-Oct-2009	KS		27-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	UP005AA	0	Left arm	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Body temperature increased, Dizziness, Feeling cold, Feeling hot, Headache, Nausea, Photophobia, Vomiting

**Symptom Text:** Developed headache that became severe around 4:00 pm. Became dizzy, weak, photophobic, and nauseous, with a temperature around 100 degrees Farenheight. Felt hot then cold. Vomited at 5:15 PM. Took two 200mg ibuprofen and took a 1 1/2 hour nap. Headache, weakness and nausea persisted but lessened over the next 24 hours. Weakness continued for about 24 more hours.

**Other Meds:** Levothyroxine 50 mcg daily in AM

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362927-1

<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>
36.0	F	23-Oct-2009	23-Oct-2009	0	26-Oct-2009	27-Oct-2009	KS		27-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	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Body temperature increased, Dizziness, Feeling cold, Feeling hot, Headache, Nausea, Photophobia, Vomiting

**Symptom Text:** Developed headache that became severe around 4:00 pm. Became dizzy, weak, photophobic, and nauseous, with a temperature around 100 degrees Fahrenheit. Felt hot then cold. Vomited at 5:15 PM. Took two 200mg ibuprofen and took a 1 1/2 hour nap. Headache, weakness and nausea persisted but lessened over the next 24 hours. Weakness continued for about 24 more hours.

**Other Meds:** Levothyroxine 50 mcg daily in AM

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362929-1

<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>
13.0	M	25-Oct-2009	26-Oct-2009	1	27-Oct-2009	27-Oct-2009	CA		27-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		Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Pyrexia

**Symptom Text:** BODY ACHES, LEG ACHES IN AM. BY 3:00 PM HAD FEVER CONTINUING FEVER THROUGH NIGHT.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362929-1

<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>
13.0	M	25-Oct-2009	26-Oct-2009	1	27-Oct-2009	27-Oct-2009	CA		27-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		Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain, Pyrexia

**Symptom Text:** BODY ACHES, LEG ACHES IN AM. BY 3:00 PM HAD FEVER CONTINUING FEVER THROUGH NIGHT.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362930-1

<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>
49.0	M	25-Oct-2009	25-Oct-2009	0	27-Oct-2009	27-Oct-2009	CA		27-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	4P002AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Pain, Pyrexia, Respiratory tract congestion

**Symptom Text:** cough, congestion, temperature, body ache

**Other Meds:**

**Lab Data:** none

**History:** Diabetes, hypertension

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362930-1

<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>
49.0	M	25-Oct-2009	25-Oct-2009	0	27-Oct-2009	27-Oct-2009	CA		27-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	4P002AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Pain, Pyrexia, Respiratory tract congestion

**Symptom Text:** cough, congestion, temperature, body ache

**Other Meds:**

**Lab Data:** none

**History:** Diabetes, hypertension

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362931-1

<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>
42.0	F	19-Oct-2009	19-Oct-2009	0	27-Oct-2009	27-Oct-2009	ID		27-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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Musculoskeletal pain, Neck pain, Pain in extremity, Pyrexia

**Symptom Text:** Fever and onset of extreme pain in neck shoulder arm and hand

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362931-1

<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>
42.0	F	19-Oct-2009	19-Oct-2009	0	27-Oct-2009	27-Oct-2009	ID		27-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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Musculoskeletal pain, Neck pain, Pain in extremity, Pyrexia

**Symptom Text:** Fever and onset of extreme pain in neck shoulder arm and hand

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362959-1

<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	M	Unknown	Unknown		27-Oct-2009	27-Oct-2009	PA		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)	SANOFI PASTEUR	UP007AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** 48 hours post imm, hives on cheeks, neck, wrist and chest per maternal report via phone.

**Other Meds:** SINGULAIR daily 5 mg; CLARITIN prn; ADVAIR 100/50

**Lab Data:** None

**History:** Allergic rhinitis; asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362960-1

<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>
40.0	F	22-Oct-2009	22-Oct-2009	0	27-Oct-2009	27-Oct-2009	KS		27-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	UP001AA		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Confusional state, Nausea, Tachypnoea

**Symptom Text:** Pt noted nausea, "queasy", feeling after H1N1 vaccine. Was starting to eat lunch at the time. Alleged to be confused-tachypneic on arrival at ER. Vs all stable, pulse ox 100%, observed for several hrs.

**Other Meds:** ALBUTEROL; COMBIVENT; LISINOPRIL

**Lab Data:** None

**History:** Hypertension; fibromyalgia; cardiomegaly

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362992-1

<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>
1.8	F	20-Oct-2009	20-Oct-2009	0	27-Oct-2009	27-Oct-2009	DC		27-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	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** Daughter received a double dose of H1N1 vaccine. She was supposed to receive 0.25ml of multidose vial and received 0.5ml of multi-dose vial.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362993-1

<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>
47.0	F	22-Oct-2009	22-Oct-2009	0	27-Oct-2009	27-Oct-2009	IN		27-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	UNKNOWN	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site reaction, Paraesthesia, Rash erythematous, Rash macular

**Symptom Text:** Tingling at injection site began 30 min after injection, lasted 6 hours. Developed a rash sige of an orange that is reddish/pinkish in color. Does not itch or hurt and is flat that has lasted into the next day. This was her first flu shot and was H1N1

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362994-1

<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>
56.0	F	22-Oct-2009	25-Oct-2009	3	27-Oct-2009	27-Oct-2009	SC	SC0901Pan	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	Right arm	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Muscle twitching

**Symptom Text:** Patient states that she noted a visible twitching of the left eye on Sunday, 10/25/09. States that the twitching has occurred less frequently each day after 10/25/09. States she only noted one time on 10/26/09.

**Other Meds:** Ibuprofen 400 mg each day, also once daily: Glucosamine Chondrotin, L-Lysine, and a multivitamin Received a seasonal Flu shot on 10/19/09- not at our facility

**Lab Data:**

**History:** PCN allergy, MVP

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362997-1

<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>
43.0	M	23-Oct-2009	26-Oct-2009	3	27-Oct-2009	27-Oct-2009	CT		27-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	UP009AA	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dry mouth, Dyspnoea, Panic attack

**Symptom Text:** reports awakening at 1 am with panic attack-sob, chest tightness, dry mouth. Symptoms resolved within one hour and he fell back asleep. Has never had panic attack in past.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 362999-1

<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>
33.0	F	16-Oct-2009	16-Oct-2009	0	27-Oct-2009	27-Oct-2009	WI		27-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	UP007A	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** co face itching, no resp difficulty, alert and oriented

**Other Meds:** Benadryl PO taken after co facial itching

**Lab Data:**

**History:** migraines

**Prex Illness:** none

**Prex Vax Illns:** facial itching~Influenza (H1N1) (Influenza (H1N1) (Influenza A (H1N1) 2009 Monovalent)~~0.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363001-1

<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>
56.0	F	22-Oct-2009	23-Oct-2009	1	27-Oct-2009	27-Oct-2009	SC	SC0902Pan	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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Muscle twitching

**Symptom Text:** Patient reports twitching in the periorbital area of the left eye (under the eye and above the cheek) beginning on Friday 10/23/09. States that the twitching was visible to others and very noticeable on 10/23 and has become less frequent each day after vaccination.

**Other Meds:** BP medication, Crestor, Ibuprofen each day States that she did receive Seasonal Flu vaccination at employer on 10/19/09

**Lab Data:**

**History:** Hypertension, Hyperlipidemia

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363003-1

<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>
52.0	F	23-Oct-2009	23-Oct-2009	0	27-Oct-2009	27-Oct-2009	NY		27-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	UP007AA	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Dyspnoea

**Symptom Text:** Chest pain, shortness of breath. Took inhaler without effect. Went to ER for treatment

**Other Meds:**

**Lab Data:** Ekg, Chest x-ray, labs

**History:** history of asthma, enviromental allergies

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363004-1

<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>
40.0	M	24-Oct-2009	24-Oct-2009	0	27-Oct-2009	27-Oct-2009	CA		27-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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pruritus, Pruritus generalised

**Symptom Text:** TOTAL BODY ITCHING ON DAY ONE. TOOK 25 MG BENADRYL. ON DAY 2, ITCHING AND REDNESS ONLY AROUND INJECTION SITE.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363005-1

<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>
39.0	F	23-Oct-2009	24-Oct-2009	1	27-Oct-2009	27-Oct-2009	CT		27-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	UP 009AA		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dizziness, Dyspnoea, Panic attack

**Symptom Text:** reports panic attack while driving. C/O SOB, dizziness, and chest tightness. Has remote history of panic attacks.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363006-1

<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>
26.0	M	16-Oct-2009	18-Oct-2009	2	27-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	UNKNOWN MANUFACTURER	NULL	3	Left arm	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Dizziness, Dyspnoea, Dysstasia, Facial paresis, Gait disturbance, Headache, Hypoaesthesia, Hypokalaemia, Hypokinesia, Migraine, Nausea, Neuropathy peripheral, Panic reaction, Paraesthesia, Photophobia, Vertigo, Vomiting

**Symptom Text:** neuropathy, vomiting, migraine, loss of movement of legs for short period of time. 10/28/09 ED records received multiple service dates 10/19/09, 10/21/09, 10/24/09. Assessment: Neuropathy, hypokalemia, anxiety. Patient presents with tingling of both hands, feet, for 3 days. Returns to ED several days later with facial weakness, paresthesia, difficulty standing / walking. Dizziness, panic, trouble breathing, light-headedness, anxiety. Presents several days later with acute headache, sensitive to light, dizziness, nausea, vomiting. Nausea, (R) side numbness, 'spinning'.

**Other Meds:**

**Lab Data:** EMG, CT Scan, MRI, blood work. LABS and DIAGNOSTICS: Urinalysis - Abnormal, ketones 1+, blood 1+, protein trace, bacteria rare, mucus moderate. CBC - Neutrophils 81.7% (H) Lymphocytes 11.8% (L) Basophils 2.5% (H) Neutrophils# 7.6 (H) Lympho

**History:** PMH: Gilbert Syndrome. Sciatica.

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363007-1

<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>
21.0	F	26-Oct-2009	26-Oct-2009	0	27-Oct-2009	27-Oct-2009	IN		27-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	UP007AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Fainting

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:** Fainting~Influenza (Seasonal) (no brand name)-1~20.83~



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363008-1

<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>
45.0	F	20-Oct-2009	22-Oct-2009	2	27-Oct-2009	27-Oct-2009	TN		27-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	UP003AA		Unknown	Unknown	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site pain, Injection site swelling

**Symptom Text:** numbless, extreme pain near injection site- swelling

**Other Meds:**

**Lab Data:**

**History:** none- good health

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363024-1

<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>
2.0	F	25-Oct-2009	25-Oct-2009	0	27-Oct-2009	27-Oct-2009	WA		27-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	0	Left leg	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough

**Symptom Text:** Worsening cough

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363026-1

<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	22-Oct-2009	22-Oct-2009	0	27-Oct-2009	27-Oct-2009	PA		27-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	UP007AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash erythematous, Rash macular, Urticaria

**Symptom Text:** Raised red blotches, looking like welts or hives all over stomach area extending to both left and right sides. Took benadryl. Symptoms dissipated on Saturday, October 24th late in the evening.

**Other Meds:**

**Lab Data:**

**History:** None, other than pregnancy

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363030-1 (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>
25.0	F	21-Oct-2009	24-Oct-2009	3	27-Oct-2009	29-Oct-2009	TX	TX090002PU	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	UP010AA	0	Right arm	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Abdominal pain, Breech presentation, Caesarean section, Cervix disorder, Cough, Drug exposure during pregnancy, Incisional drainage, Influenza like illness, Lower respiratory tract infection, Premature labour, Upper respiratory tract infection, Vaginal haemorrhage

**Symptom Text:** GRAVIDA 1 PARA 0 26 WEEK GESTATION RECEIVED SEASONAL FLU 9/17/2009. HAD FLU LIKE SYMPTOMS START 10/9. CALLED DOCTOR AND RECEIVED TAMIFLU, COUGH MED AND Z-PAK. RECEIVED H1N1 10/21/2009. WENT INTO LABOR 10/24/2009. C-SECTION DONE. DOCTOR FELT LIKE IT WAS FROM A WEAK CERVIX. 10/28/09 Medical records received for DOS 10/9-10/24. Office notes and ED H&P. Promigravida at 26 weeks. Developed cramping/abd pain post upper resp/ILI infection (cough, chest cong) and vaccine. Some vag bleeding. Fully dialted. Intact membranes bulging. fetal heart tones at 140. Footling breech. Emergency c-section w/o complication. Post c-section small amt green incisional d/c noted. No fever.

**Other Meds:**

**Lab Data:** NONE. LABS & DIAGS: WBC 19.7 (H), RBC 3.89 (L), NEUTR 86 (H), LYMPH 7 (L), NA 134 (L), ANION GAP 16 (H), RPR (-), HIV (-), HBsAG (-), KUB (NORMAL).

**History:** CLIENT WAS PREGNANT BUT DOCTOR WANTED HER TO GET H1N1. PMH: chicken pox, MMR immunity ALLERGIES:none

**Prex Illness:** NO ILLNESS

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363035-1

<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>
40.0	F	23-Oct-2009	23-Oct-2009	0	27-Oct-2009	27-Oct-2009	CA		27-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	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Paraesthesia

**Symptom Text:** Received H1N1 at 11:00 AM and began to have numbness and tingling from left elbow to left neck almost immediately.

**Other Meds:** Ibuprofen 400mg p.o. 1 or 2 tabs TID prn

**Lab Data:** Referred to neurologist for re-evaluation.

**History:** Iodine

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363040-1 (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>
26.0	M	20-Oct-2009	20-Oct-2009	0	27-Oct-2009	29-Oct-2009	MD		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Chest pain, Dyspnoea, Fatigue, Headache, Heart rate increased, Hypoaesthesia, Loss of consciousness, Memory impairment, Oropharyngeal pain, Wheezing

**Symptom Text:** Extreme sore throat and headaches soon after administration of H1N1 nasal mist vaccine. Fatigue and whizzing days following. on 10/24/2009, chest pain during the day behind left nipple became sharp, extreme chest pains, numbness of left arm and hand, difficulty breathing, couldn't catch breath, rapid heart rate, blackout or memory several times before and during ambulance transport

**Other Meds:**

**Lab Data:** EKG of heart & stress test. both came back normal. blood work came back normal

**History:** migraines

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363045-1

<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	24-Oct-2009	26-Oct-2009	2	27-Oct-2009	28-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(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Rhinorrhoea

**Symptom Text:** Mild runny nose and cough start on 10/25/2009, AM. Temperature 100.4 to 100.6. Remove his long sleeve clothes. Temperature went down. At 2:00 AM, 10/27/2009 temperature went back to 100.5. Motrin was given at around 4:00 AM. Temperature went down around 4:30 AM. He woke up, runny nose and cough worsen until now 10:00 AM. Dr. has been contacted and have been in conversation with the nurse. Decission is if he have another temperature, difficult to breath or cough worsen, he need to see Dr.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363046-1

<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>
2.0	F	23-Oct-2009	24-Oct-2009	1	27-Oct-2009	28-Oct-2009	WI		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	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives on buttocks and back of legs, disappeared by morning, came back the next night.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363054-1 (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>
24.0	F	Unknown	Unknown		27-Oct-2009	28-Oct-2009	FR	2009021003	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:** HOSPITALIZED, SERIOUS

**MedDRA PT** Feeling drunk, Malaise

**Symptom Text:** Report received from a consumer on 19-OCT-2009. A 24-year-old female patient (date of birth unknown) received H1N1 (batch unknown) on unknown date. No information on medical history or concomitant medications was provided. On unknown date after vaccination, the patient developed malaise to the point of sounding intoxicated. The patient was admitted to hospital and follow-up subsequently at another hospital a few days later. It is not known whether the patient received any treatment. Patient outcome is not known.

**Other Meds:**

**Lab Data:**

**History:** Pregnant: Unknown

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363063-1 (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>
77.0	M	05-Oct-2009	05-Oct-2009	0	27-Oct-2009	28-Oct-2009	FR	2009020925	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	UNKNOWN MANUFACTURER	25901		Unknown	Unknown	
	FLU(H1N1)	CSL LIMITED	NULL		Unknown	Unknown	

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Nausea, Palpitations

**Symptom Text:** Report received from the regulator on 14-Oct-2009. Number 257570. A 77 year-old male patient with unknown initials (Date of Birth: 28-JUN-1932)received seasonal influenza vaccine (batch number 25901) on 5-Oct-2009. PANVAX H1N1 is a co-suspect drug. On 5-Oct-2009, 15 minutes after vaccination, the patient reported feeling a racing heart and nausea. Nil chest pain. Nil signs and symptoms of anaphylaxis. Treatment included sending the patient for monitoring. The outcome of the case is unknown. The reporter considered events to be possibly due to seasonal influenza vaccine.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363163-1

<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>
16.0	F	22-Oct-2009	22-Oct-2009	0	27-Oct-2009	28-Oct-2009	OH		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)	SANOFI PASTEUR	UP006AA		Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fall, Mouth injury

**Symptom Text:** No symptoms prior-fell face first after stood up from chair and cut lip. Occurred 10 minute after vaccine admin. EMS attended patient. BP 120/80. Transport for lip sutures and evaluation. No other sx noted.

**Other Meds:** Unknown

**Lab Data:** 21 weeks pregnant

**History:** Pregnancy

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363165-1

<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>
31.0	F	21-Oct-2009	21-Oct-2009	0	27-Oct-2009	28-Oct-2009	WA		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.	500759P	0	Unknown	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP002AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** Pt got both H1N1 inj and mist. (Someone at OK health dept adv.)

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363167-1

<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>
11.0	M	21-Oct-2009	Unknown		27-Oct-2009	28-Oct-2009	WA		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)	SANOFI PASTEUR	UP002AA	0	Right arm	Unknown	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500759P	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** H1N1 mist and H1N1 inj given at same time.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363169-1

<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>
25.0	F	14-Oct-2009	14-Oct-2009	0	27-Oct-2009	28-Oct-2009	MD		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>
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Immunisation reaction, Lower extremity mass, Myalgia, Pain, Skin mass

**Symptom Text:** Muscle soreness, all over body aches. Lumps under skin on legs and back, last about 1 week, saw Dr. on 10/21/09, was told that it was a reaction to H1N1 vaccine, I also have Crohns disease and am treated with REMICADE and IMURAN.

**Other Meds:** REMICADE; IMURAN; ASACOL; SYNTHROID; ELIDEL; iron; ORTHO TRI-CYCLEN; multi vit.

**Lab Data:**

**History:** Crohns

**Prex Illness:** Crohns

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363170-1

<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>
50.0	F	19-Oct-2009	21-Oct-2009	2	27-Oct-2009	28-Oct-2009	WV		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)	SANOFI PASTEUR	UP001AA		Unknown	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA470BA		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Lip swelling, Pruritus, Urticaria

**Symptom Text:** 10-21-09-4:00 AM awoke with welts on inside of both forearms-subsided throughout the day. 10-22-09 4:00 AM awoke with welts on outside of both forearms, itchy, swollen lower lip-subsided throughout the day.

**Other Meds:** AMOXICILLIN 500 mg TID; GABAPENTIN 600 mg BID

**Lab Data:** None

**History:** Trigeminal neuralgia

**Prex Illness:** Recovering from bronchitis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363171-1

<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>
49.0	F	16-Oct-2009	16-Oct-2009	0	27-Oct-2009	28-Oct-2009	IN		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)	SANOFI PASTEUR	UP00388	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Feeling abnormal, Feeling hot, Hyperhidrosis, Palpitations

**Symptom Text:** About an hour after shot, heart racing, sweating, hot, heavy pressure down R arm to fingers and through chest, then just felt lousy for about 2 days.

**Other Meds:** XANAX; VICODIN; PHENERGAN; RESTORIL

**Lab Data:** None

**History:** Chronic bronchitis; neuropathy in legs

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363187-1

<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>
31.0	F	23-Oct-2009	24-Oct-2009	1	27-Oct-2009	28-Oct-2009	WA		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)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dry skin, Erythema, Erythema of eyelid, Eyelid oedema, Pruritus, Swelling face

**Symptom Text:** Facial Swelling, including eyelids; facial and eyelid erythema; mild itchiness. Skin dryness of face and eyelids

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363192-1

<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>
57.0	F	24-Oct-2009	24-Oct-2009	0	27-Oct-2009	28-Oct-2009	AZ		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	UNKNOWN	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Dysgeusia, Dysphonia, Flushing, Parosmia, Rash generalised, Salivary hypersecretion, Urticaria

**Symptom Text:** I received this injection at 1830 on Oct. 24, 2009. At approximately 06:34 PM, I could smell the medicene in my nose then could taste the medicene in my mouth. Excessive salivation and coughing occurred. Hoarsness and hives approximately 20 minutes later. Hives/flushing/rash all over the body, including hair. Took 25 mg. Benadryl po at 1930. Took another 25 mg at 2000. Rash and hoarseness continued approximately 36 hours.

**Other Meds:**

**Lab Data:** none to date

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363197-1

<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	F	23-Oct-2009	25-Oct-2009	2	27-Oct-2009	28-Oct-2009	MO		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)	SANOFI PASTEUR	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Heart rate increased, Lip swelling, Nasal congestion, Oropharyngeal pain, Pyrexia, Rash, Swelling face, Urticaria

**Symptom Text:** 10/25/09 headache late PM 10/26/09 fever,large whelps, face and lips swollen, sorethroat, stuffy nose. rapid heart rate, rash on scalp, back of neck and from right hip up through to rib cage. late AM early PM Motrin by mom. ER late PM on 10/26/09 tylenol, benedryl. symptoms subsided after 4 hours.

**Other Meds:** none

**Lab Data:** strep test/negative in ER Influenza/negative in ER

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363198-1

<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>
20.0	F	21-Oct-2009	25-Oct-2009	4	27-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(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Nasal congestion, Pain, Pyrexia, Sinus congestion

**Symptom Text:** on 10/25, body aches, difficulty breathing, nasal/head congestion on 10/26 all of the above mention plus a fever reaching 102.7

**Other Meds:** levothyroxine, advair, maxair, levora,

**Lab Data:**

**History:** Asthma, environmental allergies

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363199-1

<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>
18.0	F	26-Oct-2009	26-Oct-2009	0	27-Oct-2009	28-Oct-2009	TX		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)	SANOFI PASTEUR	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Nausea, Vomiting

**Symptom Text:** Severe nausea and vomiting

**Other Meds:**

**Lab Data:**

**History:** Pregnancy

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363200-1

<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>
2.0	F	26-Oct-2009	Unknown		27-Oct-2009	28-Oct-2009	MO		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)	SANOFI PASTEUR	UP010AA	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, No adverse event

**Symptom Text:** Child received an adult dose 0.5 ml of Multi-dose Fluzone. Should have received 0.25 ml. No adverse events known at this time. Contacted Sanofi Pastuer to see if anything needed to be done. They said it shouldn't cause any harm to the child. Parent contacted and notified of the stated med error.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363202-1

<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>
1.7	F	26-Oct-2009	Unknown		27-Oct-2009	28-Oct-2009	MO		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)	SANOFI PASTEUR		UP010AA	0	Right leg	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, No adverse event

**Symptom Text:** CHILD RECEIVED ADULT DOSE 0.5 ML OF FLUZONE MULTI-DOSE VACCINE. SHOULD HAVE RECEIVED 0.25 ML. NO ADVERSE EFFECTS KNOWN AT THIS TIME. CONTACTED SANOFI PASTUER. THEY STATED THAT THERE WASN'T ANYTHING THAT NEEDED TO BE DONE, AND THAT THERE SHOULDN'T BE ANY ADVERSE EFFECTS. PARENT NOTIFIED OF INCIDENT.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363233-1

<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>
59.0	F	20-Oct-2009	21-Oct-2009	1	27-Oct-2009	28-Oct-2009	SD		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)	SANOFI PASTEUR	UP001AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vertigo

**Symptom Text:** Vertigo, had to lay down on Back in bed x 2 days.

**Other Meds:**

**Lab Data:**

**History:** None reported

**Prex Illness:** None reported

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363239-1

<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>
11.0	M	26-Oct-2009	27-Oct-2009	1	27-Oct-2009	28-Oct-2009	MO		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)	SANOFI PASTEUR	UP010AA		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives on hands Treatment: Benadryl as needed

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363244-1

<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>
9.0	F	22-Oct-2009	22-Oct-2009	0	27-Oct-2009	28-Oct-2009	IL		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>
	FLU(H1N1)	SANOFI PASTEUR	UP001AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Condition aggravated, Convulsion

**Symptom Text:** had a seizure within 15 minutes of receiving immunization

**Other Meds:**

**Lab Data:**

**History:** seizure disorder

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363245-1

<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>
41.0	M	26-Oct-2009	27-Oct-2009	1	27-Oct-2009	28-Oct-2009	MI		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	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pain, Injection site reaction, Muscle twitching

**Symptom Text:** Twitching of injection site with mild dull pain. Upper arm could be visibly seen convulsing for several minutes. I've had many shots and NEVER had any similar side-effects. Recurred throughout day.

**Other Meds:** Date of seasonal influenza immunization approximate; some time in September

**Lab Data:**

**History:** HTN, hypercholesterolemia

**Prex Illness:** Getting over a cold but mainly resolved; no fever at any time

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363261-1

<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>
28.0	F	27-Oct-2009	27-Oct-2009	0	27-Oct-2009	28-Oct-2009	WI		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)	SANOFI PASTEUR	UP006AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dyspnoea, Feeling abnormal, Injection site anaesthesia, Paraesthesia oral

**Symptom Text:** "FEELS LIKE I CAN'T TAKE A FULL BREATH", CHEST TIGHTNESS, TONGUE"FEELS FUNNY", ARM NUMB FROM INJECTION TO ELBOW, "FEELS FUNNY"

**Other Meds:**

**Lab Data:** PT SENT TO URGENT CARE

**History:** ALLERGY TO AMOXICILLIN

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363266-1

<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>
0.8	M	19-Oct-2009	27-Oct-2009	8	27-Oct-2009	28-Oct-2009	IN		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	U3196AA	0	Right leg	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP007AA	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blister, Erythema, Erythema multiforme, Generalised erythema, Skin plaque

**Symptom Text:** Sudden onset of flat red patches on face, red tartetoid plaques on hands, wrists and left extensor surface of elbow, palms included. tense bulla on left hand digit. Primarily affecting hands and face. Diagnosed as Erythema Multiforme Minor

**Other Meds:** none

**Lab Data:** None

**History:** Failure to gain weight (at 4months); resolved by 5 months

**Prex Illness:** NO, but was noted to have two small red spots on the right hand/ wrist

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363267-1

<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>
59.0	F	21-Oct-2009	Unknown		27-Oct-2009	28-Oct-2009	WA		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)	SANOFI PASTEUR	UP008AA		Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** Rash on neck and chest and shoulders-itches.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363269-1

<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>
6.0	F	23-Oct-2009	23-Oct-2009	0	27-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>
	FLU(H1N1)	SANOFI PASTEUR	UP001AA		Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Lethargy, Rash, Swelling, Urticaria

**Symptom Text:** Teacher noted rash started at approx 12:30 on face, spread to both cheeks, chin, chest and back and became hivelike. Called to room at 13:01. 13:02 child lethargic and stable VS, 911. 13:04 called dad with report, rc'd hospital and Dr name. 13:06 911 here. Becoming more red and swollen. 13:13 removed by squad.

**Other Meds:** PREVACID 15 ml daily

**Lab Data:** Given BENADRYL in emergency room

**History:** No allergies; acid reflux; developmental delay

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363271-1

<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>
4.0	M	20-Oct-2009	21-Oct-2009	1	27-Oct-2009	28-Oct-2009	IL		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)	SANOFI PASTEUR		UP001AA		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Myalgia, Pyrexia

**Symptom Text:** Fever 42 degrees C, myalgias, cough. Started next day after H1N1 vaccination-continued fever 1 week later up to 40 degrees C.

**Other Meds:** MVI children's

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363272-1

<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>
46.0	F	23-Oct-2009	23-Oct-2009	0	27-Oct-2009	28-Oct-2009	NC		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)	SANOFI PASTEUR	UP003AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UT5252AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash, Swelling

**Symptom Text:** Itching, rash, swelling, received H1N1 shot 10/23 with FLUZONE shot in other arm.

**Other Meds:** HCTZ 25 mg 1 QD

**Lab Data:**

**History:** PCN

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363274-1

<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	27-Oct-2009	27-Oct-2009	0	27-Oct-2009	28-Oct-2009	FL		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)	NOVARTIS VACCINES AND DIAGNOSTICS	1008132P	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood glucose increased, Cough, Dizziness, Throat irritation

**Symptom Text:** S/S dizziness initially 30" post injection then c/o coughing intermittently with clearing of throat. Asked pt if chest tightness, stated no but had "itching of throat." Gave epinephrine 0.3 ml IM and 25 mg BENADRYL PO with + results. Staff member above received Monovalent H1N1 vaccine 0.5 ml IM to Left Deltoid (Lot #100813 2P expiration date: 02/2010) today. Patient had never had previous seasonal influenza vaccine, so after administration at 14:30, I monitored her for 15 minutes post injection. No localized or systemic reaction noted at 14:45, so I let her go. Thirty minutes post injection a co-worker of staff member above came to me and told me she c/o slight dizziness. I advised co-worker to bring her to me for evaluation. She came to me at 15:00. Initial VS include: BP 135/82, HR 76, RR 18, blood sugar: 119 (ate 2 hours prior), O2 saturation 100% on RA, BBS CTA. I placed her in a recliner with HOB elevated approximately 45 degrees, gave her juice and H2O, and continued to monitor her. Ten minutes later at 15:10, I noticed her coughing and clearing throat. I called MD available in our clinic to assist. I asked patient if she had chest tightness or dyspnea, or if her throat felt like it was closing, and she stated no. However, she stated, "itchiness in throat". Patient C/O 8/10 on scale for coughing, itchy throat and dizziness. VS: at 15:35 BP 126/81, BBS CTA (heard by myself and MD), HR 115, O2 saturation: 100% on RA. Site of injection benign. Gave epinephrine 1:1000 (verified by 2 nurses) 0.3 ml IM to Right deltoid without incident. BENADRYL 25 mg PO also given per standing order and per Dr. Patient responded well. F/U assessment: C/O 5/10 scale for symptoms, with VS at 15:40 BP 152/85, HR 114, oxygen saturation 100% RA. VS at 16:05: C/O 5/10 symptom scale; VS BP 126/74, oxygen saturation 100% RA, HR 111, BBS CTA. At 16:22, BBS CTA, C/O 3/10 on symptom scale, BP 118/71, HR 101, oxygen saturation 100% RA. Patient ambulated to restroom with assist without incident. VS at 16:40 include no complaints of any sympt

**Other Meds:** None

**Lab Data:**

**History:** Leukemia dx 2003 last chemo 8/31/09 in remission; allergies: latex (rash)

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363284-1

<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>
26.0	M	27-Oct-2009	27-Oct-2009	0	27-Oct-2009	28-Oct-2009	AZ		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)	SANOFI PASTEUR	UP002AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Flushing, Hypoaesthesia, Injection site pain

**Symptom Text:** Began with facial flushing followed pain down injection site arm followed by numbness to the hand. Feels like there is no strength in hand. Momentary dizziness.

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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, Gastrooesophageal 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 phenergan 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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363289-1

<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>
57.0	F	27-Oct-2009	27-Oct-2009	0	27-Oct-2009	28-Oct-2009	MT		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)	NOVARTIS VACCINES AND DIAGNOSTICS	100739	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Dizziness, Dyspnoea, Feeling hot, Flushing, Heart rate increased, Paraesthesia, Paraesthesia oral, Respiratory rate increased, Tremor

**Symptom Text:** facial/mouth tingling, dizziness, sensation of heat and flushing, shakiness, rapid heart rate (103), increased BP (153/94) rapid breathing, slight difficulty breathing. approx 50 minutes later bp still elevated (163/99) pulse 99, still with some facial/mouth "tingling", slight dizziness, breathing reported as "better". Took ativan at 2:40 and claritin at 3:00 pm. 4:30 pt symptoms just about resolved.

**Other Meds:** acyclovir, tylenol, prilosec,

**Lab Data:**

**History:** benadryl, compazine, tape, bactrim

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363293-1

<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	23-Oct-2009	27-Oct-2009	4	27-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(H1N1)	SANOFI PASTEUR		UP007AA	0	Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia facial

**Symptom Text:** Facial numbness, left greater than right, intermittent, no facial asymmetry, no other areas involved

**Other Meds:** Ocella

**Lab Data:** None

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363295-1

<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>
32.0	F	25-Oct-2009	26-Oct-2009	1	27-Oct-2009	28-Oct-2009	MO		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	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Fatigue, Headache

**Symptom Text:** Fatigue, H/A on 10/26/2009...Extreme fatigue, H/A, cough still present as of 10/27/2009 9:10 PM

**Other Meds:**

**Lab Data:**

**History:** Epilepsy

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363296-1

<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>
57.0	F	20-Oct-2009	20-Oct-2009	0	27-Oct-2009	28-Oct-2009	WA		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		Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthma, Chills, Dyspnoea, Lip swelling, Pain, Swelling face, Urticaria

**Symptom Text:** Facial/lip swelling, chills, body aches, some difficulty breathing. Hives on neck and trunk. Took benadryl, 24 hr. swollen face/lips. Report To regular Dr. told pt continue benadryl. x 1 week hives on trunk, flare-up Asthma.

**Other Meds:**

**Lab Data:**

**History:** Hx asthma, Hx Sulfa, Penicillin allergies. Hx walnut/nut allergies. Hx MMR reaction 1978.

**Prex Illness:** No illnesses

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363326-1

<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>
57.0	M	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	28-Oct-2009	IN		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)	SANOFI PASTEUR	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Asthenia, Pruritus generalised, Pyrexia, Vertigo

**Symptom Text:** Full body itching...continued for 8 hours and relieved with Benedryl. 10/22/2009...Abdominal pain followed by vertigo. 100.7...weakness...more vertigo. Started Cipro and Antivert...Fever broke in 14 hours. Vertigo continued until 10/26/2009 10/24/2009...Fever to

**Other Meds:** Avipro 300, Crestor 5mg,Prevacid, Maxide 75/50, Baby aspirin, Fish oil, Glucosamine/chondroitin

**Lab Data:** None

**History:** High Blood Pressure/controlled

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363327-1

<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>
53.0	F	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	28-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(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Severe skin itching on Chest, abdomen , shoulders , back

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363327-1

<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>
53.0	F	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	28-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(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus

**Symptom Text:** Severe skin itching on Chest, abdomen , shoulders , back

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363328-1

<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>
30.0	F	22-Oct-2009	28-Oct-2009	6	28-Oct-2009	28-Oct-2009	OH		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	500764P	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Sinusitis

**Symptom Text:** Woke up this morning with the what feels like the onset of a sinus infection and headache possibly caused by the flumist.

**Other Meds:** no prior shots or medications to getting flumist

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363328-1

<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>
30.0	F	22-Oct-2009	28-Oct-2009	6	28-Oct-2009	28-Oct-2009	OH		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	500764P	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Sinusitis

**Symptom Text:** Woke up this morning with the what feels like the onset of a sinus infection and headache possibly caused by the flumist.

**Other Meds:** no prior shots or medications to getting flumist

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363329-1

<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>
59.0	F	19-Oct-2009	19-Oct-2009	0	28-Oct-2009	28-Oct-2009	IN		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)	SANOFI PASTEUR	UP007AA	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Local reaction, Oedema peripheral, Skin warm

**Symptom Text:** L arm swollen and warm; from fingers up into L shoulder. No SOB. States started after injection on 10/19/09. Reported on 10/20/09. Sent to work comp MD. Dx: local vaccine reaction.

**Other Meds:** Unknown

**Lab Data:** No testing needed

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363329-1

<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>
59.0	F	19-Oct-2009	19-Oct-2009	0	28-Oct-2009	28-Oct-2009	IN		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)	SANOFI PASTEUR	UP007AA	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Local reaction, Oedema peripheral, Skin warm

**Symptom Text:** L arm swollen and warm; from fingers up into L shoulder. No SOB. States started after injection on 10/19/09. Reported on 10/20/09. Sent to work comp MD. Dx: local vaccine reaction.

**Other Meds:** Unknown

**Lab Data:** No testing needed

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363332-1

<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>
39.0	F	21-Oct-2009	25-Oct-2009	4	28-Oct-2009	28-Oct-2009	NC		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)	SANOFI PASTEUR	UP003AA	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye swelling, Headache, Pyrexia

**Symptom Text:** Employee received H1N1 vaccine on 10/21/09. On Sunday, 10/25/09, employee had an onset of HA, mild fever, and some orbital swelling. Orbital swelling decreased on Monday 10/26/09. HA continues currently. Fever lasted about 12 hrs.

**Other Meds:** LASIX; vitamins; PROTONIX; K+; SINGULAIR

**Lab Data:**

**History:** Allergy: CODEINE; FLAGYL. Conditions: pacemaker

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363332-1

<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>
39.0	F	21-Oct-2009	25-Oct-2009	4	28-Oct-2009	28-Oct-2009	NC		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)	SANOFI PASTEUR	UP003AA	1	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye swelling, Headache, Pyrexia

**Symptom Text:** Employee received H1N1 vaccine on 10/21/09. On Sunday, 10/25/09, employee had an onset of HA, mild fever, and some orbital swelling. Orbital swelling decreased on Monday 10/26/09. HA continues currently. Fever lasted about 12 hrs.

**Other Meds:** LASIX; vitamins; PROTONIX; K+; SINGULAIR

**Lab Data:**

**History:** Allergy: CODEINE; FLAGYL. Conditions: pacemaker

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363339-1

<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>
36.0	M	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	28-Oct-2009	IL		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	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site anaesthesia

**Symptom Text:** Feeling of "numbness" sensation starting from arm which recieved vaccine ascending to front and back of neck. Did not progress from there

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363339-1

<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>
36.0	M	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	28-Oct-2009	IL		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	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site anaesthesia

**Symptom Text:** Feeling of "numbness" sensation starting from arm which recieved vaccine ascending to front and back of neck. Did not progress from there

**Other Meds:**

**Lab Data:**

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363340-1

<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>
41.0	F	27-Oct-2009	27-Oct-2009	0	28-Oct-2009	28-Oct-2009	MO		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)	SANOFI PASTEUR	UP010AA	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Feeling abnormal, Hypoaesthesia, Paraesthesia, Pharyngeal oedema, Wheezing

**Symptom Text:** H1N1 vaccine given in R dlt at 9 A. Was feeling "weird" at 9:30 A tingly, numb, throat swelling up, wheezing, etc-met ambulance went to hospital given BENADRYL and EPI-sent home-returned last night about 7 PM-same symptoms.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363340-1

<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>
41.0	F	27-Oct-2009	27-Oct-2009	0	28-Oct-2009	28-Oct-2009	MO		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)	SANOFI PASTEUR	UP010AA	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Feeling abnormal, Hypoaesthesia, Paraesthesia, Pharyngeal oedema, Wheezing

**Symptom Text:** H1N1 vaccine given in R dlt at 9 A. Was feeling "weird" at 9:30 A tingly, numb, throat swelling up, wheezing, etc-met ambulance went to hospital given BENADRYL and EPI-sent home-returned last night about 7 PM-same symptoms.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363341-1

<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>
2.0	M	24-Oct-2007	28-Oct-2009	735	28-Oct-2009	28-Oct-2009	MD		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)	SANOFI PASTEUR	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Angioedema, Urticaria

**Symptom Text:** Large and Small Hives on Torso, Back, Stomach and Legs.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363341-1

<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>
2.0	M	24-Oct-2007	28-Oct-2009	735	28-Oct-2009	28-Oct-2009	MD		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)	SANOFI PASTEUR	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Angioedema, Urticaria

**Symptom Text:** Large and Small Hives on Torso, Back, Stomach and Legs.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363348-1

<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>
3.0	M	26-Oct-2009	27-Oct-2009	1	28-Oct-2009	28-Oct-2009	CO		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)	SANOFI PASTEUR	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Urticaria

**Symptom Text:** 0.5 ml H1N1 given 10/26/09. Mother brought in 10/27/09 with urticaria, temp 99. No other sx.

**Other Meds:** None

**Lab Data:** None

**History:** None; 33 preemie

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363348-1

<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>
3.0	M	26-Oct-2009	27-Oct-2009	1	28-Oct-2009	28-Oct-2009	CO		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)	SANOFI PASTEUR	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Urticaria

**Symptom Text:** 0.5 ml H1N1 given 10/26/09. Mother brought in 10/27/09 with urticaria, temp 99. No other sx.

**Other Meds:** None

**Lab Data:** None

**History:** None; 33 preemie

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363371-1

<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>
36.0	F	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	30-Oct-2009	MA		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		UP009AA	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Ear pain, Headache, Pyrexia, Throat irritation

**Symptom Text:** S/Sx began after H1N1 administration. Itchy/scratchy throat, mild cough, HA, ear pain with subjective fever/chills.

**Other Meds:** XANAX; DEPO PROVERA; labetalol; HCTZ

**Lab Data:** None

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363371-1

<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>
36.0	F	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	30-Oct-2009	MA		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		UP009AA	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Ear pain, Headache, Pyrexia, Throat irritation

**Symptom Text:** S/Sx began after H1N1 administration. Itchy/scratchy throat, mild cough, HA, ear pain with subjective fever/chills.

**Other Meds:** XANAX; DEPO PROVERA; labetalol; HCTZ

**Lab Data:** None

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363378-1

<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>
7.0	F	22-Oct-2009	23-Oct-2009	1	28-Oct-2009	28-Oct-2009	PA		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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Dyspnoea, Headache, Pain, Pyrexia, Rhinorrhoea

**Symptom Text:** High Fever 102.5 Coughing Complained of Difficulty Breathing Headache Body aches & pains Runny Nose

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363378-1

<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>
7.0	F	22-Oct-2009	23-Oct-2009	1	28-Oct-2009	28-Oct-2009	PA		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:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Dyspnoea, Headache, Pain, Pyrexia, Rhinorrhoea

**Symptom Text:** High Fever 102.5 Coughing Complained of Difficulty Breathing Headache Body aches & pains Runny Nose

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363380-1

<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>
21.0	F	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	29-Oct-2009	VA		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	UP009AA	0	Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Drug exposure during pregnancy, Headache, Nausea, Vomiting

**Symptom Text:** Had headache 9:30 A-then started throwing up later, otherwise feels fine is 11 weeks pregnant. Advised to go to ER. 11/02/09 Medical record recieved. OB/GYN record DOS 10/7. 9 weeks gestation. Vag exam WNL. RH+. Mild HA, nause/vomiting and abd pain. LMP 7/17/09. EDC 4/23/2010. Corrected EDC 5/11/2010.

**Other Meds:**

**Lab Data:** None. Labs & diags: TSH 3.08 WNL, UA neg,

**History:** PMH: Family h/o DM and hypertension. Allergies: NKDA

**Prex Illness:** Pregnancy 11 wks

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363380-1

<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>
21.0	F	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	29-Oct-2009	VA		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	UP009AA	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Drug exposure during pregnancy, Headache, Nausea, Vomiting

**Symptom Text:** Had headache 9:30 A-then started throwing up later, otherwise feels fine is 11 weeks pregnant. Advised to go to ER. 11/02/09 Medical record recieved. OB/GYN record DOS 10/7. 9 weeks gestation. Vag exam WNL. RH+. Mild HA, nause/vomiting and abd pain. LMP 7/17/09. EDC 4/23/2010. Corrected EDC 5/11/2010.

**Other Meds:**

**Lab Data:** None. Labs & diags: TSH 3.08 WNL, UA neg,

**History:** PMH: Family h/o DM and hypertension. Allergies: NKDA

**Prex Illness:** Pregnancy 11 wks

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363382-1

<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	19-Oct-2009	19-Oct-2009	0	28-Oct-2009	29-Oct-2009	VA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Eructation, Fatigue, Malaise, Oropharyngeal pain, Pallor, Pyrexia, Vomiting

**Symptom Text:** Feeling tired Monday afternoon. C/O abd pain that PM kind of sick. Later in evening c/o abd pain-burped. Sore throat. Threw up once, felt better, was pale, 99.4. 3 A fever 100.5. TYLENOL went to sleep. To Dr. later.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363382-1

<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	19-Oct-2009	19-Oct-2009	0	28-Oct-2009	29-Oct-2009	VA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain, Eructation, Fatigue, Malaise, Oropharyngeal pain, Pallor, Pyrexia, Vomiting

**Symptom Text:** Feeling tired Monday afternoon. C/O abd pain that PM kind of sick. Later in evening c/o abd pain-burped. Sore throat. Threw up once, felt better, was pale, 99.4. 3 A fever 100.5. TYLENOL went to sleep. To Dr. later.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363384-1

<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>
25.0	F	28-Oct-2009	28-Oct-2009	0	28-Oct-2009	28-Oct-2009	IN		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)	SANOFI PASTEUR	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pain

**Symptom Text:** Shot area red and burning, top of shoulder red and burning occurring within 10 minutes of vaccination. Given diphenhydramine 25 mg and hydrocortisone cream. Patient to follow-up with any further problems.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363384-1

<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>
25.0	F	28-Oct-2009	28-Oct-2009	0	28-Oct-2009	28-Oct-2009	IN		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)	SANOFI PASTEUR	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pain

**Symptom Text:** Shot area red and burning, top of shoulder red and burning occurring within 10 minutes of vaccination. Given diphenhydramine 25 mg and hydrocortisone cream. Patient to follow-up with any further problems.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363394-1

<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>
29.0	F	21-Oct-2009	22-Oct-2009	1	28-Oct-2009	29-Oct-2009	WV		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Tachycardia

**Symptom Text:** Tachycardia. Tx-rest, BENADRYL.

**Other Meds:** SYNTHROID

**Lab Data:** None

**History:** Hypothyroidism; palpitations

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363394-1

<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>
29.0	F	21-Oct-2009	22-Oct-2009	1	28-Oct-2009	29-Oct-2009	WV		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Tachycardia

**Symptom Text:** Tachycardia. Tx-rest, BENADRYL.

**Other Meds:** SYNTHROID

**Lab Data:** None

**History:** Hypothyroidism; palpitations

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363395-1

<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>
9.0	F	22-Oct-2009	24-Oct-2009	2	28-Oct-2009	29-Oct-2009	VA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP300AA	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Face oedema, Pruritus, Rash generalised, Urticaria

**Symptom Text:** Pt. developed hives, rash over entire body, itching. Within 12 hrs developed shortness of breath, facial edema. Mother gave BENADRYL PO x 3-4 doses. Took to ED 4 P 10/24. Given IV steroids. Given IM BENADRYL. Improved immediately. Sent home after 2 hrs. Improved.

**Other Meds:** CLARITAN 5 mgm PO qd

**Lab Data:** None

**History:** Seasonal allergies

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363395-1

<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>
9.0	F	22-Oct-2009	24-Oct-2009	2	28-Oct-2009	29-Oct-2009	VA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP300AA	0	Right arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Face oedema, Pruritus, Rash generalised, Urticaria

**Symptom Text:** Pt. developed hives, rash over entire body, itching. Within 12 hrs developed shortness of breath, facial edema. Mother gave BENADRYL PO x 3-4 doses. Took to ED 4 P 10/24. Given IV steroids. Given IM BENADRYL. Improved immediately. Sent home after 2 hrs. Improved.

**Other Meds:** CLARITAN 5 mgm PO qd

**Lab Data:** None

**History:** Seasonal allergies

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363402-1

<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	M	21-Oct-2008	23-Oct-2009	367	28-Oct-2009	29-Oct-2009	KY		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)	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Myalgia

**Symptom Text:** Severe myalgia across lower back approximately 48 hrs after administration. Treated with NSAID Resolved in about 36 hours.

**Other Meds:**

**Lab Data:** None. Self-limiting and resolved in 36 hours.

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363402-1

<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	M	21-Oct-2008	23-Oct-2009	367	28-Oct-2009	29-Oct-2009	KY		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)	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Myalgia

**Symptom Text:** Severe myalgia across lower back approximately 48 hrs after administration. Treated with NSAID Resolved in about 36 hours.

**Other Meds:**

**Lab Data:** None. Self-limiting and resolved in 36 hours.

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363406-1

<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>
33.0	F	15-Oct-2009	20-Oct-2009	5	28-Oct-2009	29-Oct-2009	AZ	IHS808113	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	0	Right arm	Intramuscular	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Facial palsy, Hypoaesthesia facial

**Symptom Text:** Onset of facial drooping to right side of face the morning of 10/20/09 noted by patient. Positive Numbness and inability to furrow brow documented. Rapid strep test done during physician visit. Patient had a positive RST. Treated with LA Bicillin 1.2 million units IM given in clinic on 10/20/09. Patient also treated with Acyclovir 400mg po 5x day x 10 days, Prednsione oral taper and artificial tears. 10/29/09: Medical Outpatient Record received for date of service 10/26/09. Dx: Bell's Palsy. Assessment: Presents with L sided facial pain and facial drooping since the am. Unable to completely close L eye. Discharged to home with Acyclovir and Prednisone and artificial tears.

**Other Meds:** None

**Lab Data:** 10/20/09: RST positive 10/20/09: Lyme Antibody Titer drawn, results not available at time of report. 10/29/09: Medical Outpatient Record received for date of service 10/26/09. Labs and Diagnostics: None.

**History:** None. 10/29/09: Medical Outpatient Record received for date of service 10/26/09. PMH: NKDA.

**Prex Illness:** None mentioned in vaccination screening questionnaire.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363406-1

<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>
33.0	F	15-Oct-2009	20-Oct-2009	5	28-Oct-2009	29-Oct-2009	AZ	IHS808113	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	0	Right arm	Intramuscular	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Facial palsy, Hypoaesthesia facial

**Symptom Text:** Onset of facial drooping to right side of face the morning of 10/20/09 noted by patient. Positive Numbness and inability to furrow brow documented. Rapid strep test done during physician visit. Patient had a positive RST. Treated with LA Bicillin 1.2 million units IM given in clinic on 10/20/09. Patient also treated with Acyclovir 400mg po 5x day x 10 days, Prednsione oral taper and artificial tears. 10/29/09: Medical Outpatient Record received for date of service 10/26/09. Dx: Bell's Palsy. Assessment: Presents with L sided facial pain and facial drooping since the am. Unable to completely close L eye. Discharged to home with Acyclovir and Prednisone and artificial tears.

**Other Meds:** None

**Lab Data:** 10/20/09: RST positive 10/20/09: Lyme Antibody Titer drawn, results not available at time of report. 10/29/09: Medical Outpatient Record received for date of service 10/26/09. Labs and Diagnostics: None.

**History:** None. 10/29/09: Medical Outpatient Record received for date of service 10/26/09. PMH: NKDA.

**Prex Illness:** None mentioned in vaccination screening questionnaire.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363407-1

<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	26-Oct-2009	27-Oct-2009	1	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>
	MMR	MERCK & CO. INC.	0763Y	1	Left arm	Subcutaneously	FLU
	DTAPIPV	GLAXOSMITHKLINE BIOLOGICALS	AC20B11ACB	4	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP007AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site swelling

**Symptom Text:** Left arm swelling and diffuse erythema from shoulder to elbow. Home treatment with diphenhydramine and ibuprofen. Symptoms began about 24 hrs after injections.

**Other Meds:** None

**Lab Data:** None

**History:** Optic nerve hypoplasia; esotropia

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363407-1

<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	26-Oct-2009	27-Oct-2009	1	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>
	MMR	MERCK & CO. INC.	0763Y	1	Left arm	Subcutaneously	FLU
	FLU(H1N1)	SANOFI PASTEUR	UP007AA	0	Right arm	Intramuscular	
	DTAPIPV	GLAXOSMITHKLINE BIOLOGICALS	AC20B11ACB	4	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site swelling

**Symptom Text:** Left arm swelling and diffuse erythema from shoulder to elbow. Home treatment with diphenhydramine and ibuprofen. Symptoms began about 24 hrs after injections.

**Other Meds:** None

**Lab Data:** None

**History:** Optic nerve hypoplasia; esotropia

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363408-1

<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>
60.0	M	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	29-Oct-2009	DC		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>
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Pain, Pyrexia

**Symptom Text:** On evening of 10/21/09 pt developed a fever up to but > 101 degrees, generalized body aches and fatigue. Self treated with TYLENOL and by 10/23/09 symptoms had resolved. (Pt requests VAERS be filed)

**Other Meds:** See attached

**Lab Data:**

**History:** See attached note

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363408-1

<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>
60.0	M	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	29-Oct-2009	DC		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>
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Pain, Pyrexia

**Symptom Text:** On evening of 10/21/09 pt developed a fever up to but > 101 degrees, generalized body aches and fatigue. Self treated with TYLENOL and by 10/23/09 symptoms had resolved. (Pt requests VAERS be filed)

**Other Meds:** See attached

**Lab Data:**

**History:** See attached note

**Prex Illness:** No

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363409-1

<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>
30.0	F	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	29-Oct-2009	NC		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	UP009AA		Left arm	Intramuscular	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Blood potassium decreased, Fatigue

**Symptom Text:** Unexplained weakness and fatigue since having the injection of H1N1 on 10-21-09. Seen OB/GYN. No treatment. 10/29/2009 MD records from OB-GYN 10/28/2009. States that patient was seen in ED on 10/26/2009 for c/o's weakness and fatigue post vaccine. DR's notes state that labs were normal with exception of low potassium.

**Other Meds:** Vitamin D; iron

**Lab Data:**

**History:** Pregnant PMH: Pregnant Allergies: NKDA

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363409-1

<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>
30.0	F	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	29-Oct-2009	NC		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	UP009AA		Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Blood potassium decreased, Fatigue

**Symptom Text:** Unexplained weakness and fatigue since having the injection of H1N1 on 10-21-09. Seen OB/GYN. No treatment. 10/29/2009 MD records from OB-GYN 10/28/2009. States that patient was seen in ED on 10/26/2009 for c/o's weakness and fatigue post vaccine. DR's notes state that labs were normal with exception of low potassium.

**Other Meds:** Vitamin D; iron

**Lab Data:**

**History:** Pregnant PMH: Pregnant Allergies: NKDA

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363410-1

<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>
10.0	M	Unknown	Unknown		28-Oct-2009	29-Oct-2009	NY		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>
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Pain in extremity, Throat tightness

**Symptom Text:** Pain, numbness in hand (Lt) started 5 min after injection. Throat tightness started in about 25 min (mild). Resolved after epinephrine injection. BP min 80/50/before EPI injection.

**Other Meds:**

**Lab Data:**

**History:** Nuts; citrus juices

**Prex Illness:** Asthma-stable

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363410-1

<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>
10.0	M	Unknown	Unknown		28-Oct-2009	29-Oct-2009	NY		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>
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Pain in extremity, Throat tightness

**Symptom Text:** Pain, numbness in hand (Lt) started 5 min after injection. Throat tightness started in about 25 min (mild). Resolved after epinephrine injection. BP min 80/50/before EPI injection.

**Other Meds:**

**Lab Data:**

**History:** Nuts; citrus juices

**Prex Illness:** Asthma-stable

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363413-1

<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>
2.0	M	28-Oct-2009	Unknown		28-Oct-2009	29-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>	
	FLU(H1N1)	SANOFI PASTEUR		UP003AA		Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, Unevaluable event

**Symptom Text:** 10/28/09 Pt came into office today to get the H1N1. Pt was given by mistake 0.5 ml instead of the .25 ml. Called the Imm. program-stated to have pt come back in 1 month for the H1N1 .25. Dr. spoke with father-advised to watch for fever.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363413-1

<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>
2.0	M	28-Oct-2009	Unknown		28-Oct-2009	29-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>	
	FLU(H1N1)	SANOFI PASTEUR		UP003AA		Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, Unevaluable event

**Symptom Text:** 10/28/09 Pt came into office today to get the H1N1. Pt was given by mistake 0.5 ml instead of the .25 ml. Called the Imm. program-stated to have pt come back in 1 month for the H1N1 .25. Dr. spoke with father-advised to watch for fever.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363414-1

<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>
6.0	M	28-Oct-2009	Unknown		28-Oct-2009	29-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>		
	FLU(H1N1)	SANOFI PASTEUR	UP003AA		Right arm	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, Unevaluable event

**Symptom Text:** Pt came in today at clinic and was given H1N1 vacc. Dose given was 0.25 ml. Called Imm. Program-stated to have the child come back today for another dose of H1N1 0.25 ml. Dr. called parents to bring child back into office.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363414-1

<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>
6.0	M	28-Oct-2009	Unknown		28-Oct-2009	29-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>		
	FLU(H1N1)	SANOFI PASTEUR	UP003AA		Right arm	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered, Unevaluable event

**Symptom Text:** Pt came in today at clinic and was given H1N1 vacc. Dose given was 0.25 ml. Called Imm. Program-stated to have the child come back today for another dose of H1N1 0.25 ml. Dr. called parents to bring child back into office.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363420-1

<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>
45.0	M	22-Oct-2009	22-Oct-2009	0	28-Oct-2009	29-Oct-2009	SC		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>
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	98446PIA	0	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site pruritus, Injection site urticaria, Pruritus, Urticaria

**Symptom Text:** Approximately 1 hour after the patient received injection began having mild hiving down left arm (arm in which he received the H1N1 vaccine). Hiving and itching became generalized over the next hour and 1/2. (Pt is a police officer wearing kevlar vest.) He reported off duty and took 50mg diphenhydramine with rapid relief.

**Other Meds:**

**Lab Data:** N/A

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363425-1 (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>
32.0	F	22-Oct-2009	26-Oct-2009	4	28-Oct-2009	30-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)	NOVARTIS VACCINES AND DIAGNOSTICS	1008131P	0	Right arm	Intramuscular	FLU

**Seriousness:** HOSPITALIZED, SERIOUS

**MedDRA PT** Computerised tomogram normal, Hypoaesthesia, Lumbar puncture, Nuclear magnetic resonance imaging brain normal, Paraesthesia, Reflex test normal, Scan brain

**Symptom Text:** Pt came to ER on 10/26/09 with complaints of numbness & tingling to left foot & later to right foot and then both upper extremities. Spinal tap done-negative. Placed on inpatient unit, started on ASA 81mg & neuro consult ordered. Normal EMG 10/26/09. 10/29/09 and 10/30/09 Hospital Records and Discharge Summary received for hospital dates of service 10/26/09 to 10/29/09. Final diagnosis: Left leg weakness. Assessment: Presented with numbness and tingling in the LLE extending from the ankle to the knee as well as slight parasthesia in the R foot. Two days later noted parasthesia in both hands. No weakness, slurred speech, disarthria, sx. in hands improved somewhat. EMG and nerve conduction studies were normal. DTR's in UE's and LE's 2+, MRI brain normal, head CT normal. Discharged improved on 10/27-09 with no evidence of GBS, but subsequently returned to the hospital with a spinal headache from the LP with a pain scale of 8/10 and had a blood patch performed.

**Other Meds:** YAZ-28 one tab. daily

**Lab Data:** Lumbar puncture, 10/26/09, Negative; EMG, 10/26/09, Normal 10/29/09 and 10/30/09 Hospital Records and Discharge Summary received for hospital dates of service 10/26/09 to 10/29/09. Labs and Diagnostics: Lyme antibody (Negative), osmolari

**History:** None. 10/29/09 and 10/30/09 Hospital Records and Discharge Summary received for hospital dates of service 10/26/09 to 10/29/09. PMH: UTI, Difficulty walking x 1 month at age 10, mononucleosis.

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363438-1

<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>
40.0	F	27-Oct-2009	27-Oct-2009	0	28-Oct-2009	29-Oct-2009	AZ		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>
	FLU(H1N1)	SANOFI PASTEUR	UP012AA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Hypoaesthesia facial, Nausea, Pruritus

**Symptom Text:** Left side numbness of face, headache, nausea and itching. Went to employee health.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363440-1

<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>
9.0	M	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	29-Oct-2009	CA		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>	
	FLU(H1N1)	SANOFI PASTEUR		UP006AA	0	Right arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Decreased activity, Hypophagia, Pyrexia, Upper respiratory tract congestion

**Symptom Text:** fever up to 103F. Congestion. No vomiting/diarrhea. no rash. some increased in cough. not as active as normal. less oral intake. chest: ok.

**Other Meds:** ibuprofen helping fever. as off 10/28/09 fever lower. may be improving.

**Lab Data:**

**History:** none

**Prex Illness:** slight cough on 10/25/2009. no fever.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363446-1      **Related reports:** 363446-2

<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>
17.0	F	27-Oct-2009	27-Oct-2009	0	28-Oct-2009	29-Oct-2009	MO		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Cyanosis, Dyspnoea, Fatigue, Headache

**Symptom Text:** Labored breathing, blue fingers, headache, chest pains, very tired.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363446-2      **Related reports:** 363446-1

<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>
17.0	F	27-Oct-2009	27-Oct-2009	0	28-Oct-2009	29-Oct-2009	MO		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)	SANOFI PASTEUR	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Dyspnoea, Fatigue, Headache, Nausea

**Symptom Text:** Client c/o chest pain,SOB, nausea, tired and Head ache.

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363449-1

<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>
44.0	F	14-Oct-2009	18-Oct-2009	4	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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paraesthesia

**Symptom Text:** paresthesias suddenly occurred and have been persistent, workup for stroke has been negative and while still present the sx have been slowly resolving

**Other Meds:**

**Lab Data:** CT, MRI negative for stroke, no hx of diabetes, hyperlipidemia or vascular disease

**History:** nothing significant

**Prex Illness:** 4 days later patient developed paresthesias of the left face and left arm, now slowly resolving, workup for other causes has been

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363451-1

<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>
2.0	F	27-Oct-2009	28-Oct-2009	1	28-Oct-2009	29-Oct-2009	CO		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>
	FLU(H1N1)	SANOFI PASTEUR	UP005AA	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** HIVES APPEARED ON PATIENT'S ABDOMEN AREA AND UPPER THIGHS AROUND ONE IN THE MORNING,PATIENT'S MOTHER CALLED THE ON CALL DOCTOR FOR OUR FACILITY, DR. RICHARD BUDENSIEK, WAS INSTRUCTED TO TREAT WITH BENADRYL.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** ASTHMA

**Prex Illness:** NONE

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363453-1

<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>
36.0	F	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	29-Oct-2009	CA		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Paraesthesia, Photophobia

**Symptom Text:** Severe headache, photophobia, tingling in feet reaching above knee, tingling in right fingers

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363459-1

<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>
28.0	F	22-Oct-2009	22-Oct-2009	0	28-Oct-2009	29-Oct-2009	OR		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>
	FLU(H1N1)	SANOFI PASTEUR	UP005AA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Presyncope

**Symptom Text:** Vasovagal.

**Other Meds:** LEXAPRO

**Lab Data:**

**History:** Anxiety

**Prex Illness:** No

**Prex Vax Illns:** Vasovagal~Tetanus Toxoid (no brand name)~1~27.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363464-1

<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>
1.8	F	24-Oct-2009	24-Oct-2009	0	28-Oct-2009	29-Oct-2009	PA		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)	SANOPI PASTEUR	UP007AA	0	Left leg	Unknown	FLU MMR TD

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abnormal behaviour, Cold sweat, Decreased appetite, Lacrimation increased, Pyrexia, Rhinorrhoea, Sleep disorder

**Symptom Text:** 99.8 fever/for 2 days/not hungry or thirsty/ broken sleep pattern cold clammy skin when fever broke Runny nose & eye not wanting to be comforted by touch,especially back and head Childrens Motrin given/fluids and food wanted after fever broke/wet cloth to clean eyes

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363467-1

<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>
15.0	F	26-Oct-2009	Unknown		28-Oct-2009	29-Oct-2009	CA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Loss of consciousness

**Symptom Text:** Family reported she felt dizzy, lost consciousness. Paramedics called, regained consciousness. Blood sugar and BP checked. Taken to hospital.

**Other Meds:**

**Lab Data:** BP and blood glucose WNL

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363468-1

<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>
0.8	M	28-Oct-2009	Unknown		28-Oct-2009	29-Oct-2009	TX		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>
	HEP	MERCK & CO. INC.	0715Y	2	Left leg	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP010AA		Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** Wrong dose given-0.5 ml given versus 0.25 ml (H1N1 vaccine).

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363469-1

<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>
40.0	F	23-Oct-2009	28-Oct-2009	5	28-Oct-2009	29-Oct-2009	UT		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>		
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP002AA		Left arm	Unknown	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Headache, Nausea

**Symptom Text:** Nausea-PHENERGAN. HA-ibuprofen. Chills-TYLENOL.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363470-1

<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>
2.0	M	27-Oct-2009	Unknown		28-Oct-2009	29-Oct-2009	AZ		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>
	FLU	UNKNOWN MANUFACTURER	NULL		Left leg	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP012AA		Left leg	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Feeling hot, Injection site erythema, Swelling

**Symptom Text:** Red, swelling after shot. Gave him BENADRYL, it seemed to go down but became large, swollen, red and hot. Gave him more BENADRYL and nothing happened. Mild redness at site.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363483-1

<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>
48.0	F	23-Oct-2009	23-Oct-2009	0	28-Oct-2009	30-Oct-2009	OR		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	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Feeling cold, Immunisation reaction, Malaise, Pain, Pyrexia

**Symptom Text:** low grade fever, chilled within a couple of hours. Then went home early. Over weekend became achey and didn't feel well. Saw personal MD on 10/26, he called it Hyperimmune Response to the vaccine. Unknown if patient has recovered

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:** Unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363484-1

<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>
54.0	F	23-Oct-2009	27-Oct-2009	4	28-Oct-2009	30-Oct-2009	KS		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	UP010AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** fine rash on lower extremities below the knees with severe itching

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363487-1

<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>
48.0	F	19-Oct-2009	19-Oct-2009	0	28-Oct-2009	30-Oct-2009	KY		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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Injection site discomfort, Lethargy, Malaise, Musculoskeletal discomfort, Pruritus, Rash

**Symptom Text:** Approx. 15 minutes after vaccine had general lethargy and not feeling well, arm discomfort above injection site, discomfort in neck, felt weak, rash developed on face and chest with itching. Patient took Benadryl when symptoms started and another dose of Benadryl that evening.

**Other Meds:** Lisinopril 5 mg.

**Lab Data:** None

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363488-1

<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>
0.5	F	24-Oct-2009	25-Oct-2009	1	28-Oct-2009	30-Oct-2009	WA		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		?	0	Left leg	Intramuscular	FLU	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lethargy, Pyrexia, Somnolence

**Symptom Text:** raising temp - highest was 102.8 by Monday 10-26-09, sleepy, lethargic. Was seen by family practice MD on Monday. Fever came down with Tylenol and Ibuprofen. As of today 10/28/09 baby still has low grade fever.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** not that we were aware of

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363490-1

<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>
26.0	F	23-Oct-2009	23-Oct-2009	0	28-Oct-2009	30-Oct-2009	NY		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	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Muscular weakness

**Symptom Text:** Patient reported that her right arm, the one which was vaccinated, become numb and weak soon after the inoculation. It persisted for more than 30 minutes so she came to my medical office for evaluation. the numbness and weakness persisted for at least 1 1/2 hours. Symptoms had resolved by the time she was evaluated 3 days later.

**Other Meds:**

**Lab Data:**

**History:** none known

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363491-1

<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>
44.0	F	20-Oct-2009	23-Oct-2009	3	28-Oct-2009	30-Oct-2009	AZ		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Diarrhoea, Headache, Myalgia, Nausea

**Symptom Text:** Nausea, diarrhea, muscle aches, chills, head ache

**Other Meds:**

**Lab Data:**

**History:** asthma

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363493-1

<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>
13.0	M	21-Oct-2009	26-Oct-2009	5	28-Oct-2009	30-Oct-2009	MD		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	UP008AA	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** High Fever

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363494-1

<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>
48.0	F	26-Oct-2009	26-Oct-2009	0	28-Oct-2009	30-Oct-2009	AZ		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		UP008AA	0	Left arm	Intramuscular	FLU	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Burning sensation, Dizziness, Hypoaesthesia, Neck pain, Oedema peripheral, Paraesthesia

**Symptom Text:** Neck pain L arm swelling numbness tingling. Dizzy Burning L temple and Mid back in spots. Lasting about 6 hours.

**Other Meds:**

**Lab Data:** no

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363497-1

<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>
21.0	F	19-Oct-2009	19-Oct-2009	0	28-Oct-2009	30-Oct-2009	WI		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	UP007AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Hives, itchy, occurred about two hours after the vaccine was administered

**Other Meds:** Lexapro, Zyrtec, Estradol, Estroven

**Lab Data:** None

**History:** Allergies: Codeine, Vicodin, Hydrocodone, Morphine, and Mebeudazole

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363498-1

<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>
23.0	M	22-Oct-2009	23-Oct-2009	1	28-Oct-2009	30-Oct-2009	WI		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	UP007AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives on face, neck, bilateral arms, stomach, and lower extremities

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** Cold symptoms, no fever

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363501-1

<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>
13.0	F	28-Oct-2009	28-Oct-2009	0	28-Oct-2009	30-Oct-2009	CA		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	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3216AA	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Syncope, Throat tightness

**Symptom Text:** Fainted after shot. when up in clinic, decribed feeling that her throat felt tight. Benadryl po given with resolution of symptom

**Other Meds:** none

**Lab Data:** none

**History:** eczema

**Prex Illness:** no illness

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363503-1

<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>
7.0	F	28-Oct-2009	28-Oct-2009	0	28-Oct-2009	30-Oct-2009	CA		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	SANOFI PASTEUR	U3185AA	0	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Throat irritation

**Symptom Text:** her throat felt funny

**Other Meds:** none

**Lab Data:** none

**History:** asthma

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363506-1

<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>
10.0	F	27-Oct-2009	28-Oct-2009	1	28-Oct-2009	29-Oct-2009	VA		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	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site pruritus, Injection site rash

**Symptom Text:** Localized pruritic, erythematous rash in an oval shaped area surrounding vaccination site, over the deltoid approximately 6 cm x 10 cm

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:** localized rash, not certain caused by which vaccine as 2 were given in same arm~Hep A (Havrix)-1~9.42~Patient|localized rash, not certain caused by which va

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363507-1

<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>
54.0	F	27-Oct-2009	28-Oct-2009	1	28-Oct-2009	29-Oct-2009	NY		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	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper

**Symptom Text:** Excruciating and debilitating stomach cramps.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363508-1

<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>
23.0	F	27-Oct-2009	28-Oct-2009	1	28-Oct-2009	29-Oct-2009	NY		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	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper

**Symptom Text:** Terrible stomach cramping

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363509-1

<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>
4.0	M	23-Oct-2005	27-Oct-2007	734	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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia

**Symptom Text:** cough and high fever, Well appearing on exam started 5 days after vac administration

**Other Meds:**

**Lab Data:** none

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363510-1

<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>
47.0	F	24-Oct-2009	24-Oct-2009	0	28-Oct-2009	29-Oct-2009	IN		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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives on neck and arms

**Other Meds:** Oral medications.....Iron, Paxil, Lavoxil.

**Lab Data:** I will contact my Primary Care on 10/29/2009

**History:** One kidney @ birth

**Prex Illness:** None

**Prex Vax Illns:** none~Influenza (Seasonal) (no brand name)-1~47.67~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363512-1

<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>
57.0	M	26-Oct-2009	27-Oct-2009	1	29-Oct-2009	29-Oct-2009	CT		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>
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Pruritus generalised

**Symptom Text:** global severe itching on scalp, elsewhere

**Other Meds:**

**Lab Data:** n/a

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363513-1

<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>
6.0	M	27-Oct-2009	Unknown		29-Oct-2009	29-Oct-2009	CA		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>
	VARCEL	MERCK & CO. INC.	1043Y		Right arm	Subcutaneously	
	IPV	SANOFI PASTEUR	D0052		Left arm	Subcutaneously	
	DTAP	SANOFI PASTEUR	C3157AA		Left arm	Intramuscular	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500796P	0	Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3203AA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** Child was given injectable H1N1 in addition to intranasal H1N1 vaccine and other scheduled vaccinations

**Other Meds:** none known

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363514-1

<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>
23.0	M	28-Oct-2009	29-Oct-2009	1	29-Oct-2009	29-Oct-2009	WI		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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Dizziness, Headache, Hyperhidrosis, Insomnia, Pallor, Pyrexia, Vomiting

**Symptom Text:** Headache, Pale, Chills, Fever, Dizzy, Vomiting. Couldn't sleep and soaked a couple sets of sheets in sweat. Eventually got to sleep and woke up feeling much better. Symptoms over in 8hrs.

**Other Meds:**

**Lab Data:**

**History:** No.

**Prex Illness:** No.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363515-1

<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>
53.0	F	29-Oct-2009	29-Oct-2009	0	29-Oct-2009	29-Oct-2009	NY		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)	SANOFI PASTEUR	UP007AA 0.5 ML	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Malaise, Nausea

**Symptom Text:** Nausea (in an individual who hasn't been nauseous in over 30 years), mild headache, malaise. No fever. Drank gingerale, which settled stomach. Went to sleep 9:00 p.m., woke up 4:00 a.m., 10/30/09, with mild headache, malaise.

**Other Meds:** Simvastatin, 10 mg

**Lab Data:**

**History:** NONE

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363517-1

<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>
2.0	F	23-Oct-2009	28-Oct-2009	5	29-Oct-2009	29-Oct-2009	IL		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		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Erythema, Lip swelling, Pruritus, Rash papular, Rhinorrhoea

**Symptom Text:** Upon awakening, there were multiple red, tiny raised papules (vesicular) (perioral) on her upper lip, philtrum and on the skin of the chin. The upper lip was slightly swollen. She was itching as well. It worsened over 12 hours, became more itchy/swollen. After 6.25mg of diphenhydramine and 12 more hours, the papules are resolving. The upper lip (including the vermilion) has a residual patch of erythema/mild swelling that appears more flat and is hopefully resolving. She had a mild cough & slight runny nose during the 1st 48 hours after the H1N1 nasal mist vaccine. There were no oral ulcers/lesions.

**Other Meds:** topical metronidazole cream.

**Lab Data:** None. We did call the nurse at the office, but she thought it was not concerning because there is/was no fever.

**History:** Previous history of reflux from 0-6 months, which resolved at 6 months. Addison is an atopic patient with a history of atopic dermatitis/eczema and periorificial dermatitis(neither are active now). During summer of 2008, she has 2 episodes of hand-foot-mouth dz.

**Prex Illness:** No.

**Prex Vax Illns:** truncal rash~Measles + Mumps + Rubella (no brand name)~1~1.50~Patient|fever~Measles + Mumps + Rubella (no brand name)~1~16.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363518-1 (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>
42.0	F	26-Oct-2009	26-Oct-2009	0	29-Oct-2009	02-Nov-2009	MI		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	UP006AA	0	Right arm	Intramuscular	FLU

**Seriousness:** ER VISIT, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Dizziness, Dysphagia, Headache, Lip swelling, Swollen tongue, Urticaria, Vomiting

**Symptom Text:** 15 min after vaccine pt developed hives. Swollen lips & tongue, with difficulty swallowing, vomiting, dizziness and headache.

**Other Meds:** See med list; Multivitamin; Calcium + D; Vit C

**Lab Data:** None

**History:** Bee; pcn; sulfa; AUGMENTIN; codeine; VICODIN

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363519-1

<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>
29.0	F	22-Oct-2009	23-Oct-2009	1	29-Oct-2009	30-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	UP009AA	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anxiety, Dizziness, Heart rate increased, Hyperhidrosis, Presyncope, Vertigo

**Symptom Text:** C/O dizziness/vertigo and diaphoresis at 3:00 AM 10/23/09. Seen in ED-> Caller states she received H1N1 vaccine at health dept at noon on 10/22. She just woke up this AM w/feelings of increased heart rate, sweating on hands and feet, no fever, feeling pulse in her throat. Walked through taking pt's pulse w/her and pulse is 64. States no allergy to eggs, latex, chicken protein, neomycin, polymixin. Pt then complains of feeling faint, feels like she may pass out. Advised ED for eval, 911 prn, husband is w/pt. Called ED, spoke w/RN who states pt was fine, dx anxiety, not an adverse reaction to vaccine. Pt has been seen in ED for similar anxiety related complaints. She had EKG done which was wnl, was monitored for a little while and discharged home. VSS-numbers not available.

**Other Meds:**

**Lab Data:** EKG

**History:** See attached forms ER visit to hospital

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363522-1

<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	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	29-Oct-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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Hives on knee and stomach, severe itching on knee. Put topical hydrocortisone on hives. Doctor advised us to administer 1/2 tsp benedryl, which we did. Hives and itching stopped.

**Other Meds:**

**Lab Data:**

**History:** Lactose intolerance, Ehlers-Danlos Syndrome (Hypermobility type)

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363531-1

<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>
9.0	F	23-Oct-2009	25-Oct-2009	2	29-Oct-2009	29-Oct-2009	KY		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>
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Headache, Rash

**Symptom Text:** Began getting rash on Sunday last 3-4 then would be gone then reoccur. To ER. Rx of erythromycin, BENADRYL and prednisone. C/O headache and continued rash 0 to 1=2809.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363533-1

<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>
53.0	F	26-Oct-2009	27-Oct-2009	1	29-Oct-2009	29-Oct-2009	VA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus

**Symptom Text:** Pruitis to LE'S specifically knees down and some on arms. Slight erythema.

**Other Meds:**

**Lab Data:**

**History:** GERD,Hyperlipidemia,Depression

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363535-1

<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>
36.0	F	27-Oct-2009	27-Oct-2009	0	29-Oct-2009	29-Oct-2009	MI		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	UP007AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Drug exposure during pregnancy, Fatigue, Headache, Nausea, Tremor

**Symptom Text:** Severe uncontrollable chills and shaking, extreme exhaustion, headache and nausea

**Other Meds:** Prenatal vitamins

**Lab Data:** None

**History:** anaphylactic reaction to Penicillin and aspirin

**Prex Illness:** No illnesses but pregnant (26 weeks)

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363596-1

<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>
55.0	M	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	29-Oct-2009	NC		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	NULL	0	Right arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Dyspnoea

**Symptom Text:** Chills, shortness of breath continuing into next day

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363599-1

<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>
2.0	M	26-Oct-2009	27-Oct-2009	1	29-Oct-2009	29-Oct-2009	MA		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>
	FLU(H1N1)	SANOFI PASTEUR	UP009AA	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** fever of 99.3, fever of 102.3 @ 2:30 PM

**Other Meds:**

**Lab Data:** none

**History:**

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363603-1

<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>
31.0	F	23-Oct-2009	23-Oct-2009	0	29-Oct-2009	30-Oct-2009	--		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Dizziness, Headache

**Symptom Text:** The patient received the H1N1 flu vaccine IM shot at 9 AM and started experiencing headache, dizziness, worsened cough, low grade temps.

**Other Meds:**

**Lab Data:** Temp 99

**History:** NKDA; no significant medical history

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363621-1

<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>
25.0	F	15-Oct-2009	15-Oct-2009	0	29-Oct-2009	30-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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abasia, Dizziness

**Symptom Text:** Within 12 hours of H1N1 vaccine became dizzy and was extremely dizzy. She could not walk.

**Other Meds:** LEVOTHYROID-low thyroid; CELEXA-antidepressant; NUVARING-birth control

**Lab Data:**

**History:** Low thyroid

**Prex Illness:**

**Prex Vax Illns:** Hematoma~Influenza (Seasonal) (no brand name)~UN~22.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363623-1

<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>
30.0	F	25-Oct-2009	25-Oct-2009	0	29-Oct-2009	30-Oct-2009	CA		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)	NOVARTIS VACCINES AND DIAGNOSTICS	1008131P		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Flushing, Hyperhidrosis, Nausea

**Symptom Text:** Diaphoresis, flushing, weakness, nauseated. Vasovagal. Recovered within 5-10 minutes.

**Other Meds:**

**Lab Data:** BP 120/85; pulse 90->84

**History:**

**Prex Illness:** None

**Prex Vax Illns:** Vasovagal~ ()~UN~16.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363626-1

<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>
10.0	F	21-Oct-2009	23-Oct-2009	2	29-Oct-2009	30-Oct-2009	MD		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	UP009AA	0	Left arm	Intramuscular	FLUN

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough

**Symptom Text:** 48 hours after administration of H1N1 vaccine, developed temp to 102 and cough. Temp for 3 days, cough for 7 days.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363627-1

<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>
4.0	F	20-Oct-2009	21-Oct-2009	1	29-Oct-2009	30-Oct-2009	MA		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		500754P	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye swelling, Fatigue, Feeling drunk, Gait disturbance

**Symptom Text:** Mother reports day after vaccination child was very tired, "acting drunk", "staggering", and "eyes are puffy".

**Other Meds:** None

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363631-1

<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>
54.0	F	14-Oct-2009	17-Oct-2009	3	29-Oct-2009	30-Oct-2009	MD		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)	SANOFI PASTEUR	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough

**Symptom Text:** Tempt to 102 for 3 days. Cough for 5 days. No treatment.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363634-1

<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>
10.0	M	20-Oct-2009	21-Oct-2009	1	29-Oct-2009	30-Oct-2009	GA		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	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia oral, Lip swelling

**Symptom Text:** Vaccine H1N1 shot given 10/20/09. Reported lip swelling and numbness 10/21/09 AM.

**Other Meds:**

**Lab Data:** None

**History:** ADHD

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363637-1

<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>
7.0	F	23-Oct-2009	23-Oct-2009	0	29-Oct-2009	30-Oct-2009	CT		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	Left arm	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Step-mom states that pt had a rash after she got home from receiving H1N1. Rash now resolved.

**Other Meds:** Baclofen; PREVACID; MIRALAX; ALBUTEROL; BENADRYL; EPI-PEN; KEPPRA; cefdinir; prednisone

**Lab Data:** None

**History:** Spastic quad C P; seizure disorder; stenosis of larynx

**Prex Illness:** No illness

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363639-1

<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>
6.0	F	21-Oct-2009	21-Oct-2009	0	29-Oct-2009	30-Oct-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>		
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abasia, Abdominal pain upper, Dizziness, Headache, Hypotonia, Pallor, Syncope, Vomiting

**Symptom Text:** Approx. 10 mins after H1N1 shot (1:07 PM), patient felt dizzy and then fainted. Patient very pale (greenish pale face, white lips) and floppy limbs. Patient responsive, skin warm and dry. Patient could not sit, stand, or walk. Knees/feet turned in when nurse tried to stand her up. At 1:10 PM, patient carried to nurse's office, where patient vomited. Patient alert and responsive, but very pale. Patient's legs elevated, then she could squeeze nurse's hands and began to regain motor control. At 1:15 PM, BP=98/78, HR=96, lips pink but still pale. At 1:30 PM, patient could sit and stand. Patient remained pale with headache and stomach ache until 3:30 PM.

**Other Meds:** None

**Lab Data:** No abnormal findings at doctor visit 10-23-09

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363641-1

<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>
31.0	F	21-Oct-2009	21-Oct-2009	0	29-Oct-2009	30-Oct-2009	IN		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	UP003AA	0	Unknown	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Flushing, Heart rate increased

**Symptom Text:** Flushing, rapid heart rate and shortness of breath occurred 1.5 hours after H1N1 injection. Seen ED. Rx with prednisone and BENADRYL.

**Other Meds:** SYNTHROID; vitamins

**Lab Data:** Thyroid tests done, T4 and TSH-normal

**History:** Sulfa; MINOCIN

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363645-1

<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	M	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	29-Oct-2009	FL		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	UP008AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Hypoaesthesia, Immediate post-injection reaction, Monoplegia, Oropharyngeal pain

**Symptom Text:** Whole arm went numb and paralyzed immediately. Recovered slowly within 2 hours. By 6 PM was coughing and sore throat.

**Other Meds:** He had taken a Claritin at 7:30 am

**Lab Data:** None

**History:** Allergies to cat, all pollens, mold & mildew Diagnosed with Asperger's Syndrome at age 5

**Prex Illness:** Runny nose and sneezing the morning before from allergies. Gave Claritin and it went away.

**Prex Vax Illns:** Temp paralyzation~DTaP (no brand name)~~12.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363646-1 (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	F	21-Oct-2009	23-Oct-2009	2	29-Oct-2009	30-Oct-2009	IN		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown			

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

**MedDRA PT** Asthma, Chest discomfort, Dyspnoea

**Symptom Text:** Heaviness in my chest due to asthma. It was and still is very difficult to breathe. I went to my doctor on 10/23/2009 and was ran through a battery of tests which included a thorough exam by the doctor listening to me breathe, adminstering an oxygen saturation test, peek flow meter test ,and a chest x-ray. as of today, 10/29/2009, I am still currently taking an oral steroid as well as two albuterol nebulizer treatments daily.

**Other Meds:**

**Lab Data:** I went to my doctor on 10/23/2009 and was ran through a battery of tests which included a thorough exam by the doctor listening to me breathe, adminstering an oxygen saturation test, peek flow meter test ,and a chest x-ray. I am still curr

**History:** Asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363647-1

<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>
6.0	M	28-Oct-2009	29-Oct-2009	1	29-Oct-2009	29-Oct-2009	NE		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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough

**Symptom Text:** cough

**Other Meds:**

**Lab Data:**

**History:** seasonal allergies, but not having issues when given shot

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363650-1

<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>
51.0	M	27-Oct-2009	27-Oct-2009	0	29-Oct-2009	29-Oct-2009	TN		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>
	FLU(H1N1)	SANOFI PASTEUR	NULL	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Disorientation, Lethargy, Malaise

**Symptom Text:** Lethergy, disorientation, and general malaise that occurred at appromately 1:00PM and resolved by 6:00PM.

**Other Meds:** Veramil 120mgER 1 every day

**Lab Data:** NA

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363656-1

<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>
15.0	M	24-Oct-2009	24-Oct-2009	0	29-Oct-2009	30-Oct-2009	MI		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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysphonia, Headache, Malaise, Myalgia, Oropharyngeal pain, Pyrexia, Rhinorrhoea, Sneezing

**Symptom Text:** c/o not feeling well, sneezing, progressed to headace following day sore throat, muscle achiness, day 4 sore throat continues, runny nose, hoarseness, day five nearly completely hoarse continues to c/o not feeling well, low grade fever. First time receiving any flu vaccine. Reluctant to receive 2nd recommended vaccine in one month. Given OTC pain reliever.

**Other Meds:** none

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363660-1

<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>
11.0	M	23-Oct-2009	24-Oct-2009	1	29-Oct-2009	30-Oct-2009	MD		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)	SANOFI PASTEUR		NULL		Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Condition aggravated, Convulsion, Headache, Malaise, Staring, Unresponsive to stimuli, Vomiting

**Symptom Text:** Seizure one day after having flu shot. Awoke the day after shot feeling unwell. Bad headache and vomited breakfast. No fever. Slept until 2 PM. Unable to respond to questions and absent stare for approximately 10 minutes. Reported bad headache after seizure ended. Advil administered and he slept more. Neurologist suggested possible link to vaccine since seizure was not the typical type he experiences and he is controlled on medication. By the next day the headache was gone and he had a normal day. No more seizures since. He did not have a similar reaction to the seasonal FluMist vaccine given on 9/23/2009

**Other Meds:** Trileptal Concerta

**Lab Data:**

**History:** epilepsy

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363662-1

<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>
16.0	F	29-Sep-2009	29-Oct-2009	30	29-Oct-2009	30-Oct-2009	MO		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)	NOVARTIS VACCINES AND DIAGNOSTICS	100739 3P	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Vomiting

**Symptom Text:** Nausea and Vomiting---with headache

**Other Meds:** Prenatal Vitamins, Zantac

**Lab Data:** None

**History:** Pregnant

**Prex Illness:** Feeling weel

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363664-1

<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>
33.0	F	21-Oct-2009	21-Oct-2009	0	29-Oct-2009	30-Oct-2009	MA		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	UP009AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3196AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Induration

**Symptom Text:** Erythema/induration: L arm 40 x 35 mm, R arm 50 x 45 mm.

**Other Meds:** Prenatal vit

**Lab Data:** None

**History:** Pregnant-12 wks

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363668-1

<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>
24.0	F	21-Oct-2009	22-Oct-2009	1	29-Oct-2009	30-Oct-2009	CT		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	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Productive cough, Pyrexia

**Symptom Text:** fever 101, productive cough

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** cold sx

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363669-1

<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>
0.7	M	28-Oct-2009	28-Oct-2009	0	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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Left leg	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** raised hives covering limbs. Every section of skin was covered from knees to feet, elbows to hands, bottom

**Other Meds:**

**Lab Data:** None done, dr said to watch and bring him in if it gets worse

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363671-1

<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>
42.0	M	27-Oct-2009	28-Oct-2009	1	29-Oct-2009	30-Oct-2009	CT		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	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** RASH

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363672-1

<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>
46.0	F	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	30-Oct-2009	MI		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)	NOVARTIS VACCINES AND DIAGNOSTICS	1008131P	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT:** Rash

**Symptom Text:** Developed rash all over abdomen.

**Other Meds:** unknown

**Lab Data:** none

**History:** unknown

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363673-1

<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>
57.0	F	16-Sep-2009	16-Sep-2009	0	29-Oct-2009	30-Oct-2009	ND		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)	CSL LIMITED	01949211A		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Headache, Injection site erythema

**Symptom Text:** Redness at injection site 4 days duration. Headache next day, fatigue 24 hrs.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363683-1

<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>
48.0	F	29-Oct-2009	29-Oct-2009	0	29-Oct-2009	30-Oct-2009	KS		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	UP005AA		Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Feeling cold, Tachycardia, Throat tightness

**Symptom Text:** Vaccine administered at approximately 8:20. 8:25- Patient became tachycardic with heart rate at 140 bpm. She also felt like "her throat was closing". Shortness of breath also experienced. Blood pressure held steady at 144/84. 8:30- 50mg Benadryl administered. Pulse 124. BP 149/89. 8:35- Lorazepam 0.5 mg IV administered. Pulse 112. BP 138/80. 8:45- Patient felt chilled. 9:13- Pulse 93. Blood pressure: 122/70. EKG brought in. Patient's EKG appeared normal. 9:50- Patient visited by physician. Later sent home.

**Other Meds:** Unknown

**Lab Data:** EKG normal.

**History:** Anaphylaxis reaction to ceftriaxone. Abnormal heart rhythm, heart murmur

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363684-1

<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>
21.0	F	27-Oct-2009	28-Oct-2009	1	29-Oct-2009	30-Oct-2009	TN		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)	NOVARTIS VACCINES AND DIAGNOSTICS	100813 2P		Right leg	Subcutaneously	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Muscular weakness, Pain, Sensation of heaviness

**Symptom Text:** arms, shoulders, upper spine became weak, heaviness, aching. but resolved later in day

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363701-1

<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>
49.0	F	27-Oct-2009	28-Oct-2009	1	29-Oct-2009	30-Oct-2009	IN		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	UP003AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Arthralgia, Erythema, Malaise, Swelling

**Symptom Text:** Patient complains of pain redness and swelling in her right elbow and general malaise.

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363705-1

<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>
32.0	M	27-Oct-2009	27-Oct-2009	0	29-Oct-2009	30-Oct-2009	PR	PR-09-12	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		4P00199	0	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Dyspnoea, Fatigue, Headache, Heart rate increased, Hypertension, Tachycardia

**Symptom Text:** PATIENT REFERS CHEST PAIN, HEADACHE, SHORTNESS OF BREATH AND HYPERTENSION APROXIMATELY 4 HRS AFTER VACCINE ADMINISTRATION. PATIENT REFERS HE STILL IS EXPERIENCING FATIGUE AND RAPID HEART BEAT(TACHYCARDIA).

**Other Meds:** NONE

**Lab Data:** LAB TEST ARE NEGATIVE, DOCTOR FOUND ANOMALIES IN THE HEART MONITOR IN THE EMERGENCY ROOM.

**History:** NONE

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363710-1

<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>
45.0	M	19-Oct-2004	23-Oct-2009	1830	29-Oct-2009	30-Oct-2009	WA		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	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Oral pain, Pyrexia, Tongue coated

**Symptom Text:** Began running a fever, cough, and complaining of pain at the roof of the mouth. White coating on tongue.

**Other Meds:**

**Lab Data:**

**History:** newborn infant in the home No medical conditions

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363716-1

<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>
3.0	F	24-Oct-2009	26-Oct-2009	2	29-Oct-2009	30-Oct-2009	WA		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	500759P	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Lethargy, Pyrexia

**Symptom Text:** Fever of 100.4F and lethargy.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** No

**Prex Vax Illns:** fever, letharfy~Influenza (H1N1) (Influenza (H1N1) (Influenza A (H1N1) 2009 Monovalent))~1~3.75~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363717-1

<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>
50.0	F	28-Oct-2009	29-Oct-2009	1	29-Oct-2009	30-Oct-2009	IN		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	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pyrexia

**Symptom Text:** Low grade fever (99.9), mild headache

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363719-1

<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>
42.0	F	22-Oct-2009	23-Oct-2009	1	29-Oct-2009	30-Oct-2009	WI		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)	SANOFI PASTEUR	UP007AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Condition aggravated, Joint lock, Muscular weakness

**Symptom Text:** Woke up 10/23/09 at 0600 and could not get out of bed, legs locked up; arms and legs were weak; back pain was worse than on previous days and has continued to have > back pain and extremity weakness.

**Other Meds:** PERCOET; tramadol; lisinopril; cyclobenzaprine; levothyroxine; vitamin D

**Lab Data:** None

**History:** 5 yr history of back pain; fibromyalgia

**Prex Illness:** None

**Prex Vax Illns:** ~Influenza (Seasonal) (no brand name)~1~38.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363741-1

<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>
33.0	F	20-Oct-2009	20-Oct-2009	0	29-Oct-2009	30-Oct-2009	OH		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	UP006AA		Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia facial, Pruritus

**Symptom Text:** About 30 minutes after being vaccinated, client felt itchy on one half of her face, stating it "felt as if she was coming out of Novocaine". She said she then decided to eat something and after about an hour the feeling was restored.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363745-1

<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>
29.0	M	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	30-Oct-2009	CA		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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Flatulence, Flushing

**Symptom Text:** flush with gas

**Other Meds:**

**Lab Data:**

**History:** flush allergic reaction

**Prex Illness:** yes flush face

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363746-1

<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>
29.0	F	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	30-Oct-2009	CA		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	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Headache, Pruritus

**Symptom Text:** Dizziness, weakness, itching, head ache. no treatment. continues to have mild dizziness and headache (10-29-09)

**Other Meds:**

**Lab Data:**

**History:** Allergy to latex. Asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363748-1

<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>
1.1	F	27-Oct-2009	27-Oct-2009	0	29-Oct-2009	30-Oct-2009	TN		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	UPOO8AA	0	Right leg	Intramuscular	
	PNC	WYETH PHARMACEUTICALS, INC	D50003	3	Left leg	Intramuscular	
	VARCEL	MERCK & CO. INC.	1004Y	0	Right leg	Subcutaneously	
	MMR	MERCK & CO. INC.	0855Y	0	Left leg	Subcutaneously	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Gait disturbance, Irritability

**Symptom Text:** Grandparents report staggering & Irritability

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363751-1

<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>
2.0	M	19-Oct-2009	19-Oct-2009	0	29-Oct-2009	30-Oct-2009	NC		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		UP009AA	0	Left leg	Intramuscular	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Auricular swelling, Erythema, Feeling hot, Headache, Oedema peripheral, Pruritus, Skin irritation, Swelling face

**Symptom Text:** Vaccinated in left leg. Right outer ear swollen, red, hot at 9:30. Stated head hurt and was scratching back of neck, forehead and ear. Mom says face looked puffy, hands and feet look puffy. Called UNC Nurse line and gave recommended dosage of children's diphenhydramine. Signs and symptoms gone by next morning.

**Other Meds:** Prilosec 5 mg BID

**Lab Data:**

**History:** Previous allergy to milk protein, outgrew at 1 year old. Acid reflux

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363753-1

<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>
56.0	M	21-Oct-2009	24-Oct-2009	3	29-Oct-2009	30-Oct-2009	WA		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)	SANOFI PASTEUR	UP002AA		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Malaise, Myalgia, Vertigo positional

**Symptom Text:** Dizziness & myalgias and malaise; Dizziness mimicked BPPV, and worsend over 3-4 days, mild myalgias abated over 2 days, malaise 3 days-mild. Dizziness became quite remarkable

**Other Meds:** Simvistatin

**Lab Data:** none

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363755-1

<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>
17.0	M	27-Oct-2009	29-Oct-2009	2	29-Oct-2009	30-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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Headache, Oropharyngeal pain, Pain, Pyrexia, Vomiting

**Symptom Text:** Fever, headache, body aches stomach ache, vomiting, sore throat.

**Other Meds:** Study ID# 2-09-06955 Pandemic A/H1N1 influenza nasal spray vaccine.

**Lab Data:** Vaccine administered at Temple High school by Scott & White Hospital through the Vaccines for Influenza Prevention in Schools.

**History:** Allergic to Erthromycin

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363756-1

<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>
2.0	F	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	30-Oct-2009	TN		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)	SANOFI PASTEUR	UP003AA	0	Left leg	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash erythematous, Urticaria

**Symptom Text:** 2 hours after child received H1N1 injectable vaccine in left thigh, mom noticed a red, hives type rash on buttocks and lower back. No other symptoms noted. Carried child to PCP and was given BENADRYL and a steroid liquid PO for 5 days.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363757-1

<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>
62.0	F	20-Oct-2009	22-Oct-2009	2	29-Oct-2009	30-Oct-2009	NC		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)	SANOFI PASTEUR		UP003AA	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye pain, Headache, Nausea

**Symptom Text:** On 10/22/09 at 12:30 HA present (vice-like grip on eyes and around head). Contacted provider via phone-placed on MEDROL dose pack-would become nauseated if sitting up from lying position-daily thru 10/26/09 HA decreased on 10/27/09 slight pressure behind eyes otherwise no other s/s.

**Other Meds:**

**Lab Data:** Previously dx with encephalitis 2006/Nov

**History:**

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363758-1

<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>
31.0	F	25-Oct-2009	25-Oct-2009	0	29-Oct-2009	30-Oct-2009	FL		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)	SANOFI PASTEUR	UP009AA		Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site irritation, Throat irritation

**Symptom Text:** Administered H1N1 immunization to patient. Within 15 min. patient developed skin irritation on arm where injection was given that steadily advanced. Noticed irritation in throat as well. Relieved after taking oral BENADRYL 50 mgm.

**Other Meds:** None

**Lab Data:** None

**History:** Yes-allergic to many "chemicals"; no issue w/reg. flu vaccine

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363759-1

<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>
8.0	M	23-Oct-2009	26-Oct-2009	3	29-Oct-2009	30-Oct-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>	
	FLU(H1N1)	SANOFI PASTEUR		UP004AA	0	Right arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysarthria, Tongue spasm

**Symptom Text:** On 10/26/09 at approximately 4:15 PM, mother noticed that patient's speech was slurred and tongue quivering. Episode lasted approximately 30 minutes.

**Other Meds:** PROVENTIL inhaler prn; albuterol via nebulizer prn (last used night prior to vaccine)

**Lab Data:**

**History:** Asthma; "diagnosed with irregular heart beat at age 3"

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363765-1

<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>
1.1	M	08-Oct-2009	09-Oct-2009	1	29-Oct-2009	30-Oct-2009	KS		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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abnormal behaviour, Anger, Diet refusal, Fatigue, Gait disturbance, Insomnia, Pyrexia, Screaming, Staring

**Symptom Text:** Fever, Anger,Screaming,Difficulty walking, Wouldn't eat, Exhausted but couldn't sleep, Very passive about putting saline in his nose and using nasal bulb, He would sit like a statue on my lap and blankly stare at me face for over 30 minutes at a time. Normally he puts up a pretty good fight to get to hold him. This all lasted 4 days.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** He had just gotten over a cold and had a little remaining drainage.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363770-1

<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	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	30-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>
	FLU(H1N1)	CSL LIMITED	NULL	1	Right arm	Subcutaneously	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** hives

**Other Meds:**

**Lab Data:** prescribed prednisone

**History:** penicillin, keflex

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363779-1

<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>
2.0	F	16-Oct-2009	Unknown		29-Oct-2009	30-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	1	Right leg	Intramuscular	FLUN(H1N1)	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** child received 2 doses of H1N1. The first was a spray on 10/7/09, injection was 10/16/09. Pt. has no adverse events as of 10/29/09

**Other Meds:**

**Lab Data:**

**History:** unknown

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363780-1

<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>
47.0	F	26-Oct-2009	29-Oct-2009	3	29-Oct-2009	30-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	NULL	0	Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Heart rate increased

**Symptom Text:** A headache woke me up and was with me all day with Tylenol alternating with Motrin. Also had rapid heart rate that was also felt palpating with the throbbing headache. No fever, cough, or body aches other than headache.

**Other Meds:** multivitamin, iron, zinc, B12, birth control pill, chlorophyll, vitamin D

**Lab Data:** none

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363783-1

<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>
28.0	F	26-Oct-2009	26-Oct-2009	0	29-Oct-2009	30-Oct-2009	AZ		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)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dysphonia, Headache, Immunisation reaction, Muscle tightness, Myalgia, Pyrexia

**Symptom Text:** Muscles in shoulder neck on L tight painful. Fever 101 in middle of night. Tightness in chest ~0800. Headache. Symptoms continued through 10/28. Saw Dr. on 10/28 diagnosis with reaction to H1N1 vaccine. On 10/29 hoarse voice, fever 100. Headache improved but still there.

**Other Meds:** bistic 2.5 mg once a day

**Lab Data:**

**History:** Amoxicillin

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363788-1

<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>
4.0	M	29-Oct-2009	29-Oct-2009	0	29-Oct-2009	30-Oct-2009	IL		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye swelling

**Symptom Text:** Periorbital swelling, right sided (same side vaccine was given on). Left eye unaffected.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363794-1

<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>
36.0	F	22-Oct-2009	27-Oct-2009	5	29-Oct-2009	30-Oct-2009	NH		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	NULL	0	Left arm	Unknown	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Atelectasis, Chest pain, Computerised tomogram abnormal, Pain, Pleural effusion, Pleuritic pain

**Symptom Text:** pleuritic chest pain (pain with breathing/laughing) & L upper abdominal pain with radiation to clavicle/scapula. ER visit on 10/28, CT scan dxed with small, L lung base atelectasis vs. infiltrate and small L pleural effusion.

**Other Meds:**

**Lab Data:** CT abdomen/pelvis (lower chest seen) with contrast. WBC ct ~10.5. Sxs markedly improved by 10/29/09.

**History:** seasonal & environmental allergies

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363795-1

<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>
0.8	F	28-Oct-2009	28-Oct-2009	0	29-Oct-2009	30-Oct-2009	CA		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	NULL	0	Right leg	Unknown	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Irritability, Somnolence, Vomiting

**Symptom Text:** started fussy fussy & sleepy all day threw up at 6:15 pm

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** possible cold sore-unknown

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363796-1

<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>
36.0	F	15-Oct-2009	18-Oct-2009	3	29-Oct-2009	30-Oct-2009	NJ		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		NULL		Unknown	Unknown	FLU	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Activities of daily living impaired, Adverse reaction, Dyspnoea, Respiratory tract congestion, Sneezing

**Symptom Text:** constant sneezing since then, missed four days of work, constant congestion to the point of shortness of breath--that was the worst part. as of now 10/29 still feeling adverse reactions

**Other Meds:** Zolof 100 mg/day

**Lab Data:**

**History:** seasonal allergies

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363797-1

<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>
42.0	F	08-Oct-2009	09-Oct-2009	1	29-Oct-2009	30-Oct-2009	WV		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	NULL	1	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dysphagia, Local swelling, Neck pain

**Symptom Text:** I woke up and had swelling in the left side of my neck, like a lymph node. I went back to employee health to report it, they told me to go to my PCP or urgent care. I left work to go to urgent care and was treated with Omnicef. The next day, 10/11/2009 the swelling had increased in size, it was more painful and difficult to swallow. The next day, 10/12/2009, the swelling had not improved so I went to the emergency room and was put on another antibiotic, Cleocin. Later on that evening the swelling started to improve and over the next few days it was resolved.

**Other Meds:** Cymbalta, Effexor

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363802-1

<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>
18.0	F	15-Oct-2009	28-Oct-2009	13	29-Oct-2009	30-Oct-2009	AZ		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)	SANOFI PASTEUR	UP005AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Intra-uterine death

**Symptom Text:** Intrauterine fetal demise diagnosed on 10/29/09. Last FM felt on 10/28/09. Not clear if this is related to vaccination.

**Other Meds:** albuterol inh.

**Lab Data:** CMV; Toxo; Chemistry; lupus anticoagulant to be done at time of delivery of fetus (date to be determined)

**History:** Hx chlamydia; THC use; asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363803-1

<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>
8.0	F	28-Oct-2009	Unknown		29-Oct-2009	30-Oct-2009	MA		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)	SANOFI PASTEUR		UP018AA	1	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Inappropriate schedule of drug administration

**Symptom Text:** Pt was given a H1N1 vaccine on 10/20/09 and received a 2nd one on 10/28/09.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363804-1

<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>
30.0	F	23-Oct-2009	23-Oct-2009	0	29-Oct-2009	30-Oct-2009	MI		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)	SANOFI PASTEUR	UP003AA	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Dysphagia, Dyspnoea, Flushing

**Symptom Text:** Following administration of H1N1 vaccine to L arm pt developed SOB, flushing, weird sensation in chest, difficulty swallowing. Seen immediately in ER, given epinephrine 0.4 SQ, BENADRYL 50 mg IVP, SOLU-MEDROL 250 mg IVP, ZANTAC 50 mg IVP, 1000 cc NS. Vitals 154/90, 107, 24, 98.3.

**Other Meds:** BENICAR HCT 20/2.5 QD; BYSTOLIC 5 mg daily

**Lab Data:** None

**History:** Hypertension

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363807-1

<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	M	26-Oct-2009	27-Oct-2009	1	30-Oct-2009	30-Oct-2009	IL		31-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	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Fatigue, Headache, Myalgia, Pyrexia

**Symptom Text:** I first developed a deep chest cough. That then lead to a feeling of fatigue. The Morning of 10/28/09 I developed significant headaches, muscle aches, chills and a fever. The the muscle aches have largely gone away, I still am experiencing bad headaches along with chills and fever.

**Other Meds:**

**Lab Data:** Still undergoing symptoms

**History:** None.

**Prex Illness:** None.

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363824-1

<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>
65.0	M	18-Oct-2009	19-Oct-2009	1	30-Oct-2009	02-Nov-2009	NC		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)	SANOFI PASTEUR	UP009AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blister, Pain, Pruritus, Rash, Skin disorder

**Symptom Text:** It started of with itching and developed into a very painful rash and in places small blisters. there is a strip about 2-3 inches wide going half way around my abdomin. If no changes happen today will be seeing the hospital tomorrow

**Other Meds:**

**Lab Data:**

**History:** hypercholesterol

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363852-1

<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>
25.0	F	29-Oct-2009	29-Oct-2009	0	30-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>
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	1008134P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dysgeusia, Erythema, Flushing, Injection site erythema, Nausea, Rash macular, Tachycardia

**Symptom Text:** Abrupt onset flushing, dizziness, metallic taste in mouth, feeling faint, nausea, tachycardia followed by splotches of erythema on left upper arm/shoulder and left face/neck which were still prevalent 1 hr later.

**Other Meds:** EFFEXOR 75 mg; started ATIVAN 1 mg last dose 10/23/2009

**Lab Data:**

**History:** Methergine, ZOLOFT allergies; depression; panic attacks

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363900-1

<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>
37.0	F	27-Oct-2009	27-Oct-2009	0	30-Oct-2009	02-Nov-2009	SD		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)	SANOFI PASTEUR	UP001AA	0	Right arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** H1N1 shot given approx. 9:15 AM, rash developed approx. 11:45. Started OTC BENADRYL 3 prn. Came to emp. health next day 9:30 AM with severe urticaria entire body. Prescribed prednisone 10 mg 4 x d x 2d, 2d x 2d, 1d x2d et, ATARAX 50 mg 1 q 6-8 hours prn. Afebrile, denies difficulty swallowing or breathing.

**Other Meds:** ZOLOFT; PREVACID; vitamin; fish oil; omega 3

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363914-1

<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>
11.0	M	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	FL		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)	SANOFI PASTEUR	NULL		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Diarrhoea, Flatulence

**Symptom Text:** diahrrrea, stomach ache, gassy. teated with mylanta nd tums

**Other Meds:**

**Lab Data:**

**History:** eczema, allergic to peanuts,mold, roaches, chicken.

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363916-1

<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>
36.0	M	30-Oct-2009	30-Oct-2009	0	30-Oct-2009	02-Nov-2009	GA		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)	SANOFI PASTEUR	UPOO9AA	0	Left arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA476AA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chest discomfort, Erythema, Feeling hot, Flushing, Malaise

**Symptom Text:** Hospital Employee came in to receive both seasonal & H1N1 vaccine. Administered bilateral arms & nurse applied bandaid to 2nd injection site & Stated "i don't feel good, hot & tight in my chest". Reddened / flushed face/ no visible breathing difficulty. Benadryl 50mg IM administered to Right Gluteal & transported to ER for follow-up with MD. Symptoms has subsided prior to transport.

**Other Meds:**

**Lab Data:**

**History:** NKDA Recently taking Tamiflu for flu like illness x 2 weeks ago

**Prex Illness:** no Private funds - Seasonal flu Public funds - H1N1

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363917-1

<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>
8.0	F	23-Oct-2009	27-Oct-2009	4	30-Oct-2009	02-Nov-2009	FL		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	NULL	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Burning sensation, Headache, Pruritus, Rash

**Symptom Text:** severe rash on face, lighter rash on neck, hairline, stomach and back. Itching, burning of face rash. Headaches. Rash has disappeared everywhere except face. Headaches continue and face rash continues to itch and burn, has not abated at all as of 10/30/2009. Reported to pediatrician.

**Other Meds:**

**Lab Data:** No testing scheduled. Waiting for rash to clear up. Doctor said to expect rash to clear in approx 4 days.

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363918-1

<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>
39.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	MI		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)	SANOFI PASTEUR	UP006AA	1	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Diarrhoea, Dysphonia, Headache, Heart rate increased, Nausea, Oropharyngeal pain, Pain, Pyrexia, Throat irritation, Throat lesion

**Symptom Text:** I started feeling achy, fever (101), headache, chills, heartrate rapid (twice as high as usual), cough, nauseated, itchy throat ... now today those sympt. are subsiding but I have bumps in throat and it is very sore and I am very hoarse when I talk. And I have some diarrhea.

**Other Meds:**

**Lab Data:**

**History:** 11 WEEKS PREGNANT.

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363920-1

<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>
40.0	F	22-Oct-2009	22-Oct-2009	0	30-Oct-2009	02-Nov-2009	WA		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	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Palpitations, Swelling face, Tachycardia, Wheezing

**Symptom Text:** Woke up from sleep wheezing, tachycariac, feeling like heart was pounding out of chest. facial swelling. Used Xopenex inhaler. Wheezing subsided, but heart symptoms last approx 4 hours. Facial sweeling continued until midday on 10/23/2009.

**Other Meds:** On prilosec for reflux, otherwise no other medications.

**Lab Data:** None

**History:** Allery to Flagyl, Mild asthma using xopenex seldom

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363924-1

<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>
43.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-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)	SANOFI PASTEUR	UP002AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Rash pruritic

**Symptom Text:** Pt called at 3:15 PM to report after being vaccinated, she went home to take a nap and woke up to itchy rash on chest and neck. Pt called her primary obstitritian and they told her to take benedryl. After one dose of the benedryl, the rash subsided and there is no evidence of the rash today, 10/30/2009.

**Other Meds:**

**Lab Data:** None

**History:** Pt is pregnant.

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363925-1

<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	21-Oct-2009	21-Oct-2009	0	30-Oct-2009	02-Nov-2009	MO		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)	SANOFI PASTEUR	UP001AA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3173CA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Chills, Headache, Nausea, Pain, Rash, Tremor, Vaccination complication, Vomiting

**Symptom Text:** Patient states she developed general body aches approximately 1 hour after H1N1 and seasonal influenza vaccinations were administered. About 7 hours later, she had chills with extreme shaking, body pain, and nausea. She was seen in the ED, presenting with same symptoms as well as rash on chest and temp of 100.8 degrees. Per IV, she was given Benadryl, Zofran, Toradol, and NS. She was given Tylenol PO and diagnosed with "adverse reaction to influenza vaccine." Patient was then sent home and stated that during the night, she had another episode of shaking and nausea/vomiting which was resolved with PO Benadryl. The following day, she complained of slight nausea and a slight headache. On 10/23/09, her headache remained but by 10/24/09, all symptoms had resolved.

**Other Meds:** Lexapro, Trazadone, Synthroid

**Lab Data:** None

**History:** PCN, E-mycin or A-mycin, Sulfa, Demerol, "several preservatives" Cholecystectomy, Hypothyroidism, Asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363930-1

<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>
33.0	F	26-Oct-2009	28-Oct-2009	2	30-Oct-2009	02-Nov-2009	NY		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)	SANOFI PASTEUR		UP001AA	0	Left arm	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Rash generalised, Urticaria

**Symptom Text:** Pt. show up in ER with hives/rash all over body since morning of 10/28/09. Denies SOB. Pt. is 11 weeks gestation. Rc'd H1N1 vaccine on 10/26/09. BENADRYL every 6 hrs. as needed 10/30/2009 MD and Ed records for 10/28/2009. Patient with c/o's rash and itching. Tx: benadryl Im. DC Dx acute urticaria

**Other Meds:** None

**Lab Data:** Pulse oximetry-99% room air Lab/xrays none noted

**History:** 11 weeks gestation PMH: patient is 11 weeks Pregnant Allergies: NKDA

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363933-1

<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>
48.0	F	23-Oct-2009	23-Oct-2009	0	30-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>
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Lip swelling, Pruritus, Rash erythematous

**Symptom Text:** Within 20 minutes of injection she developed a skin rash, bumps, itching in trunk and face, lip swelling with mild shortness of breath. Used all latex-free products. To ED for tx, ATARAX and ZANTAC given.

**Other Meds:** SYNTHROID 25 mg

**Lab Data:** None

**History:** Latex allergies; food allergies

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363934-1

<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	21-Oct-2009	21-Oct-2009	0	30-Oct-2009	02-Nov-2009	KS		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)	SANOFI PASTEUR	500763P	0	Left arm	Unknown	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Heart rate increased, Hypoaesthesia, Immediate post-injection reaction, Pain in extremity, Palpitations

**Symptom Text:** Immediately after she received the H1N1 vaccine she states her left arm went completely numb for 15-20 min and afterwards became very sore and started becoming very dizzy and lightheaded with heart racing. Noted resting heart rate 122.

**Other Meds:**

**Lab Data:** 24 hour urine creatinine with total protein, PIH, chem profile, CBC, BUN, creatinine, uric acid, ALT, AST

**History:**

**Prex Illness:** Loss of sensation and numb arm

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363956-1

<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>
43.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	WI		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)	SANOFI PASTEUR	UP006AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Throat tightness, Tremor, Visual impairment, Vomiting

**Symptom Text:** Vommiting,shaking, SOB, and Pt reported trouble breathing and visual problems, and throat closing.

**Other Meds:** SYMBICORT, ENALAPRIL-HCTZ, OMEPRAZOLE

**Lab Data:** none

**History:** Asthma

**Prex Illness:** no

**Prex Vax Illns:** VOMMITTING~Influenza (Seasonal) (no brand name)~1~38.25~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363961-1

<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	F	24-Oct-2009	25-Oct-2009	1	30-Oct-2009	02-Nov-2009	WV		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	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Decreased appetite, Dyspnoea, Influenza, Lethargy, Nasal congestion, Pain in extremity, Pyrexia, Respiratory tract congestion, Somnolence

**Symptom Text:** Severe nasal congestion. Tuesday 10/27 lethargic, very sleepy, complain legs hurting, no appetite. Wed 10/28 fever 104.2 , very congested in chest, labored respirations. diagnosed H1N1 flu.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363963-1

<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>
32.0	F	21-Oct-2009	21-Oct-2009	0	30-Oct-2009	02-Nov-2009	MO		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	UP008AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus generalised, Rash generalised

**Symptom Text:** whole body rash,+itching ,pt. was given Diphenhydramine 25 mg's 2 tabs, zantac 159mgs. 3 hours later received IM demethasone 10mg and Depomedrol 80mg. cont to take dphenhydramine over night. 10/22/2009 receied depomedrol 80mg and demethasone 10 mg. rash better but cont on 10/32/2009

**Other Meds:** none

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363969-1

<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>
16.0	M	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	MD		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)	SANOFI PASTEUR	UP009AA	0	Right arm	Intramuscular	
	PPV	MERCK & CO. INC.	1124X	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Discomfort, Injection site erythema, Injection site pain, Injection site swelling

**Symptom Text:** Member received Pneumovax 0.5ml in left deltoid. Several hours later, mother called to report severe swelling and redness with moderate redness to left deltoid area. When seen at 3:30, left deltoid area was approximately 3 inches larger in diameter than right, tender to touch, with minor erythema at base of swelling. Seen by MD, given Benadryl and Ibuprofen, advised to continue this with ice to area. Spoke with mother 10/30/09 at 9:30 a.m. who stated that left arm is "10% bigger than right arm", less discomfort, and no redness present. They will continue with Benadryl today and ibuprofen as needed, agree to call if other worrisome symptoms arise.

**Other Meds:** Novalog Insulin Singulair 10 mg. q hs Phytonadione 5mg. BID Amylase/Lipase/Protease (Creon 20) - 4 caps before meals, 2 caps before snacks, 7 caps before tube feedings

**Lab Data:** None

**History:** Cystic Fibrosis Diabetes Portal Hypertension

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363971-1

<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>
29.0	F	30-Oct-2009	30-Oct-2009	0	30-Oct-2009	02-Nov-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>
	FLU(H1N1)	SANOFI PASTEUR	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Flushing, Pruritus, Rash macular, Reaction to previous exposure to any vaccine

**Symptom Text:** While working with a patient she suddenly started to itch on her face and her eyeballs. She developed some blotch areas on her body. Looks a little flushed. States that she has many allergies and that with previous flu vaccines have made her feel ill. She had a Benydral tablet which she took at 8:20 this morning. I spoke with her at 8:55 a.m. and she is feeling a little better.

**Other Meds:** Had taken one Vicoden (Norco 500/325) for a procedure she had done on 10/29/09. Also uses a Nuva Ring. That is all the prescriptions she has had.

**Lab Data:**

**History:** Has many allergies as well as to some antibiotics

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363972-1

<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>
47.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	MO		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	UP008AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** right arm rash , Diphenhydramin 25 mg's and zantac 150 mg.

**Other Meds:**

**Lab Data:**

**History:** DM

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363973-1 (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>
48.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	CA		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	UP002AA	0	Right arm	Intramuscular	FLU

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Dyspnoea, Endotracheal intubation, Intensive care, Panic reaction, Throat tightness

**Symptom Text:** Complained of shortness of breath, said felt throat was constricted and refused to go to ER. Due to asthma she has been intubated 18 times previously and she did not want to go to the ER. Requested and Epipen, which the pharmacy does not carry. She took a Clariton and used an Albuterol inhaler. When she became panicky she finally went to ER where they intubated her and transferred her to SICU. 11/2/2009 ED records for date 10/29/2009. Patient with c/o's respiratory distress and wheezing post vaccination. Patient given IV Solu Medrol but despite tx, respiratory distress progressed and patient had to be intubated/vented.PTT prolonged and placed on Heparin, Resp tx's, Telemetry, IV ABX

**Other Meds:** Prozac 40mg Synthroid 260mcg Aspirin 81mg Singulair Inhaler

**Lab Data:** Labs: CBC and BMP normal, CPK, ACE, SPE, ESR, TSH, Thyroid function tests, Calcium, Magnesium Phosphate, stool for OB, Troponin, Blood cultures DX tests: EKG: Sinus Tach

**History:** Severe Asthma and numerous allergies. None to eggs or Neomycin PMH: Hypothyroidism, Asthmatic Bronchitis, Vocal cord edema Allergies:

**Prex Illness:** No illness or reaction at time of injection. Reaction occurred 3-4 hours later

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363974-1

<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>
2.0	F	28-Oct-2009	28-Oct-2009	0	30-Oct-2009	02-Nov-2009	MO		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)	SANOFI PASTEUR		UP008AA	0	Left leg	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash

**Symptom Text:** chest and abd rash ,cont x 2 days -itching

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363975-1

<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>
42.0	F	21-Oct-2009	22-Oct-2009	1	30-Oct-2009	02-Nov-2009	CA		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)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site swelling

**Symptom Text:** Redness and sl swelling at inj site.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363976-1

<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>
70.0	F	21-Oct-2009	22-Oct-2009	1	30-Oct-2009	02-Nov-2009	CA		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)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site swelling

**Symptom Text:** Redness and sl. swelling at inj. site.

**Other Meds:** Thyroid; NAPROSYN

**Lab Data:** None

**History:** NKDA

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363977-1

<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>
33.0	F	28-Oct-2009	28-Oct-2009	0	30-Oct-2009	02-Nov-2009	LA		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)	SANOFI PASTEUR	UPOOAA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Contraindication to vaccination, Dizziness, Drug exposure during pregnancy, Dysphagia, Dyspnoea, Painful respiration, Throat tightness, Vaccination complication

**Symptom Text:** Throat from vocal folds to clavicle was closing, difficulty breathing, difficulty swallowing, slight dizziness - arrived at ER at approx. 3:30 - was given 50 mg of Benadryl & monitored for approx 1.25 hours - breathing returned to normal - instructed to self administer 25-50 mg of Benadryl as needed at 6 hour intervals - took 25 mg at approx. 10:00 and was fine, then had same severity of onset as initial reaction at approx. 4:00 a.m. (10-29-09) and had to take 50 mg to get breathing back to normal. Went to ob/gyn next morning (10-29-09)for 9:00 a.m. and was given a cortisone shot to help with the recurring reactions, also had baby examined through fetal ultrasound and fetal heartbeat monitor. Had to take 25mg of Bendadryl at approx. 10:00 p.m. that night b/c entire lung area (sternum, ribs & thoracic spine) was under severe pressure and it hurt to breathe. After 1/2 hour, pain subsided - after 45 minutes could lay down to try to sleep. No further reractions so far today (10/30/09 @ 12:10 p.m.) but instructed by ob/gyn to keep the Benadryl with me at all times b/c allergic reactions can last for up to 2 weeks. I HAVE NO ALLERGIES TO EGGS!

**Other Meds:** none

**Lab Data:**

**History:** latex allergy, poly-cystic ovarian syndrome, 5 months pregnant

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363978-1

<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>
1.9	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	WI		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	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Crying, Gaze palsy, Hypotonia, Pain in extremity, Pallor, Presyncope

**Symptom Text:** Lily started to softly cry that her leg hurt about 1 minute after shot was given...her eyes were gazed over, EXTREMELY PALE, face "fell" and she went limp. She was out of it for about 15 mins. She was rushed from the clinice to the ER and they called it a vaso vagal reaction, however, I am certain it was a side effect from the shot!

**Other Meds:** she was on the child version of tamiflu

**Lab Data:** WE will be seeing a neurgoloist and infectious disease/immunology dr.

**History:**

**Prex Illness:** Had a fever 3 days prior, only for 12 hours. 3 1/2 days later seemed very healthy!

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363980-1

<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	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-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)	SANOFI PASTEUR	UPO16AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Pyrexia, Throat tightness

**Symptom Text:** Developed tightness in throat at approx. 1:30 pm, also cough. At 3:00 pm, temperature was 104. Took Benedryl adult dose. Fever broke at 1:00 am 10/30/09. No recurrence of symptoms.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363983-1

<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>
27.0	F	30-Oct-2009	30-Oct-2009	0	30-Oct-2009	02-Nov-2009	MA		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	UP009AA	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Feeling abnormal, Immediate post-injection reaction, Pulse abnormal, Tachycardia, Throat irritation

**Symptom Text:** Immediately after receiving H1N1 immunization the patient c/o "burning of her throat and feeling funny". Pt is 9 wks pregnant. Pt placed in supine position and administered apple juice. BP 106/60 palpable, P 88 and thready, R-22 unlabored. Taken to ED via ambulance. 11/2/09 Emergency Department Records received from date of service 10/30/09. Dx: Medication Reaction. Assessment: 9 week pregnant woman presented after getting H1N1 vaccine and immediately had some throat irritation and "burning" and became anxious and tachycardic. There was no syncope or feeling of throat closing, no stridor or urticaria, no SOB or abd. pain. No evidence of allergic reaction on physical exam. Pt. discharged to home.

**Other Meds:**

**Lab Data:** Dx: minor medication reaction complicated by anxious reaction. 11/2/09 Emergency Department Records received from date of service 10/30/09. Labs and Diagnostics: None.

**History:** Pt states she has had previous episodes of anxiety attacks; 9 wks pregnant 11/2/09 Emergency Department Records received from date of service 10/30/09. PMH: Allergies to SSRI's, Phenergan.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363990-1

<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>
30.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	CA		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	NOVARTIS VACCINES AND DIAGNOSTICS	97847P1	0	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Feeling hot, Paraesthesia

**Symptom Text:** patient describes feeling 'warm and tingling' over entire body starting several minutes after vaccination and lasting several hours. no loss of consciousness, no fever, no weakness, no dizziness

**Other Meds:**

**Lab Data:** none

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363991-1

<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>
6.0	F	27-Oct-2009	29-Oct-2009	2	30-Oct-2009	02-Nov-2009	MA		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)	SANOFI PASTEUR	UP003AA	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia, Vomiting

**Symptom Text:** Fever, vomiting.

**Other Meds:** Fluoride

**Lab Data:**

**History:**

**Prex Illness:** Mild URI

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363993-1

<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>
17.0	M	21-Oct-2009	21-Oct-2009	0	30-Oct-2009	02-Nov-2009	MA	200904458	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	NULL		Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blindness, Diarrhoea, Dyspnoea, Fatigue, Immediate post-injection reaction, Pain in extremity, Pallor, Tremor

**Symptom Text:** Initial report received 23 October 2009 from a consumer, who is the patient's parent. A 17-year-old male patient with a history of Down's syndrome had received an intramuscular injection of INFLUENZA VACCINE and an intramuscular injection of PANDEMIC INFLUENZA A/H1N1 VACCINE (manufacturers unknown, lot numbers and sites not reported) on 21 October 2009 and immediately after vaccination, he became short of breath, his skin became grey-white, his legs were shaking, and his "eyes went in and he said he could not see". The patient was administered oxygen and ephinephrine, and he recovered in the office within a half hour. The patient had no concurrent illness, no known allergies, no concomitant medication usage and he had not received any other vaccine during the previous four weeks. He had no history of adverse events following prior vaccinations. According to the reporter, the patient had symptoms of achy legs, diarrhea and tiredness at the time of the report (onsets not reported) and he had not recovered. Documents held by sender: None.

**Other Meds:**

**Lab Data:** Not reported

**History:** The patient had no concurrent illness, no known allergies and he had not received any other vaccines within four weeks of seasonal Influenza and Pandemic Influenza vaccines. The patient had a history of Down's syndrome and he had not experienced any adverse events following prior vaccinations.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363994-1

<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>
3.0	M	14-Oct-2009	18-Oct-2009	4	30-Oct-2009	02-Nov-2009	LA	200904480	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)	SANOFI PASTEUR	UP001AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blepharospasm, Dyskinesia, Dystonia, Electroencephalogram normal, Nuclear magnetic resonance imaging normal

**Symptom Text:** Initial case was received on 26 October 2009 from a physician. This was reported as one of a cluster of two patients who experienced adverse events following vaccination with H1N1 2009 Monovalent Vaccine - Preservative (lot number UP001AA). The other patient experienced a non-serious event, which is captured in case number 2009-04481. A three-year-old male patient, with no reported medical history, experienced dystonia after receiving an intramuscular left deltoid first injection of H1N1 2009 Monovalent Vaccine - Preservative (lot number UP001AA) on 14 October 2009. Approximately four days post-vaccination, on 17 or 18 October 2009, the patient's mother noted right eye twitching, jerking of the right arm, and occasional jerking of the right leg. The symptoms occurred daily, particularly when the child was attempting to fall asleep. He was seen by his physician on 21 October 2009 and an exam was normal at that time; however, the physician noted that the patient's mother had videotaped the events and that the videotape was "impressive". He was subsequently seen in the emergency room, and was diagnosed with dystonia. An MRI and EEG were normal. At the time of the report, the event had not recovered. The patient had not received any other vaccines within four weeks of vaccination. Per the reporter, he did receive annual seasonal influenza vaccines. Documents held by sender: None.

**Other Meds:**

**Lab Data:**

**History:** No medical history.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363995-1

<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>
16.0	M	19-Sep-2009	26-Oct-2009	37	30-Oct-2009	02-Nov-2009	PA	200904507	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	SANOFI PASTEUR	NULL		Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Influenza, Pyrexia, Respiratory tract congestion

**Symptom Text:** Initial report received on 26 Oct 2009 from a health care professional. A 16 year old male patient with a history of allergic rhinitis received FLUZONE on 19 September 2009 and H1N1 on 11 October 2009 (lot number, route and site were not provided). On an unspecified date, reported as "recently", the patient developed a fever and congestion. On 26 October 2009, the patient tested positive for Influenza A. Concomitant therapy included SINGULAIR 10 mg daily and inhalers (not specified). Recovery status was not reported. List of Documents held by Sender: none.

**Other Meds:** SINGULAIR; Inhalers

**Lab Data:** The patient tested positive for Influenza A

**History:** History of allergic rhinitis, denies chronic conditions.

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363996-1

<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>
42.0	F	26-Oct-2009	26-Oct-2009	0	30-Oct-2009	02-Nov-2009	NJ	200904508	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)	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Dyspnoea, Swollen tongue, Throat tightness

**Symptom Text:** Initial case was received on 27 October 2009 from a consumer, who is also the patient. A 42-Year-old female patient experienced chest pain, shortness of breath, tongue swelling, and felt like her throat was closing after receiving a left deltoid intramuscular injection of Influenza A (H1N1) 2009 Mono Valent vaccine - Preservative (lot not reported) on 26 October 2009. The patient had a history of asthma and was allergic to Biaxin, and was taking Albuterol concomitantly. Approximately 15 to 30 minutes post-vaccination, the patient complained of chest pain, shortness of breath, tongue swelling, and felt like her throat was closing. She was treated with Albuterol and Benadryl, and was seen by a physician. At the time of the report on 27 October 2009, all symptoms had resolved except for the tongue swelling. Follow-up information received on 27 October 2009 from a company representative. Number 1-231206115. No other relevant medically significant information was provided. Documents held by sender: None.

**Other Meds:** Albuterol

**Lab Data:** Not reported

**History:** History of asthma; allergic to BIAXIN.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 363997-1

<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>
Unknown	M	21-Oct-2009	Unknown		30-Oct-2009	02-Nov-2009	MI	200904440	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)	SANOFI PASTEUR	NULL		Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaphylactic shock, Immediate post-injection reaction

**Symptom Text:** Initial report received on 21 October 2009 from a consumer's son. A male patient (age and date of birth not reported) had received an injection of H1N1 2009 Monovalent Vaccine - Preservative (lot number, route and site not reported) on 21 October 2009 and immediately after vaccination, the patient went into anaphylactic shock. The patient was not allergic to eggs and he had previously received influenza vaccine annually with no complications. On 21 October 2009, immediately after receiving the vaccine, the patient went into anaphylactic shock. The patient, who was also a physician, had been in his clinic at the time of the event. The patient yelled for an EpiPen and asked his nurse to call 911. He was admitted to the emergency room and additional Epi-Pen doses were needed to fully recover after several hours. No additional information was provided at the time of the report. Documents held by sender: None.

**Other Meds:**

**Lab Data:** Not reported

**History:** The patient was not allergic to eggs. The patient also received influenza vaccine annually with no complications.

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364008-1

<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>
4.0	F	28-Oct-2009	28-Oct-2009	0	30-Oct-2009	02-Nov-2009	NJ		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	NULL		Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Headache, Pyrexia, Vomiting

**Symptom Text:** vomiting, fever, cough, headache

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364010-1

<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>
4.0	F	26-Oct-2009	28-Oct-2009	2	30-Oct-2009	02-Nov-2009	UT		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		NULL		Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Malaise, Pyrexia

**Symptom Text:** Fever 102-103, fatigue and general malaise for three days and counting.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364012-1

<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>
53.0	F	27-Oct-2009	27-Oct-2009	0	30-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>
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash pruritic

**Symptom Text:** Started itching on arms and neck with a fine rash under skin at 4:30 pm and this continued 10/28/09 but was worse at night. It continued to itch 10/29/09 and is starting to subside today 10/30/09. Physician was seen and she was prescribed Benadryl-she states that this has helped.

**Other Meds:**

**Lab Data:** none

**History:** high blood pressure and high cholesterol history of A. FIB. MI 8 years ago

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364015-1

<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>
3.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-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)	SANOFI PASTEUR		UP010AA	0	Left leg	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pyrexia, Vomiting

**Symptom Text:** fever 101 degrees 3 hours after vaccine, 103 degrees following AM and Child vomited x 1

**Other Meds:** Ibuprofen was given for fever.

**Lab Data:** Rapid Flu test was negative for Type A & B flu.

**History:**

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364021-1

<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>
8.0	M	27-Oct-2009	28-Oct-2009	1	30-Oct-2009	02-Nov-2009	VT		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)	SANOFI PASTEUR		UP010AA	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Pyrexia

**Symptom Text:** Teacher noted fatigue in the AM. Fever checked at noon--103.3. Student was sent home with family for rest and care. MD notified and VDH called to inquire if this report was required. They advised "Yes."

**Other Meds:** Student takes no medication, to my knowledge. I am unaware if the student had any other vaccines within 4 weeks. I have not notified the family of this report. I have notified the MD.

**Lab Data:** At time of report I believe the student is at home resting and recovering and will be returning to school on Monday.

**History:** N/A

**Prex Illness:** Did not appear to be ill.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364026-1

<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>
22.0	F	27-Oct-2009	28-Oct-2009	1	30-Oct-2009	02-Nov-2009	IL		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)	NOVARTIS VACCINES AND DIAGNOSTICS	100739	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Cough, Oropharyngeal pain, Pain, Pyrexia

**Symptom Text:** slight fever, coughing, sore throat, soreness/body aches (went to see doctor to get medicine)

**Other Meds:**

**Lab Data:**

**History:** asthma

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364027-1

<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	19-Oct-2009	21-Oct-2009	2	30-Oct-2009	02-Nov-2009	WI		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)	SANOFI PASTEUR		UP002AA	0	Left arm	Intramuscular		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Paraesthesia, Sensation of heaviness, Sleep disorder

**Symptom Text:** Left arm (injection given in left arm) "fell asleep" the night after injection. Arm felt heavy all day. Began to feel heaviness in left leg by the next day. Entire left side of body "feels as if it is heavy or under water". Symptoms decrease but do not go away during the day. Very bothersome at night and affect sleeping.

**Other Meds:**

**Lab Data:** CT scan, MRI, Neurologist consult

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364028-1

<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>
64.0	F	28-Oct-2009	28-Oct-2009	0	30-Oct-2009	02-Nov-2009	KS		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)	SANOFI PASTEUR	UP005AA	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Full body rash

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364029-1

<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>
14.0	M	20-Oct-2009	21-Oct-2009	1	30-Oct-2009	02-Nov-2009	--		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	UP005AA	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Child woke up at 2330 with hives and itching. Hives mostly on arms and sides. Benadryl was given. Taken to the ED and given Decadron and Benadryl. Improvement noted on 10/23/2009.

**Other Meds:** unknown

**Lab Data:** None

**History:** Asthma

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364052-1

<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>
49.0	F	26-Oct-2009	26-Oct-2009	0	30-Oct-2009	02-Nov-2009	IL		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	NULL		Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Pruritus generalised, Urticaria

**Symptom Text:** Hives, itchy-started from abdomen and spread all over the body next day. I took BENADRYL @ 8 PM 10/26/09. Symptoms worse 10/27/09.

**Other Meds:**

**Lab Data:**

**History:** Hypertension

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364053-1

<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>
58.0	M	23-Oct-2009	24-Oct-2009	1	30-Oct-2009	02-Nov-2009	IN		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	NULL	0	Left arm	Unknown	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Pt. states rec. vaccine early morning of 10-23-09 and began having dizziness lasting about 15 minutes. These symptoms occurred daily off and on for about 5 days. No symptoms since 10/28/09.

**Other Meds:** AVANDIA; DIOVAN; EFFEXOR; ASA; GLUCOTROL; CLARITIN; fish oil

**Lab Data:** None

**History:** Seasonal allergies; diabetes; hypertension

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364055-1

<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>
32.0	F	26-Oct-2009	26-Oct-2009	0	30-Oct-2009	02-Nov-2009	MT		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)	SANOFI PASTEUR	UP001AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site pruritus, Paraesthesia

**Symptom Text:** Reports approximately twenty minutes after vaccination right arm below injection site to fingers, numbness, tingling noted. Approx. at noon injection site "itchy". Approx at 3:26 PM right pinky finger numb.

**Other Meds:**

**Lab Data:** None performed

**History:** Allergies: sulfa; medical condition: asthma

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364056-1

<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>
57.0	F	22-Oct-2009	23-Oct-2009	1	30-Oct-2009	02-Nov-2009	WA		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)	SANOFI PASTEUR	UP008AA	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Back pain, Headache, Neurological symptom, Paraesthesia, Tremor

**Symptom Text:** Received vaccine 10-22 7 AM. Friday eve developed neurologic symptoms from neck down-tingling in all parts of body, aching from neck down back, mild headache, shakiness.

**Other Meds:**

**Lab Data:** Cervical MRI-10-27-09-negative; CRP; C3; C4; B12; METHYMALONIC ACID; UA

**History:** Sjogrens

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364058-1

<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>
3.0	F	27-Oct-2009	27-Oct-2009	0	30-Oct-2009	02-Nov-2009	IA		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)	SANOFI PASTEUR	UP010AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Vomiting

**Symptom Text:** Vomited after injection.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364059-1

<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>
3.0	F	27-Oct-2009	27-Oct-2009	0	30-Oct-2009	02-Nov-2009	IA		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)	SANOFI PASTEUR	UP010AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain in extremity, Pallor, Somnolence

**Symptom Text:** Became pale, very sleepy, c/o legs hurting.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364060-1

<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>
1.8	M	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-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)	SANOFI PASTEUR	UP010AA	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Patient was given swine flu vaccine on 10/29/09 at approx. 2:00 PM. He started with a rash from head to toe the same day at approx 6:00 PM. Rash is not bothering him and no treatment required.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364062-1

<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>
34.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash macular, Urticaria

**Symptom Text:** Hives, itching, skin blotches 10/29/09 at 04:30. BENADRYL relieved symptoms.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364063-1

<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>
1.1	M	29-Oct-2009	30-Oct-2009	1	30-Oct-2009	02-Nov-2009	IN		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)	UNKNOWN MANUFACTURER		NULL		Unknown	Unknown	FLU	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Condition aggravated, Cough, Dyskinesia, Febrile convulsion, Gaze palsy, Irritability, Pyrexia, Rhinorrhoea, Salivary hypersecretion, Tonic clonic movements

**Symptom Text:** 10/30/09 he started with very mild coughing and runny nose. Yesterday his temperature was 99-99.5. He had no vomiting or diarrhea. He received H1N1 vaccine yesterday morning at health department. He had fever of 102-102.5 degrees F yesterday after the vaccine. Parents report he was cranky and fussy. He was brought to our office today. His temperature was 100.4 when he was checked in. While walking in the room, mom noticed the baby having jerky movements of the body and screamed for the doctor. When I went in he was having tonic clonic movements of the extremities and uprolling of eyeballs and salivation in the mouth. Episode lasted less than a minute. His temperature at that time was 100.8. SO2 96-97.1 on room air. He was given dose of TYLENOL in the office. He was discharged home after discussing about febrile seizures and instructions.

**Other Meds:** TYLENOL

**Lab Data:** None

**History:** None

**Prex Illness:** Very mild coughing and runny nose

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364065-1

<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>
0.8	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	IN		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	APUT014AA	0	Right leg	Unknown	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Muscle twitching

**Symptom Text:** Arms and Legs Started twitching. Nothing rhythmic, not constant, not seizure like activity, no pattern. Just occasional twitches that lasted on and off from about 7:30 pm until around noon on 10/30/2009. symptoms went away as of now

**Other Meds:** Daily medicines: Phenobarbital - 5 ml twice daily, xopenex - 1 vial daily, and pulmicort - 1 vial daily

**Lab Data:**

**History:** Has asthma and permanent lung damage and history of seizures

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364066-1

<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>
59.0	M	19-Oct-2009	20-Oct-2009	1	30-Oct-2009	02-Nov-2009	IL		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)	SANOFI PASTEUR	UP001AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pain in extremity

**Symptom Text:** developed severe pain in the left mid foot, plantar aspect for 36 hours, it moved to the right foot for 48 hours, and then returned to the left foot heel and metatarsal area. All this started within 36 hours of injection. It is still present but tolerable.

**Other Meds:** Altace, ASAS, Bystolic, Crestor, MVI

**Lab Data:** N/A

**History:** Hypertension, mildly elevated LFT's, Hyperlipidemia

**Prex Illness:** not known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364067-1

<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>
53.0	F	28-Oct-2009	29-Oct-2009	1	30-Oct-2009	02-Nov-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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Nausea

**Symptom Text:** nausea, followed by one bout of diarrhea and mild nausea throughout the AM

**Other Meds:** Nexium, celebrex, plaquenil, timoptic and alphagan drops

**Lab Data:** none

**History:** mixed connective tissue disease, arthritis, glaucoma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364069-1

<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>
21.0	F	27-Oct-2009	27-Oct-2009	0	30-Oct-2009	02-Nov-2009	NY		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)	SANOFI PASTEUR	500779P	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyspnoea, Throat tightness

**Symptom Text:** Patient states that felt like throat was closing and had difficulty breathing, went to Mercy Ambulatory Care Center where she was given IV Benadryl and Steriods

**Other Meds:** none

**Lab Data:** patient had an episode of throat tightness and facial swelling and difficulty breathing, 48 hours after immunization of the H1N1 but patient had no visible signs of distress, patient requested that the report be filed

**History:** had a previous reaction to the Menactra vaccine but failed to inform the staff which were administering the vaccine.

**Prex Illness:** no illness at time of vaccine, patient had previous allergic reaction to Menactra but did not inform the clinic.

**Prex Vax Illns:** throat swelling~Meningococcal (Menactra)~1~18.00~Patient



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364078-1

<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>
3.0	M	28-Oct-2009	28-Oct-2009	0	30-Oct-2009	02-Nov-2009	AL	AL0925	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)	SANOFI PASTEUR	UP003AA	0	Left leg	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Crying, Decreased appetite, Hypoaesthesia, Injected limb mobility decreased, Injection site pain, Irritability, Myalgia, Pallor

**Symptom Text:** Mother reportd that the child had woke up from his nap after lunch on 10/28/09 crying, complaining of pain in his leg where shot was given. He was pale, extreme irritability, lack of appetite. Later, stated his leg don't work. No fever, mother informed muscle ache is S/E. 10/30/09 mother stated child much better today.

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364079-1

<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	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	MA		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)	SANOFI PASTEUR	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Gait disturbance, Headache, Pain in extremity, Pyrexia, Vomiting

**Symptom Text:** She began with headache, fever and vomiting which then progressed and included BL gastrocnemius pain, making it difficult for her to walk. Patient went to ED, was given IVF and, by today, symptoms resolved.

**Other Meds:**

**Lab Data:**

**History:** anemia

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364081-1

<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>
59.0	M	29-Oct-2009	30-Oct-2009	1	30-Oct-2009	02-Nov-2009	FL		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	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash, Urticaria

**Symptom Text:** HIVES/RASH AROUND BOTH ANKLES

**Other Meds:**

**Lab Data:** NONE

**History:** CORONARY ARTERY DISEASE - HYPERTENSION - MILD COPD

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364088-1

<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>
33.0	F	30-Oct-2009	30-Oct-2009	0	30-Oct-2009	02-Nov-2009	SC		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)	SANOFI PASTEUR		UP008AA	0	Right arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Aura, Drug exposure during pregnancy, Headache, Vision blurred, Visual impairment

**Symptom Text:** At 12:30pm, pt reported blurred vision and aura/black spot around objects. Vision changes followed by headache from 1:00-1:30. By 2pm all symptoms resolved.

**Other Meds:**

**Lab Data:**

**History:** Pregant. 9 wks gestation

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364089-1

<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>
45.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	GA		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)	SANOFI PASTEUR	UP003AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Lip swelling, Pruritus

**Symptom Text:** SWELLING OF LIPS . BILATERAL ARM ITCHING. TOOK OTC BENADRYL AT HOME. LIP SWELLING DECREASED BY OFFICE VISIT 10/30/2009.

**Other Meds:**

**Lab Data:**

**History:** HYPERTENSION ANEMIA

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364090-1

<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>
2.0	M	22-Oct-2009	23-Oct-2009	1	30-Oct-2009	02-Nov-2009	IL		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)	SANOFI PASTEUR		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Dyspnoea, Rhinorrhoea, Vomiting

**Symptom Text:** Friday 10/23/09: developed cough and runny nose. 10/24/09 began vomiting. 10/25/09 temperature of 105.2 degrees fahrenheit. Difficulty breathing. Went to the ER. Monday 10/26 followed up with pediatrician.

**Other Meds:** Zyrtec

**Lab Data:**

**History:** Allergies-Peanut, Cashew, Tree Spores, Canine, Feline Reactive airway disease

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364097-1 (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>
13.0	M	27-Oct-2009	29-Oct-2009	2	30-Oct-2009	02-Nov-2009	CA		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	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3211AA		Left arm	Intramuscular	

**Seriousness:** EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

**MedDRA PT** CSF glucose normal, CSF monocyte count increased, CSF polymorphonuclear cell count increased, CSF protein increased, CSF white blood cell count increased, Computerised tomogram normal, Gram stain negative, Headache, Meningitis aseptic, Red blood cells CSF positive

**Symptom Text:** sudden onset severe headache; head CT neg LP;190 wbc; 5 rbc 16% PMN 84% mono; gram stain neg gluc 63 protein 47 diagnosed with aseptic meningitis

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364099-1

<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>
2.0	M	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	CA		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	MEDIMMUNE VACCINES, INC.	500697P		Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP002AA		Unknown	Intramuscular	
	HIBV	MERCK & CO. INC.	1437U		Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash generalised, Urticaria

**Symptom Text:** urticarial rash on the face later the body after the immunization of seasonal flumist, H1N1 flushot and Hib

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364101-1

<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>
31.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Eye pruritus, Pruritus, Rash

**Symptom Text:** about 2 hours after receiving the shot at work, I started to get itchy on my chest and eyes. Then when I woke up on the 30th, I had a rash on my chest and my eyes were itchy still....I started taking Benadryl, but nothing has changed yet.

**Other Meds:** Not sure of any of these questions

**Lab Data:**

**History:** peanuts and compazine

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364103-1

<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>
51.0	F	15-Oct-2009	16-Oct-2009	1	30-Oct-2009	02-Nov-2009	FL		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	NULL	0	Left arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Heart rate increased, Palpitations

**Symptom Text:** HEART PALPITATION (FAST HEART RATE) LASTING ABOUT 3 TO 5 MINUTES; STOPPED AFTER I LAID DOWN. THEN ON 10/28/09 APPROX. 10:00 AM EXPERIENCED HEART PALPITATIONS (FAST HEART RATE) AGAIN REQUIRING EMERGENCY ROOM BECAUSE IT LASTED MORE THAN 20 MINUTES.

**Other Meds:** NORVASC 10 MG. LIPITOR 10 MG. I DO NOT KNOW THE MANUFACTURER OF THE H1N1 VACCINE NOR THE SEASONAL FLU VACCINE, CHECK WITH THE DR.S OFFICE.

**Lab Data:** PENDING FOLLOW UP APPOINTMENT WITH CARDIOLOGIST 11/12/2009.

**History:** allergic to keflex; diagnosed with high blood pressure; excema

**Prex Illness:** some sinus congestion

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364104-1

<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>
49.0	F	24-Oct-2009	25-Oct-2009	1	30-Oct-2009	02-Nov-2009	IL		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	NULL		Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Nausea, Neck pain, Tinnitus

**Symptom Text:** headache, neckache, ringing in ears. Also a little nausea. Headache & neckache continued for 2 days and subsided in the afternoon of 10/ 27/2009. Ringing in the ears is still ongoing today.

**Other Meds:** none

**Lab Data:** Ringing in the ears is still occurring.

**History:** asthma

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364106-1

<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>
42.0	M	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	IL		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)	CSL LIMITED	UP005 AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Ear pain, Eye pain, Feeling cold, Headache, Oropharyngeal pain, Pain, Pyrexia, Tremor

**Symptom Text:** First I felt so cold, fever and I was shaking alot, body pain and pain in my ears, eyes, forehead and in my throat. I have one day with this sintoms by now.

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364109-1

<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>
15.0	F	30-Oct-2009	30-Oct-2009	0	30-Oct-2009	02-Nov-2009	TN		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	UP018AA		Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** numbness in the arm administered in a dermatomal pattern

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364110-1

<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>
1.3	F	27-Oct-2009	27-Oct-2009	0	30-Oct-2009	02-Nov-2009	AZ		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>
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypophagia, Lethargy, Pyrexia, Somnolence

**Symptom Text:** Baby got low grade fever. Gave motrin fever went down to 100.1, baby stopped eating. Went to daycare that am fever was 99.1 and was fine playing and eating. Call from daycare at 10:19 am that child was febrile and lethargic, not eating or playing. Picked her up and called Dr. Lim who advised me to take her temp and bring her in right away. Temp in right ear was 102.1, in left 101.9. Dr. Lim prescribed Tamiflu and she was very sleepy and lethargic until about 7 pm on 10/28.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No, she was taken to the Dr. to receive MMR/TDAP vaccine.

**Prex Vax Illns:** Fever, lethargy~Influenza (H1N1) (Influenza (H1N1) (Influenza A (H1N1) 2009 Monovalent))~1.33~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364111-1

<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>
27.0	F	22-Oct-2009	22-Oct-2009	0	30-Oct-2009	02-Nov-2009	WA		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	NOVARTIS VACCINES AND DIAGNOSTICS	U3205CA	0	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP005AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyspnoea, Eye swelling, Ocular hyperaemia, Wheezing

**Symptom Text:** Wheezing, short of breath, red swollen eyes

**Other Meds:**

**Lab Data:** Possible allergic reaction. Pt. given both seasonal and H1N1 influenza vaccine at the same time. One dose in each arm. No redness or swelling at injection sites.

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364112-1

<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>
37.0	M	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	FL		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	UP009AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Hypokinesia, Oedema, Oedema peripheral, Pruritus

**Symptom Text:** SWELLING OF HANDS & FEET-HANDS MORE THAN FEET(UNABLE TO FLEX/BEND FINGERS OR MAKE A FIST)& ITCH WAS OVER ENTIRE AREAS OF HANDS & FEET BILATERALLY BUT >est ON PALMS OF HANDS & TOPS OF FEET. 10/30/09 SWELLING LESS-ABLE TO BEND FINGERS BUT ITCH MORE INTENSE & HAND PALMS & KNUCKLES (ALL) EXHIBITED CONFLUENT ERYTHEMA AND EDEMA AS DID TOPS OF FEET,& LUMBAR SACRAL AREA. ANTERIOR THIGHS ALSO "ITCHED" BUT HANDS MORE THAN OTHER AREAS.

**Other Meds:** NONE

**Lab Data:** NONE

**History:** NONE

**Prex Illness:** NO

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364113-1

<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>
1.4	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	CA		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>
	6VAX-F	SANOFI PASTEUR	C3394AA/C3143 AA	0	Left leg	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UPOO6AA	0	Right leg	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342AA	0	Left leg	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	UT3178CA	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abnormal behaviour, Convulsion, Cyanosis, Gaze palsy, Hypotonia, Immunisation reaction, Respiratory arrest

**Symptom Text:** Per childs Mother,childs behavior was odd,then sudden onset of child turning blue and not breathing,eyes rolled back in head,then child became limp.She came to on her own, the entire event lasted 2-3 mins.No further medical care was sought at the time. Mother called this office this AM and discussed this w Dr Wade who belives this is a minor reaction to a vaccine as it may have been a seizure. Child is now back to baseline.

**Other Meds:**

**Lab Data:** none

**History:** none

**Prex Illness:** none noted

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364115-1

<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>
40.0	F	29-Oct-2009	30-Oct-2009	1	30-Oct-2009	02-Nov-2009	MI		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)	SANOFI PASTEUR	UPOO8AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Nausea

**Symptom Text:** stomach pain, nausea.

**Other Meds:**

**Lab Data:**

**History:** lupus

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364117-1

<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>
20.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	02-Nov-2009	CA		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)	NOVARTIS VACCINES AND DIAGNOSTICS	10073801 A	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Heart rate increased

**Symptom Text:** Trouble breathing, high heart rate.and dizziness.

**Other Meds:** none

**Lab Data:**

**History:** SMA-spinal muscular atrophy.

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364118-1

<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>
39.0	F	19-Oct-2009	20-Oct-2009	1	30-Oct-2009	02-Nov-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)	UNKNOWN MANUFACTURER		NULL	1	Right arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Burning sensation, Herpes zoster, Paraesthesia, Rash

**Symptom Text:** felt a tingling burning sensation in the middle of the night around the bottom of my breast and around my back, a few days later I had a rash. I'm going to go to the Dr. Monday. I think the shot broke down my immune system, while I was stressed out over something and therefore caused me to have the Shingles. I've been stressed out on and off all my life so far and been on Zoloft for 10 years and have never had Shingles.

**Other Meds:** Zoloft 50 mg

**Lab Data:**

**History:** I currently take Zoloft and have taken it for 10 years

**Prex Illness:** I got Shingles from this vaccination and I'm only 39. I felt a burning, tinkling sensation beneath my breast and around my back

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364119-1

<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>
11.0	M	30-Sep-2009	30-Sep-2009	0	30-Oct-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	1008133P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Pruritus, Urticaria

**Symptom Text:** Hives from head to ankles. Itching. Reddness. Benadryl 25mg po. No other signs or symptoms. Resolving, may need to administer a second dose or seek family doctor if unresolved. Monitoring closely.

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364120-1

<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>
6.0	M	21-Oct-2009	22-Oct-2009	1	30-Oct-2009	03-Nov-2009	FL	FL	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)	UNKNOWN MANUFACTURER		NULL	0	Unknown	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Diarrhoea, Influenza, Pyrexia

**Symptom Text:** Diarrhea began the following day (Thursday) with a slight fever of 99.3 and continued on through Friday with the fever slightly escalating. By Saturday morning diarrhea had stopped but fever got to heights of 103.8 - 104.2. Returned to the doctors office on Sunday 10/25/2009 because could not get fever to stay down for more than three hours at a time. Was prescribed Tamiflu for five days and instructed to alternate between Tylenol and Advil to regulate fever. Three days later both my 13 yr old daughter and I were diagnosed with the Flu and had to be treated with Tamiflu as well.

**Other Meds:**

**Lab Data:** Had inside of nose swabbed for flu testing and tested positive.

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364128-1

<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>
22.0	F	29-Oct-2009	29-Oct-2009	0	30-Oct-2009	03-Nov-2009	CA		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	10073801 A	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Heart rate increased, Myalgia, Nausea

**Symptom Text:** Severe headache , muscle aches , nausea , dizziness , and fast heart rate.

**Other Meds:** none

**Lab Data:**

**History:** SMA-Spinal Muscular Atrophy

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364129-1

<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>
23.0	F	28-Oct-2009	28-Oct-2009	0	30-Oct-2009	03-Nov-2009	VA		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)	UNKNOWN MANUFACTURER	UPO18AA	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain, Crying, Fear

**Symptom Text:** crying complaining of abdominal pain and cramps fear

**Other Meds:** keppra topiramate sprinkles lantus and novolog insulin claritan singulairre sprintek

**Lab Data:** urinalysis blood work

**History:** cerebral palsy polymicrogyrea diabetes latex avelox suprax strawberries augmentin

**Prex Illness:** mild conjunctivitis pneumonia two weeks ago probably over it allergic reaction Augmentin recent

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364130-1

<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>
6.0	M	29-Oct-2009	30-Oct-2009	1	30-Oct-2009	03-Nov-2009	OH		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Oropharyngeal pain, Pain, Vomiting

**Symptom Text:** 102 Temp, coughing, sore throat, vomitting. He also appears to be in pain when he is awake.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364131-1

<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>
30.0	F	29-Oct-2009	30-Oct-2009	1	31-Oct-2009	02-Nov-2009	WI		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	NULL	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Diarrhoea, Headache, Nausea, Vomiting

**Symptom Text:** 4:30 AM Vomiting, Stomach Cramps, Nausea 5:30 AM Vomiting, Stomach Cramps, Nausea, Diarrhea 12:00 PM Pepto Bismol (524mg bismuth subsalicylate) 15:00 PM Woke-up with nausea, headache, diarrhea which continued off and on for the rest of the day. 600 mg ibuprophen taken. 23:30 PM Ibuprophen 600 mg and Imodium (loperamide HCl 4 mg) taken

**Other Meds:**

**Lab Data:** Influenza screen test with BINAXNOW testing kit performed 10/30/2009 19:00 results NEGATIVE

**History:** Unmedicated Type2 Diabetes, controlled by diet Allergies to: Naprosen (Upset stomach) Amoxicillan (Rash on trunk)

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364133-1

<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>
57.0	F	26-Oct-2009	26-Oct-2009	0	31-Oct-2009	02-Nov-2009	WA		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	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Erythema, Flushing, Pain

**Symptom Text:** Intense, extremely painful, red flushing starting at head & face, down to toes. Dizziness along with it. No sweating, no hives, no itching, no breathing problems. Felt like passing out. After about 10 min husb. called 911. Vitals ok, though they didn't check temp. I took Benadryl & symptoms quickly resolved, though face was reddish about 24 hours & had 1 minor flushing next day. I had NEVER experienced anything like this. These were NOT hot flashes.

**Other Meds:** calcium, b12, lexapro

**Lab Data:** none, paramedics checked vitals.

**History:** no drug allergies, some enviornmental ones--mold,dander

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364134-1

<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>
58.0	F	29-Oct-2009	29-Oct-2009	0	31-Oct-2009	02-Nov-2009	WA		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	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Migraine, Nausea

**Symptom Text:** Extreme migrain headache. Blood pressure spiked very high. Nausea.

**Other Meds:**

**Lab Data:**

**History:** Diabetes; heart disease

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364136-1

<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>
44.0	F	30-Oct-2009	31-Oct-2009	1	31-Oct-2009	02-Nov-2009	WI		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	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Uvulitis

**Symptom Text:** Uvulitis

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364139-1

<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>
31.0	F	20-Oct-2009	24-Oct-2009	4	31-Oct-2009	02-Nov-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	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** Rash on arms hands neck and mouth

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364140-1

<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>
33.0	F	30-Oct-2009	31-Oct-2009	1	31-Oct-2009	02-Nov-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	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Musculoskeletal stiffness, Oropharyngeal pain, Pain

**Symptom Text:** Sore throat, Severe neck and back stiffness. Overall soreness.

**Other Meds:** Ibuprophen for pain

**Lab Data:**

**History:** Sulfa

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364141-1

<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	20-Oct-2009	28-Oct-2009	8	31-Oct-2009	02-Nov-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		NULL		Unknown	Unknown	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea

**Symptom Text:** diarrhia lasting several days still continues

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364144-1

<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>
40.0	F	30-Oct-2009	30-Oct-2009	0	31-Oct-2009	02-Nov-2009	MI		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	NULL	0	Left leg	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort

**Symptom Text:** Chest tightness-Went to emergency room department and was given an albuterol nmt and 60 mg of prednisone,

**Other Meds:** Pamelor, Lyrica, Allegra, Albuterol, Singulair, Combi-Patch, Cardura, Antivert, Protonix

**Lab Data:**

**History:** Latex, PCN, Clindamycin, Erythromycin-Allergies Asthma-Medical Condition

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364145-1

<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>
7.0	M	27-Oct-2009	29-Oct-2009	2	31-Oct-2009	02-Nov-2009	CA		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	NULL	0	Unknown	Unknown	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Cough, Pyrexia, Vomiting

**Symptom Text:** Fever, Chills, vomitting, cough.

**Other Meds:**

**Lab Data:** tested + Infuleza A

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364146-1

<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>
53.0	F	29-Oct-2009	29-Oct-2009	0	31-Oct-2009	02-Nov-2009	NV		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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Eye irritation, Eye pain, Headache, Nasal congestion, Nasopharyngitis, Nausea, Oral disorder

**Symptom Text:** The evening of my shot I felt like I was getting a cold. Nose stuffed, chills,etc., but when I woke up, I felt nauseated and felt two lard lumps beneath my tongue, not PART of the tongue, but a short space from the bottom gumline. I could feel it with my tongue and also see it in the mirror. Still don't know what this is. I ate a banana and again feel nauseated and my eyes are hurting...like burning and headache as well.

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364147-1

<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>
37.0	F	29-Oct-2009	30-Oct-2009	1	31-Oct-2009	02-Nov-2009	UT		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)	SANOFI PASTEUR	NULL	0	Right arm	Unknown	
	DTAP	SANOFI PASTEUR	NULL		Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Neuralgia, Oedema peripheral, Paraesthesia

**Symptom Text:** pain, erythema, extensive limb swelling, ulnar nerve pain with left pinky tingling (pt is anesthesiologist and describes pain as neuropathic)

**Other Meds:** Prilosec prn, Motrin 800 mg q6hrs for pain related to injection

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364148-1

<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>
39.0	F	29-Oct-2009	29-Oct-2009	0	31-Oct-2009	02-Nov-2009	FL		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	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia

**Symptom Text:** I now have numbness in my fingertips. It is bad in 3 fingers. Still there after 2 days

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364150-1

<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	21-Oct-2009	22-Oct-2009	1	31-Oct-2009	02-Nov-2009	GA		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	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Headache, Lymphadenopathy, Pain, Pharyngitis streptococcal, Pyrexia

**Symptom Text:** enlarged lymph nodes, body aches, chills, fever, & headache. Strep throat

**Other Meds:**

**Lab Data:** Strep test performed - positive result

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364159-1

<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>
54.0	M	31-Oct-2009	31-Oct-2009	0	31-Oct-2009	02-Nov-2009	WA		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)	SANOFI PASTEUR	UP005AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased

**Symptom Text:** Fever of approx 99-100 for approx 1 hr

**Other Meds:** Metformin 1000 Levothroxine 150 Lisinopril 20 Lipitor 10 Lantus & Humalog Insulins 70 & 20

**Lab Data:**

**History:** Prostate Cancer - Treated / Remission

**Prex Illness:** Diabetic

**Prex Vax Illns:** ~ ()~~0.00~

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364160-1

<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>
46.0	M	16-Oct-2009	Unknown		31-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>		
	FLU(H1N1)	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Injection site anaesthesia, Injection site pain

**Symptom Text:** I have noticed that the arm that I received the H1N1 vaccine in has begun to ache and be numb. Numbness from shoulder down to finger tips. This has gone on for several days....

**Other Meds:** Niaspan, Lovaza, Aspirin, Multi Vitamin, Hdrochlorothiazide, Simvastatin

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364168-1

<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	31-Oct-2009	31-Oct-2009	0	31-Oct-2009	02-Nov-2009	WA		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)	SANOFI PASTEUR	UP005AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Feeling hot, Presyncope

**Symptom Text:** Near Syncope Warm Dizzy

**Other Meds:**

**Lab Data:**

**History:** Heart Disease Fibromyalgia

**Prex Illness:** No Known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364172-1

<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>
9.0	M	20-Oct-2009	23-Oct-2009	3	31-Oct-2009	02-Nov-2009	UT		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	NULL	0	Gluteous maxima	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Pyrexia

**Symptom Text:** fever, fatigue

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364173-1

<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>
46.0	F	29-Oct-2009	30-Oct-2009	1	31-Oct-2009	02-Nov-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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal discomfort, Asthenia, Back pain, Dizziness, Injection site pain, Pain, Vomiting

**Symptom Text:** extreme pain in injection arm so strong,from my upper back, and down to my thumb, I almost passed out, and it would not let up, I put heat on it for 8 hours and took tyloil, I became sick to my stomach, and throw up all the way home in my car, the next day I was total wiped out, and today 10/31/09, I feel like fainting all day, and I am weak allday.

**Other Meds:**

**Lab Data:**

**History:** allergies, high blood pressure, and diabetes

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364176-1

<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>
28.0	F	29-Oct-2009	31-Oct-2009	2	31-Oct-2009	02-Nov-2009	CA		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	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Myalgia, Oropharyngeal pain

**Symptom Text:** sore throat, muscle aches, headache

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364177-1

<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	F	30-Oct-2009	31-Oct-2009	1	31-Oct-2009	02-Nov-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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Fever 101.8 without antipyretics, 10/31/2009 10:15 PM fever of 102.8 without tylenol/advil

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364178-1

<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>
24.0	F	30-Oct-2009	30-Oct-2009	0	31-Oct-2009	02-Nov-2009	FR		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	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Dizziness, Paraesthesia

**Symptom Text:** Dizziness/weakness Tingling to fingers

**Other Meds:**

**Lab Data:**

**History:** Grass/dust allergy

**Prex Illness:** common cold

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364179-1

<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	F	31-Oct-2009	31-Oct-2009	0	31-Oct-2009	02-Nov-2009	IN		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	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cold sweat, Diarrhoea, Pallor, Somnolence, Vomiting

**Symptom Text:** Initial vomiting, twice, then very pale and diarrhea following about three times. Very sleepy. Clamy, no fever. Went back to bed around 11:15, no symptoms so far since going to back to bed.

**Other Meds:**

**Lab Data:**

**History:** N/A

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364181-1

<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>
30.0	F	17-Oct-2009	18-Oct-2009	1	01-Nov-2009	02-Nov-2009	DE		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	NULL		Right arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal discomfort, Arthralgia, Headache, Malaise, Myalgia, Pyrexia

**Symptom Text:** fever (100/F), severe arthralgia, myalgia, malaise, mild stomach distress, headache. fever lasted ~ 16 hours. other symptoms ~ 20 hours. malaise 2 days. no one in house sick (including 2 1/2 year old), no coworkers sick.

**Other Meds:**

**Lab Data:**

**History:** migraines, pcos, seasonal/environmental allergies, raynauds, ibs, spina bifida oculata,

**Prex Illness:** no

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364182-1

<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>
59.0	F	30-Oct-2009	31-Oct-2009	1	01-Nov-2009	02-Nov-2009	MI		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)	NOVARTIS VACCINES AND DIAGNOSTICS	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Anosmia, Nasal congestion

**Symptom Text:** I have not been able to smell . I first became aware of this on the morning of 10/31/2009. My nasal passges became completely clogged the evening of the vaccination. I have no smell sensation. This could potentially be a vary dangerous conditon as many life threatening conditons can be detected through the sense of smell.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364183-1

<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>
57.0	F	29-Oct-2009	30-Oct-2009	1	01-Nov-2009	02-Nov-2009	FR		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	SANOFI PASTEUR	E7024		Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP06AA		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site swelling

**Symptom Text:** SEWELLING AT BOTH INJECTION SITES

**Other Meds:** NONE

**Lab Data:** CBC

**History:** NONE

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364186-1

<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>
57.0	F	30-Oct-2009	30-Oct-2009	0	01-Nov-2009	02-Nov-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)	SANOFI PASTEUR	UPOLO		Unknown	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Asthenia, Diarrhoea, Diet refusal, Headache, Pain, Pyrexia, Vomiting

**Symptom Text:** severe vomiting and uncontrollable diarrhea, stomach pains, body aches, chills, headache, weakness, fever, unable to eat or drink for 12 hours.

**Other Meds:** fosomax, pravastatin sodium 40 mg, fluoxetine 20 mg

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364189-1

<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>
25.0	F	22-Oct-2009	22-Oct-2009	0	01-Nov-2009	02-Nov-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)	SANOFI PASTEUR	NULL	0	Right arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	NULL		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cold sweat, Dyspnoea, Hypoaesthesia facial, Injection site anaesthesia, Injection site reaction, Muscle twitching, Palpitations, Paraesthesia, Paraesthesia oral, Pruritus generalised

**Symptom Text:** Heart racing,sob, tongue felt heavy, face felt numb and tingly, right arm where i received injection was numb tingly and clammy. Started to itch all over, right eye began twitching. Took and antihistamine.

**Other Meds:**

**Lab Data:** None performed. Ws told to report.

**History:** PCOS

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364190-1

<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>
40.0	M	31-Oct-2009	31-Oct-2009	0	01-Nov-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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP012AA		Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Gait disturbance, Headache, Lymphadenopathy, Muscle tightness, Nausea, No reaction on previous exposure to drug, Pain in jaw

**Symptom Text:** With-in 1 hour of shot I developed swelling in glands under each ear. Tightness in neck muscles. jaw pain. About 6 hours after injection had dizziness, mild nausea, headache, and poor motor skills. I was walking as if I was dizzy. No fever. Tylenol had no postive effect. 24 hrs after shot my symptoms have NOT improved. I have had the season flu shot every year for the past 3 yrs wil no bad sice effect at all.

**Other Meds:** None

**Lab Data:** none

**History:** None

**Prex Illness:** No illness

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364192-1

<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>
7.0	M	30-Oct-2009	31-Oct-2009	1	01-Nov-2009	02-Nov-2009	CA		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	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** Fever >102 degrees Children's motrin administered

**Other Meds:**

**Lab Data:**

**History:** seasonal allergies

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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 10:23

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

**Vaers Id:** 364198-1

<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>
41.0	F	28-Oct-2009	28-Oct-2009	0	01-Nov-2009	02-Nov-2009	LA		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)	SANOFI PASTEUR		UP001AA	0	Right arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Nasal congestion, Sinus congestion, Sneezing

**Symptom Text:** sneezing, headache, dizziness, nasal and sinus congestion

**Other Meds:**

**Lab Data:** none

**History:** Keflex, seasonal allergies

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364199-1 (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>
50.0	F	24-Oct-2009	24-Oct-2009	0	01-Nov-2009	02-Nov-2009	CA		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, SERIOUS

**MedDRA PT** Atrial fibrillation, Cardioversion, Heart rate increased, Heart rate irregular, Intensive care

**Symptom Text:** Rapid, irregular heartbeat - atrial fibrillation -continued after getting up in am - heart rate 155 bpm. Visit to urgent care center, referred to Hospital. Medically reduced heart rate, cardio conversion needed to convert back to normal rhythm. Spent 36 hours in ED and CCU units of hospital. Many tests, labs, xrays, electrocardiograms completed to assess heart normalcy.

**Other Meds:**

**Lab Data:** Medically reduced heart rate (IV with medicines added, cardio conversion (under anesthesia) needed to convert back to normal rhythm. Spent 36 hours in ED and CCU units of hospital. Many tests, labs, xrays, electrocardiograms completed to

**History:** asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364202-1

<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>
50.0	F	30-Oct-2009	30-Oct-2009	0	01-Nov-2009	02-Nov-2009	AK		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	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthma, Headache, Nausea, Pain, Vomiting

**Symptom Text:** Asthma attack went to clinic needed nebulizer as inhaler not helping (have not had and attack like this in two years. by 10/31/2009 9am developed severe headache and Nausea and vomiting that lasted til 5pm that night. feel somewhat better on 11/1/2009 just achy all over

**Other Meds:** Climara 0.1 patch zetia 10mg Vit D 50,000 units omega 3 fatty acid capsules b12 1000mg injection albuterol inhaler PRN zantac 150mg zyrtec 10mg

**Lab Data:**

**History:** environmental allergies, sulfa,AVC suppositories, Kefzol,Asthma,Mitral valve prolapse,aortic stenosis,menapausal

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364203-1

<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>
6.0	F	23-Oct-2009	23-Oct-2009	0	01-Nov-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>		
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP003AA	0	Left arm	Intramuscular			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness

**Symptom Text:** Severe dizziness

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364206-1

<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>
37.0	F	27-Oct-2009	27-Oct-2009	0	01-Nov-2009	02-Nov-2009	ID		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	NULL	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Palpitations

**Symptom Text:** Five or six times throughout the day I had a racing heartbeat and once or twice I felt light-headed.

**Other Meds:** Levothyroxine

**Lab Data:**

**History:** Hypo-thyroid, pregnant

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364207-1

<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>
2.0	M	30-Oct-2009	31-Oct-2009	1	01-Nov-2009	02-Nov-2009	AR		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	NULL		Right arm	Unknown	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthma

**Symptom Text:** Asthma attack, inhaler, cold air outside, oral steroid

**Other Meds:** zantac

**Lab Data:**

**History:** asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364209-1

<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>
8.0	F	28-Oct-2009	29-Oct-2009	1	01-Nov-2009	02-Nov-2009	IL		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)	NOVARTIS VACCINES AND DIAGNOSTICS	100739ZP	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Pyrexia, Rash

**Symptom Text:** DEVELOPED A LOW GRADE FEVER AT SCHOOL AND WAS SENT HOME. 10/31/09 STARTED DEVELOPING A RASH ON ARMS LEGS BACK AND TORSO AREAS. PROBABLY ABOUT 20 SPOTS, GIVEN BENEDRYL TO STOP THE REACTION AND THE ITCHING.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364211-1

<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>
10.0	M	31-Oct-2009	31-Oct-2009	0	02-Nov-2009	02-Nov-2009	FL		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)	NOVARTIS VACCINES AND DIAGNOSTICS	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Headache, Lethargy, Muscle spasms, Pyrexia, Vomiting

**Symptom Text:** Severe stomach cramps, headache for 18 hours, lethargic, vomiting, 103.6 fever, muscle spasms in legs

**Other Meds:** Motrin

**Lab Data:** ER did blood work and confirmed symptoms were not being caused by an underlying bacterial infection

**History:** asthma, premature atrial contractions, supraventricular tachycardia, history of seizures

**Prex Illness:** no

**Prex Vax Illns:** 5 min Grand mal seizure. Had seizures and was on medications for 6 years following event~Measles + Mumps + Rubella (no brand name)~1~1.25~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364212-1

<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	F	22-Oct-2009	23-Oct-2009	1	02-Nov-2009	02-Nov-2009	IL		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	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia

**Symptom Text:** started running high fever between 103 and 104 degrees. coughing

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364213-1

<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>
4.0	F	22-Oct-2009	23-Oct-2009	1	02-Nov-2009	02-Nov-2009	IL		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	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia

**Symptom Text:** Running high fever with a cough

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364214-1

<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>
3.0	M	22-Oct-2009	23-Oct-2009	1	02-Nov-2009	02-Nov-2009	IL		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	NULL	0	Right arm	Unknown			

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Pyrexia

**Symptom Text:** Running fever over 104 degrees, coughing

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364217-1

<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>
37.0	F	27-Oct-2009	27-Oct-2009	0	01-Nov-2009	02-Nov-2009	MA		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)	UNKNOWN MANUFACTURER	100813 2P		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Drug exposure during pregnancy, Urticaria

**Symptom Text:** HIVES 11/2/2009 records from OB-GYN MD stating patient called to MD office stating had hives post vaccination, patient took Benadryl and hives cleared.

**Other Meds:**

**Lab Data:** Labs/Xrays none

**History:** PREGNANCY, HEALTHY PMH: pregnant EDC 11/9/2009 Allergies: PCN, ERYTHROMYCIN

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364228-1

<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>
10.0	F	29-Oct-2009	29-Oct-2009	0	02-Nov-2009	03-Nov-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)	SANOFI PASTEUR	UP010AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Nausea, Syncope

**Symptom Text:** Reported feeling nauseous following vaccination and then fainted. Responsive within minutes, cold compress applied to forehead. Remained supine for approx. 30 minutes then returned to classroom.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364232-1

<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>
6.0	F	28-Oct-2009	28-Oct-2009	0	02-Nov-2009	02-Nov-2009	--		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>
	HEPA	MERCK & CO. INC.	0287Y	1	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3263DA	1	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Urticaria, Wheezing

**Symptom Text:** Patient developed hives and wheezing and chest pain. Patient seen in the emergency room and Johns Hopkins and given an Albuterol neb, Benadryl and Zantac

**Other Meds:** Coumadin

**Lab Data:** None

**History:** Patient is on Coumadin for mitral valve replacement. Patient is known asthmatic. Good condition when vaccinated ( well child health assessment)

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364233-1

<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>
9.0	M	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	02-Nov-2009	WV		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)	NOVARTIS VACCINES AND DIAGNOSTICS	10127603	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Fall, Haemorrhage, Loss of consciousness, Pain in extremity, Skin laceration, Tooth injury, Vertigo

**Symptom Text:** Patient left Health Department with mother and sister after receiving Influenza A H1N1 injectable vaccine in left deltoid. Family went to video store to rent movie when patient complained to mother that his arm was hurting. She instructed the child to go sit in the family vehicle, just outside the store. He returned to his mother, inside the store in approximately 30 seconds with complaints of vertigo, and bloodied face, stating he passed out, face first. He was taken to primary care center with facial lacerations and 3 broken teeth.

**Other Meds:** None

**Lab Data:** None

**History:** None

**Prex Illness:** Dry cough, no fever.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364234-1

<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>
50.0	F	28-Oct-2009	29-Oct-2009	1	02-Nov-2009	03-Nov-2009	NC		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	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysphonia, Headache, Pain, Pyrexia

**Symptom Text:** Voice hoarse, body aches, headache, low grade fever. Put pt on a course of LEVAQUIN 500 mg one everyday for seven days.

**Other Meds:**

**Lab Data:** Chest x-ray

**History:** COPD

**Prex Illness:** COPD

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364236-1

<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>
56.0	F	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	MI		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	UP01388		Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Facial paresis, Malaise, Nausea, Paraesthesia

**Symptom Text:** Acute severe malaise, weakness, facial weakness, sl nausea, funny sensation on back of head.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** None

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364237-1

<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>
39.0	M	29-Oct-2009	29-Oct-2009	0	02-Nov-2009	03-Nov-2009	FL		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	UP003AA	0	Left arm	Subcutaneously	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Blood pressure increased, Palpitations

**Symptom Text:** HEART RATE 210, BP 180/120.PALPITATION.WENT TO ER. HR DID NOT GO DOWN UNTIL MIDNIGHT. BP WAS UP 140/110 FOR 2 DAYS.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364251-1

<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>
32.0	F	26-Oct-2009	28-Oct-2009	2	02-Nov-2009	03-Nov-2009	MA		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		UP004AA	0	Left arm	Intramuscular	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Dyspnoea, Ear pain, Influenza, Pain, Respiratory tract congestion, Retching, Sneezing, Wheezing

**Symptom Text:** This 32 yr old female presents with a cough and wheeze. She has some shortness of breath, chills, sneezing, stuffiness and slight ear pain. she is achy as well and gagging from the cough. She has a low grade fever as well. She was diagnosed with H1N1 virus based on a positive rapid influenza swab in the office. She was treated with tamiflu and a proair inhaler.

**Other Meds:** precare premiere prenatal vitamins

**Lab Data:** Rapid influenza test positive for influenza A.

**History:** 8 weeks pregnant

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364252-1

<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>
54.0	F	30-Oct-2009	01-Nov-2009	2	02-Nov-2009	03-Nov-2009	CO		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	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Muscular weakness, Pain in extremity

**Symptom Text:** Right arm became sore, painful and weak

**Other Meds:** Celexa, Nortriptiline, Tramadol

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364253-1

<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>
13.0	M	31-Oct-2009	31-Oct-2009	0	02-Nov-2009	03-Nov-2009	OH	UP013AA	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	UP013AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Cough, Fatigue, Pyrexia

**Symptom Text:** Within 2 hours after shot, coughing, fatigue, 30 hrs later, chills and fever. Treating at home.

**Other Meds:**

**Lab Data:**

**History:** Mild asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364256-1

<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	29-Oct-2009	30-Oct-2009	1	02-Nov-2009	03-Nov-2009	MD		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	UP003AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site urticaria, Pruritus, Urticaria

**Symptom Text:** Hives on arm. Shot was given-on entire arm but more by injection site. They itched-went away in 2 days.

**Other Meds:** SINGULAIR

**Lab Data:**

**History:** Allergic to dust mites

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364265-1

<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>
54.0	M	15-Oct-2009	16-Oct-2009	1	02-Nov-2009	03-Nov-2009	IA		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	UP001AA		Unknown	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Diarrhoea, Muscular weakness, Nausea, Vertigo, Vomiting

**Symptom Text:** Nausea, vomiting for 2 days Diarrhea 3 days Left upper extremity weakness and vertigo that is ongoing

**Other Meds:**

**Lab Data:** Going to Iowa City for hearing test, EMG and MRI

**History:** hypertension

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364275-1

<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>
33.0	M	22-Oct-2009	22-Oct-2009	0	02-Nov-2009	03-Nov-2009	KY		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	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Adverse event, Drug exposure during pregnancy, Erythema, Feeling hot, Heart rate increased, Hypoaesthesia

**Symptom Text:** Adverse event began approximately 2 hours after vaccine was given. Patient stated that her body and face became really hot and red. She also felt that her pulse was racing. She had some numbness on her left side. All had been resolved by the next day.

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** Patient is 7 1/2 months pregnant

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364276-1

<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	M	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	TX		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	UP010AA	0	Right arm	Intramuscular	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Adverse reaction, Dysphonia, Fatigue, Heart rate increased, Malaise, Pruritus generalised, Pyrexia, Urticaria

**Symptom Text:** H1N1 vaccine was administered at 2:15 pm on 10/30/2009 IM in the right deltoid. Injection tolerated well. Patient reported an adverse reaction on 11/2/2009 at 8 am. He noticed a rapid heart beat & fever by about 5 pm on the day of the injection. Slept well. On 10/31/2009 rapid heartbeat subsided and hoarseness in voice noted. Noticed itching, hives over most of body. Used topical Benadryl to no avail and then used OTC Benadryl 25 mg capsules x2 to some avail. General malaise on 10/31/2009. Slept most of the day. On 11/1/2009 felt tired and rested most of the day. Continues to have hoarseness and to itch today, 11/2/2009.

**Other Meds:**

**Lab Data:**

**History:** Allergic to Biaxin.

**Prex Illness:** none

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364277-1

<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>
26.0	F	29-Oct-2009	30-Oct-2009	1	02-Nov-2009	03-Nov-2009	AZ		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site haematoma

**Symptom Text:** Bruising at injection site

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364280-1

<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>
43.0	M	27-Oct-2009	28-Oct-2009	1	02-Nov-2009	03-Nov-2009	VA		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Acoustic stimulation tests, Tinnitus

**Symptom Text:** Sudden onset loud left tinnitus. Still present 5 days later. Hearing test scheduled tomorrow. Likely permanent according to ENT

**Other Meds:**

**Lab Data:**

**History:** Short-fiber sensory neuropathy

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364281-1

<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>
23.0	F	27-Oct-2009	27-Oct-2009	0	02-Nov-2009	03-Nov-2009	IL		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	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Urticaria

**Symptom Text:** Hives on face, neck,abdomen, arms, and feets. Took Benadryl 50mg by mouth. 15 to 20 minutes later hives gone.

**Other Meds:** Rocephin; Penicillin; Erythromycin; Tetracycline; Z-pack; Compazine

**Lab Data:**

**History:** Rocephin--Anaphylactic shock; Penicillin--open sores; Erythromycin--Hives; Tetracycline--Hives; Z-pack--Hives; Compazine--Involuntary twitching, agitated and wheezing.

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364282-1

<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>
52.0	M	29-Oct-2009	31-Oct-2009	2	02-Nov-2009	03-Nov-2009	TX		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	1007392P	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Urticaria

**Symptom Text:** Hives, Itching

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364294-1

<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>
16.0	F	15-Oct-2009	16-Oct-2009	1	02-Nov-2009	03-Nov-2009	AZ		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	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500721P		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal discomfort, Cough, Headache

**Symptom Text:** Coughing at night and off/on during day. Headache is main complaint (off and on). No fever noted. No vomiting currently. Did have "upset" stomach after vaccination.

**Other Meds:** None

**Lab Data:**

**History:** Seasonal allergies

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364299-1

<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>
1.3	M	26-Oct-2009	27-Oct-2009	1	02-Nov-2009	03-Nov-2009	OH		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)	UNKNOWN MANUFACTURER	NULL	0	Left leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Face oedema, Oropharyngeal pain

**Symptom Text:** Facial edema and sorethroat lasted about 24 hours; given Benadryl x 2 which helped transiently; symptoms resolved by 10/28/2009

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364300-1

<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>
66.0	M	29-Oct-2009	31-Oct-2009	2	02-Nov-2009	03-Nov-2009	NJ		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	UP015AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash generalised

**Symptom Text:** Rash over your entire body, started on abdomen to extremities. Not using any different detergent

**Other Meds:** none

**Lab Data:** none

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364326-1

<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>
31.0	F	24-Oct-2009	24-Oct-2009	0	02-Nov-2009	03-Nov-2009	AZ		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		UP006AA		Right arm	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Hypoaesthesia, Muscular weakness, Paraesthesia, Sensory disturbance

**Symptom Text:** Bilateral numbness, sensitivity, tingling, weakness in hands beginning 10 minutes after vaccine-not resolving 4 days post vaccine.

**Other Meds:**

**Lab Data:**

**History:** Polycystic kidney disease; KEFLEX

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364330-1

<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>
2.0	F	27-Oct-2009	Unknown		02-Nov-2009	03-Nov-2009	--		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)	UNKNOWN MANUFACTURER	UP009AA	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Incorrect dose administered

**Symptom Text:** Child here for H1N1 vaccine. .5 ml given IM by mistake. Call to mother. Felt tired yesterday but better today 10/28/09.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364335-1

<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	21-Oct-2009	21-Oct-2009	0	02-Nov-2009	03-Nov-2009	VA		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Rash erythematous

**Symptom Text:** Red rash to chest, back and legs occurred within 24 hours.

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364336-1

<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>
49.0	F	20-Oct-2009	25-Oct-2009	5	02-Nov-2009	03-Nov-2009	OH		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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Back pain, Injected limb mobility decreased, Musculoskeletal pain, Neck pain, Pain in extremity

**Symptom Text:** L arm pain, neck pain, shoulder and L back pain. 1st episode was Sunday evening around 8 PM. Unable to lift arm very painful for 20 mins. 2nd episode Tuesday 1 or 2 AM same pain not as hard but couldn't lift arm. Called on call Dr. was told to see PCP.

**Other Meds:** None at the time

**Lab Data:**

**History:** Sarcoidosis

**Prex Illness:** Sarcoidosis

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364350-1

<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>
27.0	F	15-Oct-2009	15-Oct-2009	0	02-Nov-2009	03-Nov-2009	NY		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	UP003AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Pruritus generalised, Skin warm, Vomiting

**Symptom Text:** Advised after getting first flu vaccine ever to sit and be monitored for 15 min. When told she could leave pt stated that she would stay awhile longer. Few minutes later, stated she was itching all over body. VS at 1:08 PM BP150/100, P 90 reg. BENADRYL 50 mg IM given. Breath sounds clear. 1:17 PM BP 146/98, P 80. Breath sounds clear, no wheezing, pt had small emesis. Pt in NAD=eg was sending and receiving text messages and conversing calmly and coherently. Refused epinephrine. Stated she thought she should go to ER and get SOLU-MEDROL. Transported to ER. Skin warm, dry, no color changes, no urticaria. Pt received BENADRYL 25 mg IM at ER, ZOFRAN 8 mg and SOLU-MEDROL 125 mg. Spoke with pt at 5 PM. Feeling fine.

**Other Meds:** Supplied at no cost

**Lab Data:**

**History:** LEVAQUIN; gentamicin; ampicillin; RELPAX; IMITREX; CELEXA

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364358-1

<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>
7.0	M	19-Oct-2009	21-Oct-2009	2	02-Nov-2009	03-Nov-2009	VA		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia, Rash

**Symptom Text:** Rash to face and trunk. Fever 101 degrees.

**Other Meds:** None

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364421-1

<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>
32.0	F	20-Oct-2009	27-Oct-2009	7	02-Nov-2009	03-Nov-2009	CA		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	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Myalgia, Pruritus

**Symptom Text:** Patient developed muscle aches and severe itching a week after having H1N1 vaccine. Patient has not seen a doctor. Patient has soaked in a tub of cold water for relief of itching.

**Other Meds:** Levothyroxine-0.1 mg-1 daily; CELEXA-20 mg-1 daily

**Lab Data:**

**History:** Thyroids

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364436-1

<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>
29.0	F	26-Oct-2009	28-Oct-2009	2	02-Nov-2009	03-Nov-2009	MS		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	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Burning sensation, Immunisation reaction, Paraesthesia

**Symptom Text:** Pt complained of burning and tingling sensations throughout legs, arms, face. Also complained of weakness upon standing. Went to local physician the next day. Labs were done which were all negative. Physician states it is a reaction to the H1N1 vaccine. No treatment. Pt referred to a neurologist.

**Other Meds:**

**Lab Data:** labs were done. It was reported that they were all normal results. Pt has been referred to a neurologist but that is still in process.

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364438-1

<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>
0.5	M	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	MO		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	UPO1OAA	0	Left leg	Intramuscular	
	FLU	SANOFI PASTEUR	U3261AA	0	Right leg	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Incorrect dose administered

**Symptom Text:** .05ml given to 6 month infant instructed mother and grandmother of the vaccine error. Clent sat in facility for 20min to ensure no complications. Incident occurred at 11:30am on 11/02/2009

**Other Meds:**

**Lab Data:**

**History:** No pre existing illness

**Prex Illness:** No reported illness at time of vaccination

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364439-1

<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>
46.0	M	29-Oct-2009	30-Oct-2009	1	02-Nov-2009	03-Nov-2009	MI		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	UP001AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site papule, Injection site pruritus

**Symptom Text:** 4"x5" Scattered papular eruption, left deltoid (near injection site). Erythematous. Puritic

**Other Meds:** Monopril, Lipitor, Nexium, Ambien

**Lab Data:** None performed as of yet

**History:** Allergy: Isopropyl Alcohol Hx. Bone Marrow Transplant Hypertension Hypercholesterolemia

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364440-1

<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>
7.0	F	27-Oct-2009	27-Oct-2009	0	02-Nov-2009	03-Nov-2009	MO	MO-2009-26	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		Left arm	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Flushing, Rash macular

**Symptom Text:** Child given vaccine at public clinic. No history of previous flu shot. Was sitting in waiting area at the time vaccine was given. Approx 10 minutes later mother reported child had flushed cheeks. 15-20 minutes later blotchy areas observed in back and shoulders. Sent to ER where Dr. gave benadryl. Child recovered.

**Other Meds:** none

**Lab Data:**

**History:** none

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364441-1

<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>
1.9	M	24-Oct-2009	24-Oct-2009	0	02-Nov-2009	03-Nov-2009	MD		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	UPOO4AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Balance disorder, Coordination abnormal, Dysstasia, Epilepsy, Fall

**Symptom Text:** began falling frequently-balance/coordination appeared off and would topple over while walking. Additionally, legs appeared to "buckle" @ knees at times while walking resulting in falling. did not appear to be in pain, did not appear disoriented, was alert, and was not irritable. Is diagnosed w/ epilepsy, however has been seizure free for over 1 1/2 years and no signs/symptoms of seizure activity appeared present during this time period. The symptoms lasted from Saturday afternoon until about 5 PM the next day on Sunday-woke up from a nap Sunday evening, got up and appeared perfectly fine-no longer appeared to be having problems w/ balance/coordination, knees weren't "buckeling" and wasn't falling.

**Other Meds:** Topamax 15 mg sprinkle BID

**Lab Data:**

**History:** epilepsy-seizure free since March 2008 allergic to penicillin recurrent wheezing winter 2008 mild developmental delay

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364442-1

<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>
16.0	M	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	NJ		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	UP006AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Headache

**Symptom Text:** Student reported to School Nurses office C/O dizziness for the previous 1 Hr. C/o headache at 11:50 AM. Dizziness ceased at 12 noon. Stepfather states patient has history of migraines. Patient transported to local ER by stepfather per Dr. instructions.

**Other Meds:**

**Lab Data:**

**History:** Stepfather states patient has Migraines

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364444-1

<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>
13.0	M	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	ID		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	UP012AA	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest discomfort, Cough, Dyspnoea, Headache, Pain, Paraesthesia

**Symptom Text:** Tingling arm, headache. difficulty breathing, chest felt like it has a 20 pound weight on it, needle like pain when breathing out, coughing

**Other Meds:**

**Lab Data:**

**History:** Asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364445-1

<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>
35.0	F	19-Oct-2009	20-Oct-2009	1	02-Nov-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	UP003AA	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Intra-uterine death

**Symptom Text:** Discovered Intra-uterine Fetal Demise. Probably occurred 1 week prior.

**Other Meds:**

**Lab Data:**

**History:** Pregnant (14 weeks)

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364446-1

<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>
60.0	F	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	NJ		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	UP006AA	1	Unknown	Unknown	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Glossodynia, Rash, Swollen tongue, Tongue discolouration

**Symptom Text:** TONGUE TURNED WHITE ANE SWELLED UP. RED RASH AND HIVES ON FACE CHEST, ARMS & STINGING ON MY TONGUE. WITHIN 1 HOUR OF INJECTION HAD SYMTOMS AND TOOK BENADRYL WHEN THAT WORE OFF WAS MUCH WORSE AND REQUIRED GOING TO EMERGENCY DOCTOR CENTER

**Other Meds:** CELEBREX,PROCARDIA, ZANAX, SYNTHROID, PROTOXIT, VALTRAX, BABY ASPERIN, VITAMIN, ONE A DAY ADAIR, EMERGENCY INHALER

**Lab Data:**

**History:** PARALYZED RIGHT DIAPHRAGM, ASTHMA, LYMPHODEMIA ON RIGHT SIDE, ARTHRITIS

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364447-1

<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>
30.0	M	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-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>
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash erythematous, Urticaria

**Symptom Text:** A FEW MIN. AFTER I TOOK THE SHOT, MY BODY STARTED ITCHING..THE SECOND DAY I WOKE UP WITH ALOT OF SMALL RED ITCHY BUMPS ALL OVER MY BODY, IM THINKING THEIR HIVES

**Other Meds:** NONE

**Lab Data:**

**History:**

**Prex Illness:** a few min after i took the h1n1 flu shot, my skin started itching..the second i woke up wit alot of little red itchy bumps all o

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364449-1

<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>
57.0	F	30-Oct-2009	01-Nov-2009	2	02-Nov-2009	03-Nov-2009	OR		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	UP004AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Syncope

**Symptom Text:** Patient reports syncopal episode - resolved without any further treatment

**Other Meds:**

**Lab Data:**

**History:** Denies

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364454-1

<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>
58.0	M	26-Oct-2009	01-Nov-2009	6	02-Nov-2009	03-Nov-2009	FL		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)	UNKNOWN MANUFACTURER	UP009AA	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pruritus, Rash generalised, Urticaria

**Symptom Text:** Hives. Rash covering entire body. Itchy.

**Other Meds:** niaspan calcium lovasa lipataur

**Lab Data:** administered Benadryl, Prednesone, Zyrtec over the course of several hours

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364456-1

<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>
59.0	M	21-Oct-2009	22-Oct-2009	1	02-Nov-2009	03-Nov-2009	ID		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	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Bronchitis, Fatigue, Hypersomnia, Malaise

**Symptom Text:** Very weak and tired the next day after the shot. Went home sick and slept the entire day. Three days after the shot came down with heavy bronchitis. Patient stated he was also aware of two other people with similiar symptoms but not nearly as bad as his.

**Other Meds:**

**Lab Data:**

**History:** Asthma

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364457-1

<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>
2.0	M	30-Oct-2009	02-Nov-2009	3	02-Nov-2009	03-Nov-2009	TX		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)	UNKNOWN MANUFACTURER	NULL	0	Right leg	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Agitation, Body temperature increased, Dyspnoea, Livedo reticularis, Respiratory tract congestion

**Symptom Text:** trouble breathing, elevated body temperature, skin mottling, agatation, congestion

**Other Meds:**

**Lab Data:** lung X ray rapid influenza test general exam

**History:** Lactose Intolerance

**Prex Illness:** No illnesses or fever at time of vaccine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364460-1

<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>
42.0	M	29-Oct-2009	29-Oct-2009	0	02-Nov-2009	03-Nov-2009	FL		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	UP012AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Feeling abnormal, Loss of consciousness, Musculoskeletal stiffness, Syncope, Tongue biting, Tremor

**Symptom Text:** During the 15 minute waiting period, patient stiffened up and lost consciousness. He bit his tongue, sat to the floor and shook for approximately 4 minutes according to his wife. His spouse called for help because her husband was not feeling good. Patient was found lying on the floor, vital signs assessed all within normal ranges, rescue (911) was called to the scene then patient was taken to Emergency Department. Patient was awake, alert and oriented to self, place and time upon awakening.

**Other Meds:**

**Lab Data:** Urine Toxicity, negative. MRI, normal. EEG, no epileptiform activity. Neurologic exam performed at the hospital showed no abnormalities.

**History:** none

**Prex Illness:** Client fainted after receiving vaccine

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364465-1

<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>
50.0	F	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	NY		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	UP006AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chest pain, Dyspnoea, Injection site pain, Pain in extremity

**Symptom Text:** employee called her work unit to say she went shopping after receiving H1N1, employee had finished working night tour, received vaccine at 8:30 am, while driving home at 10:30 experienced chest pain, pain in left arm ( received vaccine in left arm) difficulty breathing, called 911 went via ambulance to St. Catherins's Hospital called at 2:30 pm to notify of condition will remain for observation for 24 hours as per employee

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364467-1

<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>
22.0	M	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	MS		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Renal pain

**Symptom Text:** severe pain in my sides around kidneys. Very week feeling

**Other Meds:**

**Lab Data:**

**History:** Alports Syndrome

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364468-1

<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>
27.0	F	23-Oct-2009	25-Oct-2009	2	02-Nov-2009	03-Nov-2009	MA		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)	UNKNOWN MANUFACTURER		NULL		Unknown	Unknown		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Acne, Biopsy skin abnormal, Injection site macule, Pruritus generalised, Rash, Rash macular

**Symptom Text:** Started out looking like pimples on my right hip (injection site was left arm). By noon (3 hours later) there were about 15 spots that looked like mosquito bites. By 6 PM, the spots had spread up my side and down my entire right arm. By 9 PM, I had spots on my left side and left arm. I also had spots on my right eyelid, right ear, scalp, and both knees. I went to a dermatologist (Dr. Michael Pugliese, Concord Dermatology Associates, Baker Ave in Concord, MA) at 10:00 AM the following day (10/26/09) and he had never seen a reaction like that. The other 3 doctors in the practice were also stumped. They did a biopsy in case it didn't go away. The doctor called an infectious disease doctor who said that I could be reacting to an impurity in the vaccine. I took Benadryl and Claritin, they did not help at all. I put Benadryl cream on the itchiest spots (right ear, both wrists, right eyelid, and knees) and it helped a little bit. The rash was completely gone by Thursday (10/29/09). Photo: <http://i36.tinypic.com/29dtv11.jpg>

**Other Meds:**

**Lab Data:** Results not yet received from Biopsy.

**History:** Pregnancy (6 weeks, 6 days)

**Prex Illness:**

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364470-1

<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>
2.0	M	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	MA		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	UPO18AA	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Injection site rash, Rash generalised

**Symptom Text:** Widespread rash on trunk and arms. Timing suspicious for rxn to H1N1 vaccine. Little change in rash with Benadryl. 72 hours after onset, still present

**Other Meds:**

**Lab Data:** None. Will test for egg allergy in near future.

**History:** ALLERGIC TO AMOXICILLIN

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364477-1

<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>
54.0	F	26-Oct-2009	27-Oct-2009	1	02-Nov-2009	03-Nov-2009	MD		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyspnoea, Fatigue, Nasal congestion

**Symptom Text:** the first 4hrs after administration of vaccine, extreme tiredness was evident,with nasal stuffiness. 24hrs after administration, shortness of breath was noted, which lasted at least 36 hours.

**Other Meds:** Levothyroxine

**Lab Data:** None

**History:** Hoshimotos

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364479-1

<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>
1.3	F	28-Oct-2009	29-Oct-2009	1	02-Nov-2009	03-Nov-2009	MN		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)	UNKNOWN MANUFACTURER	NULL	0	Left leg	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Erythema, Rash generalised, Urticaria

**Symptom Text:** After H1N1 vaccination, hives-like rash appearing on any and all parts of body--stays on arm, leg, hand, face, etc., for about 10 minutes and then disappears. Quite red, but does not appear itchy or painful.

**Other Meds:**

**Lab Data:** Day care center required visit to doctor and note that rash/hives were not contagious. Doctor said it was not contagious and did not diagnose hives because rash did not appear itchy.

**History:**

**Prex Illness:** Possible cold.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364483-1

<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>
9.0	F	31-Oct-2009	31-Oct-2009	0	02-Nov-2009	03-Nov-2009	MD		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	10073802	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Feeling abnormal

**Symptom Text:** PATIENT RECEIVED INJECTION WHILE STANDING, STATED THAT SHE FELT LIKE SHE WAS FLOATING, AND WAS LOWERED TO THE FLOOR BY A FAMILY FRIEND.

**Other Meds:**

**Lab Data:** NONE

**History:** NONE NOTED

**Prex Illness:** NONE NOTED

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364486-1

<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>
31.0	F	19-Oct-2009	19-Oct-2009	0	02-Nov-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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dysgeusia

**Symptom Text:** Metallic taste in mouth following h1n1 shot. No tx warranted.

**Other Meds:**

**Lab Data:** none

**History:** NKDA

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364487-1

<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>
53.0	F	21-Oct-2009	21-Oct-2009	0	02-Nov-2009	03-Nov-2009	KS		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	UP001AA	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Pallor

**Symptom Text:** About 15 mins after getting the vaccine became lightheaded, dizzy and was pale. Did not faint.

**Other Meds:**

**Lab Data:**

**History:** Cephlosporins

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364492-1

<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>
1.3	M	26-Oct-2009	Unknown		02-Nov-2009	03-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	SANOFI PASTEUR	U3201AA	0	Unknown	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP002AA	0	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Blister, Rash, Rash generalised, Rash papular, Rash pruritic, Rash pustular

**Symptom Text:** Diffuse marbilliform (pink tiny papules-some semi-coalescent) rash on cheeks (face) and entire trunk, some on arms and a few on legs-many in groin area. - itchy, - hives, - pustules, -vesicles.

**Other Meds:**

**Lab Data:** None

**History:**

**Prex Illness:** None

**Prex Vax Illns:** Marbilliform rash~Measles + Mumps + Rubella (no brand name)-1~0.00~Patient|Marbillorm rash~Varicella (no brand name)-1~0.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364495-1

<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>
45.0	F	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	IA		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	UP001AA	0	Left arm	Intramuscular	FLU

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Flushing, Injection site pain, Injection site swelling, Oedema peripheral, Pain in extremity

**Symptom Text:** Swelling and pain at the site and the arm. Patient flushed and complains of being light headed.

**Other Meds:**

**Lab Data:** None

**History:** Asthma

**Prex Illness:** None known

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364529-1

<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>
61.0	F	23-Oct-2009	23-Oct-2009	0	02-Nov-2009	03-Nov-2009	MT		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	UP001AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Wheezing

**Symptom Text:** Shortness of breath, wheezing.

**Other Meds:**

**Lab Data:** CXR-negative

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364531-1

<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>
45.0	F	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	IL		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	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Erythema, Urticaria

**Symptom Text:** Red, raised welts appeared on left cheek of face - did not itch - were actually noticed by a co-worker - still slightly apparent on 11-2-09 - still light pink and just slightly raised

**Other Meds:**

**Lab Data:**

**History:** Allergic to penicillin and codeine

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364532-1

<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>
16.0	M	24-Oct-2009	01-Nov-2009	8	02-Nov-2009	03-Nov-2009	NJ		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	UP007AA	0	Unknown	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Muscular weakness

**Symptom Text:** Mother states that Matthew is complaining of extreme weakness of the arms and legs

**Other Meds:** Lexapro Trasadone Claritin Inhaler as needed

**Lab Data:** Referred to private physician for follow up

**History:** Unknown

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364536-1

<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>
6.0	F	29-Oct-2009	30-Oct-2009	1	02-Nov-2009	03-Nov-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)	UNKNOWN MANUFACTURER		NULL	0	Left arm	Unknown		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Confusional state, Cough, Dizziness, Fatigue, Pyrexia

**Symptom Text:** Fever of 102, extreme fatigue, dizziness, confusion, cough. Lasted until about 10:00 AM on 11/01/2009.

**Other Meds:**

**Lab Data:** None

**History:** None.

**Prex Illness:** None.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364544-1

<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>
10.0	M	29-Oct-2009	31-Oct-2009	2	02-Nov-2009	03-Nov-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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Fatigue, Pain, Pyrexia

**Symptom Text:** Fever of 100+, extreme fatigue, body aches and cough. Lasted until about 8:00 AM on 11/02/2009.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364545-1

<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>
42.0	F	28-Oct-2009	28-Oct-2009	0	02-Nov-2009	03-Nov-2009	AK		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)	UNKNOWN MANUFACTURER		NULL	0	Left arm	Unknown	FLU	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal distension, Abdominal pain upper, Activities of daily living impaired, Body temperature increased, Diarrhoea, Frequent bowel movements, Headache, Hyperhidrosis, Malaise, Nausea, Pallor, Vomiting

**Symptom Text:** Within 30 minutes turned pale, started sweating, waves of severe nausea (lasted 36 hours), vomiting (lasted 4 hours), painful stomach cramps (lasted 3 days), bloated stomach (lasted 3 days), severe headache (1 day), frequent bowel movements/diarrhea (3 days), low grade fever (36 hours), feeling ill (3 days). Lost three days work and still recovering after 5 days. Fortunately, my asthma did not act up and there were no respiratory distress experienced.

**Other Meds:** This is my first vaccination reaction. I do have prior allergic reactions to penicillan, codeine and sulfa drugs.

**Lab Data:** None

**History:** Seasonal allergies, asthma (late summer and fall), migraines

**Prex Illness:** None

**Prex Vax Illns:** None~ ()~0.00~Patient

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364546-1

<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>
10.0	M	29-Oct-2009	29-Oct-2009	0	02-Nov-2009	03-Nov-2009	AL		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dyspnoea, Feeling abnormal, Heart rate increased, Vomiting

**Symptom Text:** he started to feel bad that afternoon and began having problems breathing that night,very short and rapid breaths,he also developed a rapid heart rate and had to vomit 4 times between midnight and 5:00 AM

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364551-1

<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>
28.0	F	31-Oct-2009	31-Oct-2009	0	02-Nov-2009	03-Nov-2009	CA		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		UP006AA	0	Left arm	Intramuscular		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dyspnoea, Fatigue, Influenza, Respiratory tract congestion, Sneezing

**Symptom Text:** Per patient, on 10/31/09 at 2 pm, she began to have flu symptoms of sneezing and congestion. On 11/1/09 at 4 pm, she felt tired and found it hard to breathe. She has not sought medical attention yet.

**Other Meds:** Patient reported taking Ibuprofen on 10/30/09 at 9 pm and on 10/31/09 at 8 pm.

**Lab Data:** None

**History:** Per administrating clinic, conditions documented in medical record include dyspepsia, breast lump (resolved), and infertility.

**Prex Illness:** Per administrating clinic, no illnesses at time of vaccination (temp was 96.8). Per patient, she had flu symptoms (fever, runny

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364553-1

<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>
28.0	M	17-Oct-2009	20-Oct-2009	3	02-Nov-2009	03-Nov-2009	SC		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue

**Symptom Text:** Extreme fatigue lasted about half the day

**Other Meds:**

**Lab Data:**

**History:** no

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364554-1

<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	F	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	OR		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)	UNKNOWN MANUFACTURER	NULL	0	Left leg	Intramuscular	FLU(H1N1)		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Body temperature increased, Crying, Incorrect storage of drug, Lethargy

**Symptom Text:** Became somewhat lethargic and often crying. Took a long afternoon nap which is unusual for her. Complained of stomach hurting. Verified temperature of 101.7 (orally with digital thermometer) at approximately 3:45 PM. Please note that on 10\23\09, Sophia was given an IM injection of the Swine Flu Vaccine. The Doctor's office called one week later stating that the initial vaccine was stored at too low of a temperature and that another "1st" vaccine needed to be given again. This occurred approximately 1 week later with a nasal injection and is appearing to be correlated to Sophia's temperature, etc.

**Other Meds:** Fluticasone Propionate 100mcg x 1\day

**Lab Data:** NA at time of this report.

**History:** Allergies. Mild runny nose at time of nasal vaccine. No other complaints

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364557-1

<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	M	24-Oct-2009	28-Oct-2009	4	02-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	MIST500757P	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Diarrhoea, Headache, Myalgia, Pyrexia

**Symptom Text:** Headache, fever 102, diarrhea, muscle aches, joint pain. regular flu treatment at home, fluids, rest, popsicles, cool compress. lasted for 3 days.

**Other Meds:** None

**Lab Data:** None

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364559-1

<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>
49.0	M	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	UP001AA	0	Right arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injected limb mobility decreased

**Symptom Text:** Handwriting illegible with arm that vaccine was injected. No treatment given, Handwriting improved 8 hours after adverse event.

**Other Meds:**

**Lab Data:** None

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364560-1

<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>
47.0	F	24-Oct-2009	31-Oct-2009	7	02-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	INJUP007AA	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Arthralgia, Chills, Diarrhoea, Headache, Myalgia, Pyrexia

**Symptom Text:** headache, chills, fever 103, joint pain, muscle aches, diarrhea. treated athome with fluids, cool compress, rest, sleep. still having symptoms

**Other Meds:**

**Lab Data:**

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364561-1

<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>
44.0	M	24-Oct-2009	02-Nov-2009	9	02-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	MIST500757P	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Pain

**Symptom Text:** Aches, pains, headache

**Other Meds:**

**Lab Data:** None

**History:** No

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364563-1

<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>
6.0	F	29-Oct-2009	30-Oct-2009	1	02-Nov-2009	03-Nov-2009	CT	CT	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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Pyrexia

**Symptom Text:** fever 103\*...tylenol or motrin, fluids....fever broke 10/31/2009 around 2:00 PM...fever very consistent 102.7\*-103\* entire time

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364565-1

<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>
57.0	F	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	IL		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU		

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Flushing, Headache

**Symptom Text:** Flushing feeling thru whole body Face flushing Headhache

**Other Meds:** 10 mg Prozac, 25 mg diruetic, .5 Norvasc Librax, fish oil, 2000 vitamin D 81 mg asprin

**Lab Data:**

**History:** penicillin, high blood pressure, high ldl

**Prex Illness:** no

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364566-1

<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>
59.0	F	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	FL		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	UP009AA	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Lip swelling, Paraesthesia oral

**Symptom Text:** I began to experience a tingling on the upper right side of my lip. This resulted in a swollen lip which extends up to my right nostril.

**Other Meds:**

**Lab Data:**

**History:** red dye #40

**Prex Illness:** no illness at time

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364569-1

<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>
39.0	F	31-Oct-2009	31-Oct-2009	0	02-Nov-2009	03-Nov-2009	MI		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	UP013AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthma, Headache, Hypoaesthesia, Local swelling, Paraesthesia, Paraesthesia oral, Swelling face

**Symptom Text:** Facial swelling, neck swelling, tingling in bilateral hands, headache (not relieved by medication), intermittent lip and mouth tingling, hand numbness (intermittent), (asthma attacks occurred approximately an hour after injection lasting most of the day relieved by Benedryl and inhaler) all other symptoms not relieved with any medications tried.

**Other Meds:**

**Lab Data:** Patient is a RN and works in a hospital and is in contact with physician and other hospital staff.

**History:** History of Migraine Headaches, SVT, Asthma (last attack 13 years ago)

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364577-1

<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>
1.3	M	30-Oct-2009	30-Oct-2009	0	02-Nov-2009	03-Nov-2009	AZ		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>
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC14B100BA	3	Left leg	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB326AA	0	Left leg	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Left leg	Unknown	
	PNC	WYETH PHARMACEUTICALS, INC	D46875	3	Right leg	Unknown	
	FLU	SANOFI PASTEUR	U3259BA	0	Right leg	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Anaemia, Breath holding, Crying, Cyanosis, Tremor

**Symptom Text:** Child received vaccines (5 shots), cried, held his breath and turned blue, shaking. The administering nurse called a code blue, the team arrived, child recovered spontaneously and was taken to ER for observation.

**Other Meds:**

**Lab Data:** none

**History:** 8/4/09 had a febrile illness and anemia noted - ferrous sulfate ordered. No verification of ongoing anemia or resolution.

**Prex Illness:** None. Child had just had a well check up and proceeded to receive immunizations.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364580-1

<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>
18.0	M	02-Nov-2009	02-Nov-2009	0	02-Nov-2009	03-Nov-2009	IL	IL	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	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Headache

**Symptom Text:** Dizziness, lightheadedness, headache, difficulty breathing. These symptoms only lasted a couple of minutes and then they passed. I've had a headache all day since the vaccination and have had on-and-off lightheadedness. No treatment received

**Other Meds:**

**Lab Data:**

**History:** Born with heart murmur Allergic to ceclor

**Prex Illness:** Dizziness, lightheadedness, headache, chest tightness/difficulty breathing. I started feeling strange right as the vaccine was i

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364582-1

<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>
48.0	F	27-Oct-2009	31-Oct-2009	4	02-Nov-2009	03-Nov-2009	CA		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Asthenia, Diarrhoea, Headache, Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth, Neuralgia, Pyrexia

**Symptom Text:** nerve pain in legs,diarrhea, headache, weakness, fever. The site where h1n1 was given was red, swollen and hot and painful

**Other Meds:**

**Lab Data:**

**History:** none

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364583-1

<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>
24.0	F	19-Oct-2009	Unknown		03-Nov-2009	03-Nov-2009	GA	H1N1 LIVE NASAL MIST	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)	CSL LIMITED	NULL	0	Unknown	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Asthenia, Back pain, Migraine

**Symptom Text:** MIGRAINE HEADACHES AND PAIN IN MY BACK AND WEAKNESS

**Other Meds:**

**Lab Data:**

**History:** NO

**Prex Illness:** NO

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364585-1

<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>
39.0	F	29-Oct-2009	30-Oct-2009	1	03-Nov-2009	03-Nov-2009	AZ		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	FLU		

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Chills, Cough, Dyspnoea, Headache, Nasal congestion, Oropharyngeal pain, Pyrexia, Wheezing

**Symptom Text:** At first, it was a dry cough. Then, on Saturday (10/31/09) I developed a fever, chills, sore throat, wheezing, difficulty breathing, bad violent cough, bad headache, some nasal congestion

**Other Meds:** Actoplus Met; Vytarin; Armor Thyroid; Aciphex

**Lab Data:** At the doctor's office, I was seen immediately but by a nurse, not a doctor. I'm still recovering. I was prescribed medicine for the cough to help me sleep but the nurse wouldn't give me anything for the wheezing even though I'm still havi

**History:** allergic to antibiotic: penicillin; allergic to dust/mold/animal hair/weeds; diabetes

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364587-1

<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>
23.0	F	30-Oct-2009	31-Oct-2009	1	03-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Cough, Dizziness, Dysphonia, Dyspnoea, Myalgia

**Symptom Text:** Hourseness, dizziness, muscle aches, trouble breathing, coughing...10/30/2009 to present

**Other Meds:** None

**Lab Data:** None

**History:** Asthama

**Prex Illness:** NO

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364588-1

<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>
23.0	F	30-Oct-2009	31-Oct-2009	1	03-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Dyspnoea, Headache, Myalgia, Nausea, Oropharyngeal pain, Pyrexia

**Symptom Text:** High fever (102.5), muscle aches, sore throat, trouble breathing, headache, dizziness, nausea, lightheadness

**Other Meds:** None

**Lab Data:** None

**History:** Asthama

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364590-1

<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	F	31-Oct-2009	01-Nov-2009	1	03-Nov-2009	03-Nov-2009	NY		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	UP007AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Cough, Fatigue, Headache, Nausea, Vomiting, Wheezing

**Symptom Text:** Low-grade temperature 99.9 with headache. The next morning, headache, temperature of 100 with nausea and fatigue. That night, temp of 100.2 with fatigue and a random cough, nausea. Now, it's 11/3 at 2:30 am and she awoken with temp of 102.2, vommitted, wheezing cough. I called Pediatrician and he thinks she has H1N1. The last day any of my 3 children were in school was Wed. 10/28/09 because we wanted hannah vaccinated for 10 days before they went back to school to insure Hannah had full immunity to H1N1. We also have avoided the public. We did not trick or treat, nor did we give out candy. When we've had to go into public, we've worn face masks. I really think this injectible vaccine gave her H1N1.

**Other Meds:** none

**Lab Data:**

**History:** Giant Axonal Neuropathy (GAN) - a rare, recessive, genetic, neurodegenerative disorder

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364592-1

<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>
18.0	M	02-Nov-2009	03-Nov-2009	1	03-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Chills, Headache, Pain, Pyrexia

**Symptom Text:** Fever 101, chills, body aches, headache

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** No

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364593-1

<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>
10.0	M	27-Oct-2009	27-Oct-2009	0	03-Nov-2009	03-Nov-2009	FL		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	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Injection site erythema, Injection site reaction, Rash macular

**Symptom Text:** Onset of red, blotchy areas at injection site, along left arm and neck

**Other Meds:**

**Lab Data:**

**History:** None Known

**Prex Illness:** None Known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364594-1

<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>
11.0	F	28-Oct-2009	28-Oct-2009	0	03-Nov-2009	03-Nov-2009	FL		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	Unknown	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Hyperhidrosis, Pallor

**Symptom Text:** Child became pale and sweaty. Temp: 98.8, BP: 90/68, P: 70

**Other Meds:**

**Lab Data:**

**History:** None Known

**Prex Illness:** None known

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364595-1

<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>
36.0	F	02-Nov-2009	02-Nov-2009	0	03-Nov-2009	03-Nov-2009	VA		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)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Headache, Hypoaesthesia, Injection site pain

**Symptom Text:** Started getting headache which became really bad in a matter of minutes with a little bit of numbness at base of neck. I rarely get headaches and it came so quickly and severe. I have only experienced this previously when very ill. I insisted my husband wake me up throughout the night to make sure it was OK. It went away overnight and this morning is minimal. I do have more than usual tenderness at injection site which started soon after getting the shot. I normally don't experience tenderness after the flu shot

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364621-1

<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>
2.0	F	28-Oct-2009	01-Nov-2009	4	03-Nov-2009	03-Nov-2009	MI		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)	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Rash

**Symptom Text:** A rash appeared on her neck and back...worsening the next day and spreading down to buttocks with a small amount on stomach and left leg. Still there on 11/3/2009. Made a doctor's appointment to have it checked this afternoon.

**Other Meds:** None of the above. She did just come off of a second dose of Zythromax, but has been on this before several times with no reaction.

**Lab Data:**

**History:** none

**Prex Illness:** No, but a week prior was getting over microplasma pneumonia.

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364624-1

<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	31-Oct-2009	31-Oct-2009	0	03-Nov-2009	03-Nov-2009	MD		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	10073802	0	Left arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT:** Syncope

**Symptom Text:** RECEIVED H1N1 VACCINE WHILE SEATED IN A CHAIR. SHE FAINTED, BUT DID NOT FALL.

**Other Meds:**

**Lab Data:**

**History:** NONE NOTED

**Prex Illness:** NONE NOTED

**Prex Vax Illns:**



# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364639-1

<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>
4.0	M	30-Oct-2009	30-Oct-2009	0	03-Nov-2009	03-Nov-2009	NY		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	CSL LIMITED	07049111A	0	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Body temperature increased, Vomiting

**Symptom Text:** emesis x2, low grade fever x 12 hours

**Other Meds:** flovent - 2 puffs bid zrytec 4ml/day amoxicillin bid

**Lab Data:** none

**History:** asthma

**Prex Illness:** none

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364641-1

<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>
10.0	M	31-Oct-2009	01-Nov-2009	1	03-Nov-2009	03-Nov-2009	NJ		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)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Dizziness, Headache, Nausea, Pyrexia

**Symptom Text:** Fever,headache,dizziness and nausea. After 24 hours of fever gave tylenol.

**Other Meds:** Albuteral inhaler

**Lab Data:**

**History:** Asthma

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364646-1

<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>
21.0	M	28-Oct-2009	28-Oct-2009	0	03-Nov-2009	03-Nov-2009	NY		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	UP007AA	0	Right arm	Intramuscular	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Abdominal pain upper, Cough, Pyrexia

**Symptom Text:** cough, high fever, stomachache

**Other Meds:** allegra D

**Lab Data:** bloodwork chest xray ekg

**History:** allergy to dust mites

**Prex Illness:** no

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364648-1

<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>
58.0	M	26-Oct-2009	28-Oct-2009	2	03-Nov-2009	03-Nov-2009	NY		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	UP002AA	0	Left arm	Intramuscular	FLU

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Fatigue, Headache, Pain

**Symptom Text:** 10/28/2009 felt very achey, general muscle ache, tired, headache. Lasted until 10/31/2009. Has completely resolved. Never had a fever.

**Other Meds:** Lisinopril, Crestor, Nadolol

**Lab Data:** None

**History:** High Blood Pressure high Cholesterol

**Prex Illness:** None

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364649-1

<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>
10.0	F	02-Nov-2009	03-Nov-2009	1	03-Nov-2009	03-Nov-2009	TN		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)	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Diarrhoea, Nausea

**Symptom Text:** nausea and diarrhea

**Other Meds:**

**Lab Data:**

**History:** ALLERGIC TO PENICILLEN

**Prex Illness:** NONE

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364650-1

<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>
62.0	F	24-Oct-2009	Unknown		03-Nov-2009	03-Nov-2009	WV		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	UP010AA		Unknown	Intramuscular			

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Musculoskeletal pain

**Symptom Text:** Complaint of shoulder pain day after injection

**Other Meds:**

**Lab Data:**

**History:**

**Prex Illness:**

**Prex Vax Illns:**

# VAERS Line List Report

Report run on: 04 NOV 2009 10:23

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

**Vaers Id:** 364651-1

<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>
49.0	F	30-Oct-2009	31-Oct-2009	1	03-Nov-2009	03-Nov-2009	MD		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	UP018AA	1	Left arm	Unknown	

**Seriousness:** ER VISIT, NOT SERIOUS

**MedDRA PT** Dizziness, Nausea

**Symptom Text:** Nausea and dizziness

**Other Meds:**

**Lab Data:** Vertigo

**History:** Hypothyroid

**Prex Illness:** None

**Prex Vax Illns:**

**Total Non Serious**            697    96%

**Total Serious Non Fatal**    27     4%

**Total Death:**                3      0%

**Total All Reports:**           727