Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 1

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

Vaers Id: 360012-1

Gender Days Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** 9.0 F 07-Oct-2009 07-Oct-2009 08-Oct-2009 NC 0 08-Oct-2009 08-Oct-2009 Site VAX Detail: Type <u>Lot</u> Prev Doses **Other Vaccine** Manufacturer Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Pyrexia

Symptom Text: Chills, fever of 101 F

Other Meds:

Lab Data:

History: Reflux of the kidneys, but mild and no longer in active treatment for it.

Prex Illness: Mild sore throat, no fever or other symptoms

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360113-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days AL6.0 Μ 08-Oct-2009 08-Oct-2009 0 09-Oct-2009 09-Oct-2009 09-Oct-2009

<u>VAX Detail:</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. 500757P 0 Unknown By Mouth

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: MY SON BROKE OUT IN WHAT APPEARED TO BE BUG BITES AND HE W AS REAL ITCHY THEN IT SPREAD FROM HIS NECK TO UNDERARMS

CHEST SCALP STOMACH LEGS AND FEET

Other Meds:

Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360231-1

Gender **Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date Vaccine Date** Days State <u>Age</u> F 39.0 08-Oct-2009 08-Oct-2009 0 09-Oct-2009 28-Oct-2009 WA 28-Oct-2009 Other Vaccine

VAX Detail: **Type** Site **Prev Doses** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 5007649 Unknown Unknown

ER VISIT, NOT SERIOUS Seriousness:

MedDRA PT Dizziness, Flushing, Hypoaesthesia oral, Malaise, Palpitations, Throat tightness

Within moments of vaccine administration, patient reported not feeling well, dizzy, wanted to lie down after lying down, feet elevated, she reported her throat Symptom Text:

feeling tight, face flushed, around mouth feeling numb, heart feeling fast. HR ED, BP 140/80 911 called, pt transported to Emerg Dept (went to hosp)

Other Meds: Birth control pills

None Lab Data: None History: Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 360288-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received [Date St	atus Date	<u>State</u>	Mfr Report Id	Last Edit Date
3.0	F	08-Oct-2009	09-Oct-2009	1	09-Oct-20	09 12	-Oct-2009	OR		14-Oct-2009
VAX Detai	I: Type	<u>Manuf</u>	<u>acturer</u>		<u>Lot</u>	Prev Doses	3	<u>Site</u>	Route	Other Vaccine
	FLU	SANO	FI PASTEUR		U3260DA	4	Rig	ht leg	Intramuscular	

Unknown

Unknown

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 5007751P

NO CONDITIONS, NOT SERIOUS Seriousness: Pyrexia

Symptom Text: 103.6 degree F fever

Other Meds: Lab Data:

MedDRA PT

History: None **Prex Illness:** None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360291-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> 22.0 Μ 07-Oct-2009 08-Oct-2009 1 09-Oct-2009 12-Oct-2009 MO 12-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P DTAP Unknown Unknown

FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed mood, Fatigue, Feeling hot, Headache, Nasal congestion, Oropharyngeal pain, Pain, Pulmonary congestion

Symptom Text: General fatigue, body aches, feeling of fever (however none), nasal congestion, headache, sore throat, cough, lung congestion, and depressed mood.

Other Meds:

Lab Data:

<u>History:</u> None <u>Prex Illness:</u> No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360322-1

Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days State <u>Age</u> F 39.0 09-Oct-2009 09-Oct-2009 0 11-Oct-2009 12-Oct-2009 MD 12-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Herpes simplex, Lip blister, Paraesthesia oral

Symptom Text: Lip tingling, burning, developed blister, HSV appearance w/no previous history of HSV outbreak. Next day, further HSV like lesions appeared on

torso/back/buttocks/chest. Vaccine given was live flu mist.

Other Meds:

Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360327-1

<u>Age</u> Gender **Onset Date Received Date** State Mfr Report Id **Last Edit Date Vaccine Date** Days **Status Date** F 23.0 10-Oct-2009 10-Oct-2009 0 11-Oct-2009 12-Oct-2009 IΑ 12-Oct-2009

<u>VAX Detail:</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 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dyspnoea, Nausea, Vomiting

Symptom Text: Recieved h1n1 laiv around 12:15pm. At 4:30 I developed nausea and I vimitted four times. Nausea ended around 8pm. At around 8:30pm I noticed a sharp

pain under right rib cage and I had difficulty breathing. This continued until 10:00pm

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360338-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> F 26.0 06-Oct-2009 08-Oct-2009 2 11-Oct-2009 14-Oct-2009 CA 14-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500760P Unknown Unknown
FLU SANOFI PASTEUR U3205CA Unknown Intramuscular

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Influenza, Pyrexia

Symptom Text: I took the 2009 H1N1 influenza vaccine (LAIV which is sprayed into the nose). After taking the vaccine, I have fever, cough and other symptoms as H1N1 flu.

Other Meds:

Lab Data:

History:

Prex Illness: started on the evening of 10/08/2009

Prex Vax IIIns: fever, cough and etc~Influenza (H1N1) (Influenza A (H1N1) 2009 Monovalent, Intranasal Spray)~~26.83~Patient

VAERS Line List Report

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

Vaers Id: 360339-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 37.0 11-Oct-2009 12-Oct-2009 OR Μ 09-Oct-2009 10-Oct-2009 1 12-Oct-2009

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

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Ear infection, Eustachian tube dysfunction

Symptom Text: Stuffy head feeling. Eustacian tube dysfunction. Serous otitis. Dizziness. Syptoms resolved in 36 hours.

Other Meds:

Lab Data:N/AHistory:No.Prex Illness:No.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360346-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 5.0 F 08-Oct-2009 09-Oct-2009 1 09-Oct-2009 12-Oct-2009 MA 12-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Nasal congestion, Oropharyngeal pain, Pyrexia, Rhinorrhoea, Vomiting

Symptom Text: Fever 101 10/8/09 during night followed by vomiting early AM 10/9/09; vomiting every hour. Also with nasal congestion, runny nose, sore throat and headache.

Other Meds: None

Lab Data:

History: No Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360451-1

Onset Date State Mfr Report Id Gender **Vaccine Date Days Received Date Status Date Last Edit Date** Age F 15.0 09-Oct-2009 10-Oct-2009 1 12-Oct-2009 12-Oct-2009 NC 13-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Fatigue, Headache, Hypoaesthesia, Oropharyngeal pain, Pain in extremity, Peripheral coldness, Pyrexia, Vomiting

Symptom Text: sudden sever headache followed by vomiting; numbness in hands followed by aching in arms which moved into legs; cold hands/feet; fever 101; administered acetminophen; symptoms subsided after a few hours then returned the next day as extreme fatigue; cold hands; fever 101.5; treated with acetimenophen;

symptoms subsided then changed by this morning to sore throat and chest with occasional mild cough, no sputnam, fever has not returned as of 11:05 am.

Other Meds: multivitamins and certizine hydrochloride 10 mg for seasonal hayfever

Lab Data:noneHistory:noPrex Illness:no

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 360454-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 47.0 F 07-Oct-2009 12-Oct-2009 03-Oct-2009 4 12-Oct-2009 MD 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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness postural

Symptom Text: Dizziness when changing positions - especially when getting up from lying down. Has lasted until today (Oct 12). I plan to call my primary doctor today.

Other Meds:

Lab Data:

History: No Prex Illness: No

Prex Vax IIIns:

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

Vaers Id: 360456-1 (S)

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received	Date	Status D	ate Sta	te Mfr Report Id	Last Edit Date
29.0	F	08-Oct-2009	10-Oct-2009	2	12-Oct-2	009	12-Oct-20	009 MN	I	30-Oct-2009
VAX Deta	ail: Type	<u>Manu</u>	<u>ıfacturer</u>		<u>Lot</u>	Prev	Doses	<u>Site</u>	<u>Route</u>	Other Vaccine
	FLUI	N(H1N1) MEDI	IMMUNE VACCINES	S, INC.	500756P		0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

Anxiety, Asthenia, Chest pain, Chills, Condition aggravated, Cough, Dizziness, Dyspnoea, Headache, Influenza like illness, Nausea, Painful respiration, MedDRA PT

MedDRA PT

Pharyngeal erythema, Productive cough, Pyrexia, Respiratory distress, Respiratory rate increased, Rhinorrhoea, Sinus disorder, Sputum discoloured, Steroid

therapy, Tachycardia, Vomiting

Symptom Text: Please note that this individual is a HCW. Developed fever, SOB, N/V with coughing, headache. Initial episode of ILI began on 10/1 (out from work until 10/8.

Saw physician 1 week ago (10/5)for follow-up after having been on Prednisone, Albuterol and Codiene cough medication and received clearance to return to work. Stated since receiving the H1N1 FluMist vaccine on 10/8 her symptoms worsened. 10/13/09 ED/Outpatient Clinic records received service dates 9/30/09 to 10/11/09 Assessment: H1N1 Suspected. Patient presents with fever, productive cough, weakness, chills, shortness of breath, runny nose, sinus drainage, hurts to breath, headache, vomiting. Mild erythema pharynx. Respiratory distress, rapid respiratory rate, tachycardia. 10/13/09 PCP medical records from 9/15/09 to 9/30/09 hospital records 10/11/09 to 10/13/09. Assessment: Influenza like illness. Patient presents with anxiety, productive cough with yellow sputum, fatigue. Dizzy spells. Chest pain. Admitted for influenza like illness, respiratory distress and tachycardia. Shortness of breath with activity. Head pain. 10/29/2009 Discharge summary received for DOS 10/11-10/12. Final DX not provided. Brief discharge summary noting multiple treatment meds including

prednisone, Duoneb, and Tamiflu. Pateint to rtc in 5-10 days for follow-up

Other Meds:

Lab Data: 10/13/09 ED/Outpatient Clinic records received service dates 9/30/09 to 10/11/09 10/13/09 PCP medical records from 9/15/09 to 9/30/09 hospital records

10/11/09 to 10/13/09. LABS and DIAGNOSTICS: Rapid FLU A/B Antigen (-). CBC - WNL. CHEM

History: Employee neglected to share with vaccinator that she had been diagnosed with exercise induced asthma as a child. Screening tool was also used and this did

not trigger acknowledgement of this history by the employee. 10/13/09 ED/Outpatient Clinic records received service dates 9/30/09 to 10/11/00. Postinfectious

cough. Anxiety. Patient presented with runny nose, congestion, coughi

Prex Illness: HCW Employee had just ended a prescribed course of Prednisone on 10/5/09 and had recently been away from work (HCW) for approx.

Prex Vax Ilins:

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

Vaers Id: 360458-1

<u>Age</u>	<u>Gender</u>	Vaccine Dat	e Onset Date	<u>Days</u>	Received Da	ate St	atus Date	<u>State</u>	Mfr Report Id	Last Edit Date
5.0	M	12-Oct-2009	12-Oct-2009	0	12-Oct-200	9 12	-Oct-2009	NC		12-Oct-2009
VAX Deta	ail: <u>Type</u>	<u>M</u> :	<u>anufacturer</u>		<u>Lot</u>	Prev Doses	<u> </u>	<u>ite</u>	Route	Other Vaccine
	FLUN	I(H1N1) MI	EDIMMUNE VACCINE	S, INC.	500754P	0	Unkı	nown	Unknown	
	FLU	NO	OVARTIS VACCINES A	AND	9721601	2	Left	arm	Intramuscular	

DIAGNOSTICS

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor, Syncope

Symptom Text: diaphoresis, pallor and fainting within ~ 5 minutes of vaccination; rescue squad was called, child stabilized and mom chose not to go to ER via rescue

Other Meds:

Lab Data: 02 sat 99% at time of EMS assessment, left clinic ambulatory in no distress approximately 30 minutes from onset of sx.

History: No

Prex Illness: No, mom reported as healthy

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360520-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 29.0 F 09-Oct-2009 10-Oct-2009 12-Oct-2009 13-Oct-2009 MO 1 13-Oct-2009

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500756P1UnknownUnknownFLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Oropharyngeal pain, Pain, Pyrexia

Symptom Text: SORE THROAT, FEVER BODY ACHE, HEAD ACHE

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360526-1

<u>Age</u>	<u>Gender</u>	Vaccine D	Onset Date	<u>Days</u>	Received Da	ate St	atus Date	<u>State</u>	Mfr Report Id	Last Edit Date
46.0	F	11-Oct-20	09 11-Oct-2009	0	13-Oct-200	9 13	-Oct-2009	WI		13-Oct-2009
VAX Deta	<u>iil:</u> Type		<u>Manufacturer</u>		<u>Lot</u>	Prev Doses	<u>s</u>	<u>Site</u>	Route	Other Vaccine
	FLUN	N(H1N1)	MEDIMMUNE VACCINE	S, INC.	500756P	0	Un	known	Unknown	
	FLU		GLAXOSMITHKLINE		AFLUA476AA	0	Le	eft arm	Intramuscular	

BIOLOGICALS

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Paraesthesia oral, Pruritus, Wheezing

Symptom Text: Intense itching in areas of sweating. Arm Pits, groin, between breasts. Lip tingling and wheezing. Itching & wheezing relieved with benadryl. Itching continued

with less severity for 36 hrs.

Other Meds: Prilosec, Synthroid, Vytorin, Zyrtec, Zoloft

Lab Data:

<u>History:</u> GERD, Hypothyroid, Ragweed, tree & grass allergies

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 360528-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received D	<u>ate</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
3.0	M	06-Oct-2009	06-Oct-2009	0	12-Oct-200	09	13-Oct-2009	NY		13-Oct-2009
VAX Deta	il: Type	<u>Man</u>	<u>ufacturer</u>		<u>Lot</u>	Prev Dos	es	Site	Route	Other Vaccine
	FLUN	MED	IMMUNE VACCINE	S, INC.	500687P	0	Ur	nknown	Unknown	
	FLUN	(H1N1) MED	IMMUNE VACCINE	S, INC.	500756P	0	Ur	nknown	Unknown	

ER VISIT, NOT SERIOUS Seriousness:

MedDRA PT Cough, Nasal congestion, Rhinorrhoea

Symptom Text: Pt returned to clinic on 10/9/09 complaining of runny nose and cough for three days and was diagnosed with nasal congestion and

Other Meds:

Lab Data:

History: Well child visit - Pt has NKDA. Pt also with phimosis & dysuria on DOS.

None documented **Prex Illness:**

Prex Vax Illns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Page 18

Vaers Id: 360555-1

Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days State <u>Age</u> F WV 19.0 12-Oct-2004 12-Oct-2009 1826 13-Oct-2009 22-Oct-2009 22-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Ear discomfort, Feeling hot, Headache, Pruritus, Urticaria

Symptom Text: Developed headache, ears burning, hives on trunk, neck and head with itching. Felt hot and difficulty taking deep breath. Rx Famotidine 20 mg Atarax 50mg /

Solumedrol 125 mg.

Other Meds:

Lab Data:

History: No allergies; Mitral Valve prolapse

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360588-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 55.0 F CO 13-Oct-2009 Unknown 13-Oct-2009 14-Oct-2009 14-Oct-2009

<u>VAX Detail:</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. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: I gave vaccine that was indicated for 2-49 years of age. The client was a 55 year old healthcare worker working in our jail. Client will inform us about possible

adverse events.

Other Meds:

Lab Data:

History: No Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360622-1

Onset Date Days **Received Date** Mfr Report Id <u>Age</u> Gender **Vaccine Date Status Date** State **Last Edit Date** 22.0 07-Oct-2009 08-Oct-2009 13-Oct-2009 23-Oct-2009 TN Μ 1 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Received INFLUENZA A H1N1 FLU MIST 10-7-09, next day had N/V for short period of time.

Other Meds: None

Lab Data:

History: None
Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360627-1

Gender Days **Received Date** <u>Age</u> **Vaccine Date Onset Date Status Date** State Mfr Report Id **Last Edit Date** 24.0 F 07-Oct-2009 07-Oct-2009 13-Oct-2009 23-Oct-2009 TN 0 23-Oct-2009 Site VAX Detail: Type <u>Lot</u> Manufacturer **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Nausea, Vomiting

Symptom Text: Received H1N1 mist 10-7-09- started s/s of N/V- low grade temp that HS- improved next.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360656-1

Gender **Vaccine Date Onset Date Days Received Date Status Date** State Mfr Report Id **Last Edit Date** Age F 8.0 09-Oct-2009 10-Oct-2009 1 13-Oct-2009 14-Oct-2009 UT 14-Oct-2009

<u>VAX Detail:</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. 500751P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Cough, Diarrhoea, Dysphonia, Nasal congestion, Oropharyngeal pain, Productive cough, Rhinorrhoea

Symptom Text: 10/09/09 4:00PM H1N1 Vaccine (Live, Attenuated) nasal spray administered. 10/10/09 Upon waking at 7:00AM noted coughing and sore throat. Temp. 99

range 10/11/09 Continued coughing and sore throat with hoarseness and diarrhea. Temp. 99 range. 10/12/09 Coughing, sore throat, hoarseness, diarrhea, with nasal congestion and runny nose. Temp.99 range 10/13/09 Cough has worsened and slightly productive, nasal congestion has worsened. Temp. 99

range. The following symptoms have subsided: sore throat and hoarseness. A visit to her doctor today as a precautionary. Continue to monitor symptoms.

Other Meds: No

Lab Data:

History: No Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360692-1

Gender **Vaccine Date Onset Date Days Received Date Status Date** State Mfr Report Id **Last Edit Date** Age F 48.0 10-Oct-2009 10-Oct-2009 0 13-Oct-2009 14-Oct-2009 WA 21-Oct-2009 Site VAX Detail: **Type Prev Doses** Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma, Chest discomfort, Condition aggravated, Cough, Dyspnoea, Headache, Nausea, Pain, Postnasal drip, Sneezing

Symptom Text: Began with post-nasal drip, then headache, sneezing. Over next 30 hours, progressed to severe headache with aches across chest and arms, nausea,

'adrenaline rush' sensation with tightening of chest and asthma symptoms-short of breath, cough, continued tight-chested feeling. So far, this has lasted

through today, 10/13 at 1700. I will be seeing my own PCP tomorrow as symptoms have persisted.

Other Meds: None prior to vaccine.

Lab Data:

History: Very mild asthma that hasn't bothered me for the last 3 years or so, as long as allergies are kept under control. I had no symptoms until receiving the

vaccination.

Prex Illness: None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 360696-1

Mfr Report Id Gender **Onset Date** Days **Received Date** <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 3.0 F 13-Oct-2009 13-Oct-2009 14-Oct-2009 OR 13-Oct-2009 0 OR 21-Oct-2009 Site VAX Detail: Type Manufacturer Lot **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Vomiting

Symptom Text: Stomach cramping from 4:35-5:45 Vomiting at 5:45

Other Meds: Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360699-1

Gender **Vaccine Date Onset Date Days Received Date Status Date** State Mfr Report Id **Last Edit Date** Age F SC 30.0 09-Oct-2009 11-Oct-2009 2 14-Oct-2009 14-Oct-2009 21-Oct-2009 Site VAX Detail: **Type Prev Doses** Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500757P 0

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Activities of daily living impaired, Chills, Cough, Headache, Influenza, Oropharyngeal pain, Pain, Postnasal drip, Pyrexia, Sinus

congestion, Sneezing

Symptom Text: It started with sore throat and post nasal drainage the first night (10/11). The next day it progressed to sinus congestion, headache, cough, sneezing, sore

throat. On 10/13 I had fever, chills, body aches, cough, sore throat, upset stomach. I started Tamiflu mid day on 10/13 after being tested. I did not have to work

Unknown

Unknown

on 10/13 anyway, and am unable to work on 10/14 due to this illness. As a physician, I exposed my patients unknowingly on 10/12, and it is a huge

inconvenience (to my patients and to my office) to have to miss work due to illness.

Other Meds: Zyrtec, Advair, Apri OCPs, glucosamine chondroitin, multivitamin

Lab Data: Influenza A +, Flu B neg
History: asthma, allergic rhinitis

Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360786-1 (S)

Mfr Report Id Gender **Vaccine Date Onset Date Days Received Date Status Date** State **Last Edit Date** Age 47.0 Μ 12-Oct-2009 12-Oct-2009 0 14-Oct-2009 14-Oct-2009 NC 21-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Allergy to vaccine, Hypersensitivity, Pharyngeal oedema, Swollen tongue

Symptom Text: Throat and tongue swelling. I was treated in the ER for allergic reaction. Received IV benadryl, solumedrol and Tagamet. Released after 2 and one half hours.

10/14/09 ED records received service date 10/12/09. Assessment: Allergic reaction to FluMist. Patient complained of throat swelling. Later said he felt better

and was discharged.

Other Meds:

Lab Data: 10/14/09 ED records received service date 10/12/09. LABS and DIAGNOSTICS: Puls Ox 100% Room Air.

History: none. 10/14/09 ED records received service date 10/12/09. Occasional alcohol use.

Prex Illness: no.

Prex Vax Illns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Vaers Id: 360874-1

<u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Gender Days 28.0 Μ 13-Oct-2009 13-Oct-2009 0 14-Oct-2009 15-Oct-2009 ΤN 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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: 10/13/09 MedImmune Flu Mist at 630PM. C/O dizziness shortly after. Observation: VS, P 84, R 20, B/P 130/80: Color good after having pt rest with cool

cloth. He was able to stand and walk with steady gait. Refuse - 911 ask to allow friend to be called.

Other Meds: Unknown

Lab Data: Flu Mist Clinic

History: NKDA

Prex Illness: Brief dizziness

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 360877-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received	Date S	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
4.0	F	08-Oct-2009	12-Oct-2009	4	14-Oct-20	009 1	4-Oct-2009	PA		14-Oct-2009
VAX Detai	il: Type	Man	<u>ufacturer</u>		<u>Lot</u>	Prev Dose	es S	<u>Site</u>	Route	Other Vaccine
	MMR	MER	CK & CO. INC.		0764Y	1	Lef	t arm	Subcutaneously	
	FLUN	I(H1N1) MED	IMMUNE VACCINES	INC.	500754P	0	Unk	nown	Unknown	
	DTAF	SAN	OFI PASTEUR		C3142AA	4	Lef	t arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye pain, Headache, Lethargy, Pyrexia

Symptom Text: Woke up lethargic, with severe headache, and fever (Temp 101.5). Neck supple. Advised tylenol for H/A & fever. Called back for office visit that evening.

Temp up to 102.5 oral with eye pain, head pain top & front of head.

Other Meds:

Lab Data:

History: None.

Prex Illness: No.

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 29

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

Vaers Id: 360880-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received D	<u>Date</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
25.0	F	07-Oct-2009	08-Oct-2009	1	14-Oct-20	09	15-Oct-2009	NE		15-Oct-2009
VAX Deta	ail: Type	<u>Ma</u>	<u>nufacturer</u>		<u>Lot</u>	Prev Do	oses	<u>Site</u>	Route	Other Vaccine
	FLU	SA	NOFI PASTEUR		UP002AA	7	U	Inknown	Intramuscular	
	FLUN	I(H1N1) ME	DIMMUNE VACCINES	S, INC.	500751P	0	U	Inknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Pt. had hives and itching approx. 5 hrs. post administration.

Other Meds: No Lab Data: None

History: Penicillin & Sulfa

Prex Illness: No Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 360902-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days LA 9.0 Μ 14-Oct-2009 14-Oct-2009 0 14-Oct-2009 15-Oct-2009 21-Oct-2009

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500756PUnknownUnknownFLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Hyperhidrosis, Mechanical urticaria

Symptom Text: Sweating, flushing of face, and dermatographism treatment Benadryl and Motrin.

Other Meds:

Lab Data:

History: Rocephin; local reation to seasonal flu vaccine several years ago

Prex Illness: no

Prex Vax IIIns: local reaction~Influenza (Seasonal) (no brand name)~~0.00~Patient

VAERS Line List Report

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

Vaers Id: 360905-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 42.0 F 14-Oct-2009 14-Oct-2009 14-Oct-2009 15-Oct-2009 OR 0 21-Oct-2009 Site VAX Detail: Type Prev Doses Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Chest pain, Dyspnoea

Symptom Text: shortness of breath, tightness in chest, pain in chest

Other Meds:

Lab Data:

History: None.
Prex Illness: None.

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 32

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

Vaers Id: 360991-1

Onset Date Days **Received Date** Mfr Report Id <u>Age</u> Gender **Vaccine Date Status Date** State **Last Edit Date** 3.0 13-Oct-2009 13-Oct-2009 15-Oct-2009 28-Oct-2009 PΑ Μ 0 29-Oct-2009 Site VAX Detail: Type Prev Doses **Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Croup infectious

Symptom Text: Croup symptoms - 12 hr after mist given with fever. Steroids given.

Other Meds:

Lab Data:

<u>History:</u> H/O Croup Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361015-1

<u>Age</u>	<u>Gender</u>	Vaccine Da	ate Onset Date	Days	Received D	<u>ate</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
29.0	M	Unknown	n Unknown		15-Oct-200)9	16-Oct-2009	OK		16-Oct-2009
VAX Deta	ail: Type	<u>!</u>	<u>Manufacturer</u>		<u>Lot</u>	Prev Do	ses	<u>Site</u>	Route	Other Vaccine
	FLUN	N(H1N1) I	MEDIMMUNE VACCINE	S, INC.	500758P	0	U	nknown	Unknown	
	FLUN	J I	MEDIMMUNE VACCINES	S, INC.	NULL	0	U	nknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: None. H1N1 nasal mist given same day as FLUMIST.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361016-1

Age	Gender	Vaccine Da	ote Onset Date	<u>Days</u>	Received D	ate	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
7.0	F	Unknown	Unknown		15-Oct-200	09	16-Oct-2009	OK		16-Oct-2009
VAX Deta	ail: Type	<u> </u>	<u>Manufacturer</u>		<u>Lot</u>	Prev Dos	ses	<u>Site</u>	Route	Other Vaccine
	FLUN	N(H1N1) N	MEDIMMUNE VACCINES	, INC.	500758P	0	Uı	nknown	Unknown	
	FLUN	N N	MEDIMMUNE VACCINES	, INC.	NULL	0	Uı	nknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: None. H1N1 nasal mist given same day as FLUMIST.

Other Meds: None

Lab Data:
History:
Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361018-1

<u>Age</u>	<u>Gender</u>	Vaccine Da	te Onset Date	Days	Received I	<u>Date</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
50.0	F	14-Oct-2009	9 14-Oct-2009	0	15-Oct-20	009	16-Oct-2009	CA		16-Oct-2009
VAX Det	ail: Type	<u>N</u>	lanufacturer		<u>Lot</u>	Prev Do	ses	<u>Site</u>	Route	Other Vaccine
	FLU	N(H1N1) M	MEDIMMUNE VACCINES	S, INC.	500759P	0	U	nknown	Unknown	
	FLU	N	IOVARTIS VACCINES A	AND	960363P	0	L	eft arm	Intramuscular	

DIAGNOSTICS
Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Rash

Symptom Text: Rash on neck, head, arms, and slightly on legs - began approx. 2 hours after vaccine was administered. No treatment given.

Other Meds: LIPITOR; Levothyroxine

Lab Data:

History: Hypothyroidism; Hyperlipidemia

Prex Illness: Back pain

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 36

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

Vaers Id: 361024-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F KS 31.0 13-Oct-2009 13-Oct-2009 0 15-Oct-2009 16-Oct-2009 16-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Condition aggravated, Cough, Headache, Wheezing

Symptom Text: WHEEZING, HEAD ACHE, STOMACH ACHE AND COUGHING

Other Meds:

Lab Data: X RAYS SO FAR AND INHALER

History: none

Prex Illness: wheezing, and short of breath with head ache and stomach aches

Prex Vax IIIns:

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

Page 37

Vaers Id: 361049-1

Gender **Vaccine Date Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** 3.0 F 07-Oct-2009 08-Oct-2009 15-Oct-2009 16-Oct-2009 CA 16-Oct-2009 1

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500760P0UnknownUnknownFLUN

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety

Symptom Text: SUDDEN ONSET ANXIETY

Other Meds: Lab Data:

History: NO

Prex Illness: NO

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

Vaers Id: 361065-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 44.0 U 15-Oct-2009 15-Oct-2009 15-Oct-2009 29-Oct-2009 ΑZ 0 29-Oct-2009 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea

Symptom Text: SOB, tightness in the chest

Other Meds: Lab Data:

History: None Prex Illness: none

VAERS Line List Report

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

Vaers Id: 361123-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 13.0 F 14-Oct-2009 15-Oct-2009 16-Oct-2009 19-Oct-2009 CA 1 23-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500760 Unknown Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash on both legs, arms, buttocks and waist. She was given Benadryl-D.

Other Meds:

Lab Data:

History: no Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361124-1

Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days State <u>Age</u> 45.0 F 15-Oct-2009 15-Oct-2009 0 16-Oct-2009 16-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia facial

Symptom Text: Right side of mouth to chin became red and numb. Over the next 10 minutes or so whole face, from eyes down became numb. No breathing problems.

Numbness/redness lasted 4 hours then slowly subsided.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax Illns: redness, swollen arm~Influenza (Seasonal) (Fluvirin)~~0.00~Patient

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

Vaers Id: 361137-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 32.0 F 14-Oct-2009 14-Oct-2009 0 16-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash

Symptom Text: Pt c/o itching and rash from neck down to thighs for 3 hrs. Itching subsided, redness still present 48 hrs later. BENADRYL relieved itching. Denies any

respiratory problems.

Other Meds: Depo-shot 1 1/2 months ago

Lab Data:

History: None Prex Illness: None

Prex Vax Ilins:

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

Vaers Id: 361140-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 45.0 F 15-Oct-2009 15-Oct-2009 0 16-Oct-2009 29-Oct-2009 NY 29-Oct-2009 VAX Detail: Type <u>Lot</u> Site Manufacturer **Prev Doses** Other Vaccine Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Throat irritation

Symptom Text: c/o hives across trunk of body and scratchy throat- relieved by BENADRYL. 7 hrs later after receiving vaccine.

Other Meds:

Lab Data:

History: Allergy Penicillin, E-mycin, tetracycline, Sulfa and Celebrex

Prex Illness: None

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

Vaers Id: 361200-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 5.0 F CA 14-Oct-2009 15-Oct-2009 1 16-Oct-2009 16-Oct-2009 19-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P Unknown Unknown
FLU SANOFI PASTEUR U3205CA Left arm Intramuscular

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Vomiting

Symptom Text: At dinner time child vomited and fever was 100 degree Fahrenheit. Mother gave Ibuprofen every 6 hours and fever continued off and on. This morning vomited

again and fever went to 102 degree Fahrenheit.

Other Meds:

Lab Data:NoneHistory:NonePrex Illness:No

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

Vaers Id: 361202-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 3.0 14-Oct-2009 14-Oct-2009 16-Oct-2009 16-Oct-2009 MA Μ 0 21-Oct-2009 <u>Site</u> VAX Detail: Type Prev Doses Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Respiratory distress, Wheezing

Symptom Text: Croupy cough/wheezing/respiratory distress

Other Meds:

Lab Data: Chest Xray with Right lower lobe infiltrate

History: History of febrile seizures

Prex Illness: None

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

Vaers Id: 361257-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 2.0 F RΙ 14-Oct-2009 15-Oct-2009 1 16-Oct-2009 19-Oct-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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Paraesthesia oral, Swelling face

Symptom Text: Pt was treated at Hasbro ER. Awaiting reports 10/18/09 Spoke with reporter's office. Seen for allergic rxn of facial swelling and itchy tongue and released on

Benadryl

Other Meds:

Lab Data:

History: Recent labwork (9/09) revealed elevated lead level of 10..

Prex Illness:

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

Page 46

Vaers Id: 361259-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 7.0 F 14-Oct-2009 15-Oct-2009 1 16-Oct-2009 19-Oct-2009 PΑ 21-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives - Torso, neck, head, arms, legs. Initial treatment - Benadryl 25 mg. every 6 hrs. Symptoms worsened. Treated with prednisone 10mg. taper and

Hydroyzine 9 ml. every 8 hours

Other Meds: N/A Lab Data: N/A

History: No Allergies MRSA

Prex Illness: NO

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

Page 47

Vaers Id: 361263-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 46.0 IL Μ 09-Oct-2009 12-Oct-2009 3 16-Oct-2009 19-Oct-2009 21-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Malaise, Pain, Rhinorrhoea

Symptom Text: runny nose, headache that increased in intendsity over 2 days, Body aches by 3rd day of symptoms with c/o malaise

Other Meds: vitamin, Fish oil

<u>Lab Data:</u> No testing-

History: minor-mold treated with OTC meds

Prex Illness: none

VAERS Line List Report

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

<u>Vaers Id:</u> **361270-1** <u>Related reports:</u> 361270-2

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 5.0 15-Oct-2009 15-Oct-2009 CT Μ 0 16-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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Croup infectious, Stridor

Symptom Text: 4 hours after vaccine -pt had severe strider - received EPONEPHRINE and ambulance transport to ED. Dx spasmoodic croup

Other Meds: None

Lab Data:

History: None

Prex Illness: Upper respiratory

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361270-2 (S) Related reports: 361270-1 Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days CT 5.0 М 15-Oct-2009 15-Oct-2009 0 20-Oct-2009 22-Oct-2009 500757PMEDIMMUNE 26-Oct-2009 **VAX Detail:** Site **Other Vaccine Type** Manufacturer Lot **Prev Doses** Route FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500757 Unknown Unknown

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Condition aggravated, Cough, Croup infectious, Cyanosis, Dyspnoea, Stridor, Tachypnoea, Vomiting

Symptom Text: CROUP SOUNDING COUGH-WITHIN 3-5 MINUTES..HE COULD NOT BREATH,OR EVEN TRIED CRYING-HE WAS NOT ABLE TO GET AIR IN HIS

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

Dx: Acute Croup

Other Meds:

Lab Data: XRAYS TAKEN @ CLINIC TO CHECK FOR OBSTRUCTIONS-N/A.. Lab: none Dx studies: CXR and Xrays of neck normal

History: NO PMH: Otitis Media Allergies: Bactrim and Keflex 10/22/09 PCP records service dates 9/7/09 to 10/7/09. PMH: Clear fluid from nares. Dizziness secondary

rrom epistaxis

Prex Illness: WOKE UP IN THE MORNING OF 10/15/09 W\SLIGHT COUGH-NO FEVER-SENT TO SCHOOL-WAS OK ALL DAY-SO I WENT AHEAD WITH THE VACCINE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361275-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State Age ΑZ 3.0 Μ 14-Oct-2009 15-Oct-2009 1 16-Oct-2009 19-Oct-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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Diet refusal, Urine output decreased, Vomiting

Symptom Text: Temp of 99 degrees began on 10/15/2009, axillary temp in the am 10/16/2009 was 101.5 degrees farenheight, vomited x1 10/16/2009. No void over 18 hours,

refused fluids. Seen in our office today 10/16/2009 for fluids. After 2 hours of pushing fluids pt voided.

Other Meds: none Lab Data: None

<u>History:</u> No known allergies or chronic conditions

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 361281-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 25.0 F 09-Oct-2009 10-Oct-2009 16-Oct-2009 19-Oct-2009 WA 1 19-Oct-2009 Site VAX Detail: Type Prev Doses Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Cough, Rhinorrhoea

Symptom Text: 102.5 F temp at highest, cough, runny nose

Other Meds: None
Lab Data: none
History: none
Prex Illness: no
Prex Vax Illns:

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

Vaers Id: 361291-1

<u>Age</u>	<u>Gender</u>	Vaccine [Onset Date	<u>Days</u>	Received D	ate St	atus Date	<u>State</u>	Mfr Report Id	Last Edit Date
7.0	F	14-Oct-20	009 14-Oct-2009	0	16-Oct-200	9 19	-Oct-2009	OK		19-Oct-2009
VAX Deta	ail: Type	<u> </u>	<u>Manufacturer</u>		<u>Lot</u>	Prev Doses	<u>s</u> <u>S</u>	ite	Route	Other Vaccine
	FLUN	N(H1N1)	MEDIMMUNE VACCINE	S, INC.	500759P	0	Unk	nown	Unknown	
	FLU		SANOFI PASTEUR		U3210AA	0	Righ	it arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Hallucination, visual, Headache, Muscle twitching, Nausea, Pain, Respiratory tract infection viral

Symptom Text: headache, body aches, and nausea; No fever, no vomiting on night of 10/14. s/s continued until 10/15, when child developed "twitching" and visual

hallucinations of "dancing purple hearts" Child was taken to hospital ED 10/15, dx: "viral respiratory illness." Developed cough on 10/16. No congestion, No

fever, No stiff neck, no diarrhea. Mother treating with tylenol.

Other Meds:tylenolLab Data:none knownHistory:none known

Prex Illness: none

VAERS Line List Report

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

Vaers Id: 361297-1

Gender Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date** State **Last Edit Date** 2.0 09-Oct-2009 14-Oct-2009 16-Oct-2009 19-Oct-2009 OR Μ 5 19-Oct-2009 VAX Detail: Type <u>Lot</u> Prev Doses Site Manufacturer Other Vaccine Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P Unknown Unknown
DTAP SANOFI PASTEUR C3141AA 2 Left leg Intramuscular

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: urticarial rash with no other likely precipitating cause. Treated with benedryl. No respiratory or GI symptoms.

Other Meds:

Lab Data: none
History: no
Prex Illness: no

Prex Vax IIIns:

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

Vaers Id: 361302-1

Days Mfr Report Id Gender **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** Age 31.0 M 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphonia, Chest discomfort, Dysphagia, Dyspnoea, Muscular weakness, Oropharyngeal pain, Throat tightness

Symptom Text: It got harder to swallow food and drink not due to pain but muscle weakness but I did have a slight sore throat. Then at about 2:00 PM after I woke up I had lost

my voice and when I try to talk or if I cough it is very hard to get air out it almost feels like my throat is swollen and a heavy pressure on my chest or lungs(when I take a breath my air movement is good) it is just when I talk or cough. My throat does not bother meat all any more today. I have not seen a Dr. as of yet but I

will go in if I do not get better in the next day or two or instructed by you.

Other Meds: Baclofen 10mg 3x a day Lyrica 75mg 4x a day

Lab Data:

<u>History:</u> Cervical Dystonia **Prex Illness:** Seasonal Allergies

Prex Vax IIIns:

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

Vaers Id: 361325-1

Gender Days State <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** 2.0 F 15-Oct-2009 18-Oct-2009 19-Oct-2009 CA 15-Oct-2009 0 19-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Vomiting

Symptom Text: Diarrhea around 7:30 PM, then at 1:00 AM vomiting, followed by 2 other days of diarrhea. So far, diarrhea continues.

Other Meds:

Lab Data:

History: None Prex Illness: None

VAERS Line List Report

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

Vaers Id: 361328-1

Gender **Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** State 15.0 Μ 15-Oct-2009 16-Oct-2009 18-Oct-2009 19-Oct-2009 OR 1 19-Oct-2009 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Cough, Pain, Pyrexia

Symptom Text: coughing, fever (102.5), chills, achy

Other Meds: none

Lab Data:

History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361332-1

State <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days F ΑZ 24.0 17-Oct-2009 17-Oct-2009 0 18-Oct-2009 19-Oct-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown By Mouth

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Chills, Cough, Dyspnoea, Headache, Myalgia, Nasal congestion, Oropharyngeal pain, Pyrexia

Symptom Text: Headache, Cough, fever, shortness of breath, weakness, nasal congestion, sore throat, fever and chills, abdominal pain, muscle aches

Other Meds:

Lab Data:

History: None Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361343-1

Onset Date Received Date State Mfr Report Id Gender **Vaccine Date Days Status Date Last Edit Date** Age F 14.0 13-Oct-2009 15-Oct-2009 2 18-Oct-2009 19-Oct-2009 FL 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous, Rash pruritic, Urticaria

Symptom Text: Symptoms started Thursday night 10/15 with itchy legs, feet and hands during the night, no rash identified. After the second night(Friday 10/16), small faint red

bumps appeared on lower legs. Sunday morning 10/18 woke to severly itchy rash/hives all over legs, feet, arms, hands and belly. Gave dose of benadryl @

12:10 pm. At this point, almost 3 hours later (2:40 pm) rash and hives are gone. Do not know if they will return after Benadryl wears off.

Other Meds: Focalin XR 10 MG Capsules once daily

Lab Data:

History: None Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 361353-1 (D)

Report run on: 04 NOV 2009 10:32

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received D	ate	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
9.0	F	08-Oct-2009	14-Oct-2009	6	16-Oct-200	09	19-Oct-2009	CA		28-Oct-2009
VAX Deta	il: Type	<u>Man</u>	<u>ufacturer</u>		<u>Lot</u>	Prev Do	ses	<u>Site</u>	Route	Other Vaccine
	FLU	SAN	OFI PASTEUR		U3203AA	2	L	eft arm	Intramuscular	
	FLUN	(H1N1) MED	IMMUNE VACCINES	i. INC.	500751P	0	U	Inknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Apnoea, Cardiac arrest, Chills, Death, Lividity, Lung consolidation, Mydriasis, Pallor, Pupil fixed, Resuscitation

Symptom Text: None Stated. On 10/19/09, the PCP stated that coroner called him and told him that he found consolidation of the lungs on autopsy. Autopsy report is not

complete yet. 10/20/09 ER records received service date 10/14/09. Assessment: Cardiac arrest. CPR initiated. Pupils fixed and dilated. Apnea, pale. Rigor, lividity. 1022/09 PCP /Nursing medical records received, service dates 11/11/03 to 10/14/09. Assessment: Death. Office staff unable to contact patient's family.

eventually visited patient's home. learnd that patient was found dead at home and taken to ER.

Other Meds: None

Lab Data: CBC: 2.5, 7.5, 21.3, 207; Sed rate 125. 10/20/09 ER records received service date 10/14/09. LABS and Diagnostics: EEG - Asystole. CHEM - Glucose 107

mg/dL (H) Calcium 3.5 mg/dL (L) Albumin 3.4 g/dL (L) Alk Phos 170 U/L (L). CBC - WBC 2.5

History: H/O Leukemia 2002; Down's Syndrome. 1022/09 PCP /Nursing medical records received, service dates 11/11/03 to 10/14/09. Down Syndrome. Cough, fever.

Frequent colds. Discharge from eyes. Vomiting and diarrhea. Lymphadenopathy. Foot pain. CBC abnormal.

Prex Illness: Limping

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 361426-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 46.0 F 16-Oct-2009 18-Oct-2009 2 19-Oct-2009 20-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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug eruption, Rash erythematous, Rash macular

Symptom Text: Noticed diffuse macular red rash/drug eruption rash over entire trunk, lower extremities and some on arms. Also on neck and around hair line.

Other Meds:

Lab Data:

<u>History:</u> allergy to sulfa no other medical conditions

Prex Illness: not ill

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361430-1

Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days State <u>Age</u> 11.0 F 18-Oct-2009 19-Oct-2009 1 19-Oct-2009 20-Oct-2009 PΑ 20-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

<u>Seriousness:</u> NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Vomiting

Symptom Text: Severe stomach pains and vomiting. Vomited 12 times within 2 hours. Severe stomach pains subsided after 1.5 hour, but vomiting continued. Stomach pains

so severe that she was writhing on the floor and in bed. After 3 hours, no additional vomiting or pains.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id:	361454-1	Relat	ed reports: 361454-2							
<u>Age</u>	Gender	Vaccine I	Date Onset Date	Days	Received Date		Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
1.3	F	19-Oct-20	Unknown		19-Oct-20	009	20-Oct-2009	GA		20-Oct-2009
VAX Detai	I: Type	<u> </u>	<u>Manufacturer</u>		<u>Lot</u>	Prev Dos	ses	<u>Site</u>	Route	Other Vaccine
	FLUN	N(H1N1)	MEDIMMUNE VACCINES	, INC.	500754P	0	Ur	nknown	Unknown	
	DTAI	Þ	SANOFI PASTEUR		U2470BA	3	L	eft leg	Intramuscular	
	FLU		SANOFI PASTEUR		U3260AA	0	Ri	ight leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: vaccine administered to a 15 month old. vaccine licensed for 24 month and up. No adverse reaction at this time

Other Meds:MOTHER DENIESLab Data:none at this timeHistory:mother deniesPrex Illness:mother denies

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id:	361454-2	Relate	ed reports	<u>:</u> 361454-1								
<u>Age</u>	<u>Gender</u>	Vaccine D	<u>ate</u>	Onset Date	<u>Days</u>	Received I	<u>Date</u>	Status Date	<u> </u>	State	Mfr Report Id	Last Edit Date
1.3	F	19-Oct-20	009	19-Oct-2009	0	19-Oct-20	009	20-Oct-2009) (GA		21-Oct-2009
VAX Detai	il: Type		Manufact	urer		<u>Lot</u>	Prev D	oses	<u>Site</u>		<u>Route</u>	Other Vaccine
	FLUN	I(H1N1)	MEDIMM	UNE VACCINES	, INC.	500754P	0	ι	Unknown		Unknown	
	DTAF	•	SANOFI I	PASTEUR		U2470BA	3		Left leg		Intramuscular	
	FLU		SANOFI I	PASTEUR		U3260AA	0	F	Right leg		Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: H1N1 INFLUENZA ADMINISTERED TO 15 MONTH OLD. LICENSED FOR 24 MONTH'S AND UP. NO ADVERSE SYMPTOMS AT THIS TIME.

Other Meds:MOTHER DENIESLab Data:NONE AT THIS TIMEHistory:MOTHER DENIESPrex Illness:MOTHER DENIES

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361493-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 31.0 F 15-Oct-2009 15-Oct-2009 19-Oct-2009 20-Oct-2009 KS 0 20-Oct-2009 Site VAX Detail: Type <u>Lot</u> Prev Doses Manufacturer Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PTChest discomfort, WheezingSymptom Text:Thightness of chest, wheezing

Other Meds:

<u>Lab Data:</u> patient failed to mention had history of egg allergy

History: history of asthma

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361494-1

Gender **Vaccine Date Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** 49.0 Μ 15-Oct-2009 16-Oct-2009 19-Oct-2009 20-Oct-2009 MT 20-Oct-2009 1 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tinnitus

Symptom Text: Left Ear tinnitis

Other Meds:

Lab Data: none
History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361499-1

Mfr Report Id Gender **Vaccine Date Onset Date** Days **Received Date Status Date** State **Last Edit Date** Age F 7.0 16-Oct-2009 19-Oct-2009 3 19-Oct-2009 20-Oct-2009 VA 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. UNKNOWN 0 Unknown Unknown FLUN

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Inappropriate schedule of drug administration, Pyrexia, Respiratory tract congestion

Symptom Text: PT WITH FEVER, CONGESTION, STOMACH ACHE. MOM REALIZED THAT PATIENT HAD RECEIVED FLUMIST IN OUR OFFICE ON 10/02/2009 AND

THEN RECEIVED THE H1N1 MIST AT SCHOOL THROUGH THE HEALTH DEPARTMENT ON 10/16/2009. MOM HAD SIGNED PERMIT TO GIVE AND

ANSWERED THE QUESTION ABOUT LIVE VACCINE IN THE LAST 30 DAYS INCORRECTLY.

Other Meds:

Lab Data:NONEHistory:NONEPrex Illness:NONE

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 361523-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> 33.0 F 16-Oct-2009 17-Oct-2009 1 19-Oct-2009 20-Oct-2009 ΜI 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500779P Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Myalgia, Oedema peripheral, Pain, Vomiting, Wheezing

Symptom Text: vomiting x4 from 1:00 - 6:00am, muscle aches to whole body 8:30am, chills, no fever 11-17-09, 10-18-09 c/o pain to hands, arms legs feet & lower back. 10-19-

09 swelling noted to all extrimites, wheezing started 6:00am.

Other Meds:

Lab Data: influenza A & B neg strep test neg

History: allergic to sulfa

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361532-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 22.0 F 18-Oct-2009 19-Oct-2009 19-Oct-2009 20-Oct-2009 ОН 1 20-Oct-2009 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764 P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, Vomiting

Symptom Text: Diarrhea, Nausea, Vomiting

Other Meds: Ortho tricyclin

Lab Data:

History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report Report run on: 04 NOV 2009 10:32 Page 69

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

Vaers Id: 361563-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received Da	ate Sta	tus Date	State	Mfr Report Id	Last Edit Date
29.0	F	16-Oct-2009 17-Oct-2009		17-Oct-2009 1		9 29-0	Oct-2009	WA		29-Oct-2009
VAX Detai	I: Type	Manu	<u>ufacturer</u>		<u>Lot</u>	Prev Doses	Site		Route	Other Vaccine
	FLU	~	KOSMITHKLINE OGICALS		AFLLA283AA	1	Left ar	m	Intramuscular	
	FLUN	_	IMMUNE VACCINES	, INC.	500764P	0	Unknov	vn	Unknown	

NO CONDITIONS, NOT SERIOUS Seriousness:

MedDRA PT Diarrhoea, Fatigue, Headache, Hot flush, Nausea

Symptom Text: Nausea, headache, fatigue, hot flashes-(no actual fever), diarrhea. No treatment required.

Other Meds:

Lab Data: None History: None

Prex Illness: Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361578-1

Onset Date Received Date Status Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date Days** State Age F 24.0 15-Oct-2009 15-Oct-2009 0 19-Oct-2009 20-Oct-2009 ΜI 20-Oct-2009 **Type** Site VAX Detail: **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 50751P 0 Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous, Rash macular

Symptom Text: Had a rash that started on her legs with intense itching. The rash was very red and blotchy (she said it looked strange), somewhat raised. It moved up to her

neck and back. She asked her boss, who is a physician and he gave her an allergy medication. She did not know the name. She did say it was not Benadryl.

She said she had the rash for a couple of days and continued to take the medication for that time. She has no known allergies

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361586-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days CA 4.0 Μ 15-Oct-2009 18-Oct-2009 3 19-Oct-2009 20-Oct-2009 20-Oct-2009 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: 4 y/o previously healthy boy with history of erythema multiforme reaction to penicillin (3/16/09) took H1N1 FLUMIST 10/15/09 and developed itchy hive like rash

10/18/09. Seen in clinic 10/19 for hives (some almost erythema multiforme appearing).

Other Meds: None

Lab Data:

History: Erythema multiforme reaction to penicillin 3/16/09, resolved

Prex Illness: None

Prex Vax IIIns:

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

Page 72

Vaers Id: 361590-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 5.0 F 15-Oct-2009 15-Oct-2009 0 19-Oct-2009 20-Oct-2009 NJ 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on arms. Advised mother to give benadryl and call if no better. No shortness of breath, no vomiting. Hives went away after one dose of benadryl.

Other Meds: Tums chewable was also given on the same day.

Lab Data: none History: none

Prex Illness: patient had a stomach ache, but no nausea, vomiting or fever.

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

Vaers Id: 361591-1

Gender **Onset Date** Days Mfr Report Id <u>Age</u> **Vaccine Date Received Date Status Date** State **Last Edit Date** 5.0 F 15-Oct-2009 16-Oct-2009 19-Oct-2009 20-Oct-2009 NJ 1 20-Oct-2009 VAX Detail: Type <u>Lot</u> Site Manufacturer **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Fatigue, Pyrexia, Sneezing

Symptom Text: Fever up to 102, cough, sneezing, fatigue. Advised to give motrin, watch symptoms. Call if any changes

Other Meds: Lab Data:

History: no
Prex Illness: no

VAERS Line List Report

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

Vaers Id: 361617-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 15.0 F 14-Oct-2009 18-Oct-2009 4 20-Oct-2009 21-Oct-2009 NJ 21-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Cough, Lung disorder, Throat irritation

Symptom Text: patient began complaining of throat burning, lungs burning that feels like after she is running. She also has a dry cough. No fever. Asked mother to just

monitor symptoms, and let us know if they don't resolve or they get worse.

Other Meds:

Lab Data:

History: no Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361620-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 53.0 F 17-Oct-2009 17-Oct-2009 20-Oct-2009 21-Oct-2009 SC 0 21-Oct-2009 <u>Site</u> VAX Detail: Type Manufacturer Lot **Prev Doses** Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Heart rate increased, Inappropriate schedule of drug administration, Urticaria

Symptom Text: Redness, increased heart rate, slight hives

Other Meds: birth control

Lab Data:

History: kidney stone

Prex Illness: none

Prex Vax IIIns:

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

Vaers Id: 361636-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State Age F 28.0 16-Oct-2009 17-Oct-2009 1 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500776P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Muscular weakness

Symptom Text: On October 17 & 18 had 5 episodes where my knees went weak & felt like jelly causing me to fall to the ground. Only lasted a few seconds & there was no

numbness at all. Just felt like jelly and gave out. Called local hospital (I was out of town) and talked to Doc on call. Told me if it got worse to come to ED

otherwise report the employer as possible reaction to H1N1 vaccine.

Other Meds: MIRTIPINE; DISIPTIMINE; ORTHO TRI CYCLIN

Lab Data:

History: Coarctation of aorta; VSD

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 361638-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F TN 20.0 14-Oct-2009 Unknown 20-Oct-2009 21-Oct-2009 21-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: H1N1 mist was provided to pt during early pregnancy. Provider was not aware pt. was pregnant at the time she administered vaccine. Pt. not "late" on menstrual

cycle at time of administration.

Other Meds: FLEXERIL

Lab Data:

History: None

Prex Illness: None except unknown pregnancy

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361646-1

Gender **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date** State **Last Edit Date** Days 1.9 F 09-Oct-2009 21-Oct-2009 UT Unknown 20-Oct-2009 21-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Mother documented wrong age & incorrect DOB. Child was too young not two years old.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361647-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days CA 4.0 Μ 12-Oct-2009 13-Oct-2009 1 20-Oct-2009 21-Oct-2009 21-Oct-2009 VAX Detail: Site Type **Prev Doses** Other Vaccine

 VAX Detail:
 Type
 Manufacturer
 Lot
 Prev Doses
 Site
 Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Pyrexia, Respiratory tract congestion

Symptom Text: Developed 103-104 fever 12-16 hours after receiving H1N1 vaccine (live). Also has cough & congestion. No treatment other than symptomatic treatment with

TYLENOL/ADVIL, flds, etc. Sibling given H1N1 same day. No fever until 4 days after receiving vaccine.

Other Meds:NoneLab Data:NoneHistory:NonePrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361654-1

Gender **Onset Date Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** Days 66.0 F 14-Oct-2009 20-Oct-2009 21-Oct-2009 GΑ Unknown 21-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: None.

Other Meds: None
Lab Data: None
History: None
Prex Illness: None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 361660-1

Vaccine Date Onset Date Received Date Status Date State Mfr Report Id **Last Edit Date** Age Gender Days OR 6.0 Μ 12-Oct-2009 12-Oct-2009 0 20-Oct-2009 22-Oct-2009 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Hyperhidrosis, Pallor

Symptom Text: 915 gave patient H1N1 spray - while giving sibling N/S H1N1 I noticed patient very pale - complained of stomach ache - laid down & put cool cloth on forehead

- BP 90/60, HR-80 - diaphoretic - T-97.4 ax. 9:30 recovered & went home. Mom thought anxiety attack.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax Illns:

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

Vaers Id: 361665-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 40.0 F 15-Oct-2009 16-Oct-2009 20-Oct-2009 21-Oct-2009 MI 21-Oct-2009 1

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Pain, Pyrexia

Symptom Text: fever, body aches weak

Other Meds: Lab Data:

History: no no no

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

Vaers Id: 361666-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F NC 4.0 16-Oct-2009 16-Oct-2009 0 20-Oct-2009 21-Oct-2009 21-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Vomiting

Symptom Text: Began with fever after receiving H1N1 intranasal vaccine on Friday, fever 103 Monday, 10/19, vomitting began Tuesday, 10/20--referred to pediatrician for eval.

Other Meds: None reported, mom denied reactions to prior vaccinations

Lab Data:

History: None reported

Prex Illness: None reported, mom denied asthma or wheezing last 12 mos.

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

Vaers Id: 361669-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 20.0 Μ 19-Oct-2009 19-Oct-2009 0 20-Oct-2009 21-Oct-2009 NE 21-Oct-2009

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

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode lasting approx. 30 seconds. BP 80/40. P 40. Given PO fluids and carbohydrate snack, elevated feet. VS stable within 5 minutes (116/70, P

64).

Other Meds:

Lab Data:

History: sports induced asthma as a child

Prex Illness: Headache, no fever-later discovered hadn't eaten since breakfast

VAERS Line List Report

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

Vaers Id: 361671-1

Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days State <u>Age</u> 22.0 F 15-Oct-2009 15-Oct-2009 0 20-Oct-2009 21-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Feeling cold, Feeling hot, Syncope

Symptom Text: 11:50AM felt hot after receiving FLUMIST then lightheaded and dizzy at 12:10pm fainted when she awoke after about 2-3 minutes felt "out of it" very cold B/P

118/84, P 80. Laid on table did not get up on her own until 2:30pm.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361684-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 6.0 F 15-Oct-2009 15-Oct-2009 MT 0 20-Oct-2009 21-Oct-2009 21-Oct-2009

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

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Productive cough, Pyrexia

Symptom Text: Low grade Fever (not taken with a thermometer). Had a cough productive of small amount of sputum

Other Meds: No regular medications

Lab Data: None

<u>History:</u> Viral induced asthma about once a year

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361688-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days 6.0 M 16-Oct-2009 16-Oct-2009 0 20-Oct-2009 21-Oct-2009 CA 21-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Increased upper airway secretion, Nasal congestion, Nasopharyngitis

Symptom Text: By the time we went to swim class at 4:30 his nose was signifigantly congested! HE RECEIVED THE NASAL VACCINE, NOT NEEDLE. By 10/17/09 he

seemed to have a moderate cold. By 10/19/09 he had a pretty bad cough (I could hear phlegm in his lungs). He still has this cough which wakes him at night today, 10/20/09. He has only had coughs twice in his life. He generally developes cold symptoms without cough. He's never had a flu in his life. I think this moderate to severe cold with cough is directly related to the nasal vaccine. He has had no fever so far, but it is 4 days after the vaccine, and he's still sick. I

Unknown

thought this was worth reporting, since it is causing pretty bad coughing.

Other Meds: It is important to note my son has NEVER had even mild syptoms following a vaccine of any kind. That is why I think this is signifigant.

Lab Data:

History: None

Prex Illness: None whatsoever!

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361696-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 4.0 F GΑ 20-Oct-2009 20-Oct-2009 0 20-Oct-2009 22-Oct-2009 22-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500776P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis, Haematemesis

Symptom Text: Pt began to have a severe nosebleed. Pt also began to vomit clots of blood. Provider applied Neosynephrine to a cotton ball and packed pt nose.

Other Meds:

Lab Data:

History:

Prex Illness: N/a

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361723-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 6.0 F 16-Oct-2009 20-Oct-2009 22-Oct-2009 19-Oct-2009 3 22-Oct-2009 VAX Detail: Type Prev Doses Site Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 50759P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Fatigue, Pyrexia

Symptom Text: Fever, stomach discomfort and fatigue

Other Meds:

Lab Data:

History: Fine Mmtor delay

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361763-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 16.0 Μ 14-Oct-2009 17-Oct-2009 3 20-Oct-2009 30-Oct-2009 MA 31-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500761 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Headache, Oropharyngeal pain, Pyrexia, Vomiting

Symptom Text: About 3 days after H1N1 Flu Vax he developed cough sore throat headache, and active fever. He also vomited 3 times with no diarrhea.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361843-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received Da	ate Status	Date State	Mfr Report Id	Last Edit Date
3.0	F	14-Oct-2009	16-Oct-2009	2	20-Oct-200	9 31-Oct	-2009 CA		01-Nov-2009
VAX Deta	ail: Type	Mai	nufacturer		<u>Lot</u>	Prev Doses	Site	Route	Other Vaccine
	FLUN	(H1N1) ME	DIMMUNE VACCINES	INC.	500776P	0	Unknown	Unknown	
	HEPA		AXOSMITHKLINE LOGICALS		AHAVB286AA	1	Right arm	Unknown	
	HIBV	SAI	NOFI PASTEUR		UF577AA	3	Left arm	Unknown	
	VARC	EI ME	RCK & CO_INC		0228Y	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash

Symptom Text: Rash on torso, fever.

Other Meds:

Lab Data: History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

<u>Vaers Id:</u> 361844-1 (S) <u>Related reports:</u> 361844-2

Mfr Report Id Gender **Vaccine Date Onset Date Days Received Date Status Date** State **Last Edit Date** Age F 38.0 17-Oct-2009 17-Oct-2009 0 20-Oct-2009 26-Oct-2009 IΑ 28-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest discomfort, Fatigue, Headache, Influenza serology negative, Pain, Pyrexia, Vomiting

Symptom Text: Received intranasal vaccine-4 hrs later began to get a headache and chest discomfort as well as achy all over. Fever 102-103. Headache became severe.

Aches all over, fatigued, vomiting. Has not been around ill people-no one in household ill. Her rapid test for Influenza was negative for A and B.

Other Meds: CYMBALTA; LYRICA-stopped using; multivitamin

Lab Data: WBC-3.7;blood c/s-negative; UA-clear; chloride 107

History: Fibromyalgia; hx MVA; 3 C-sections

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Related reports: 361844-1 Vaers Id: 361844-2 (S) <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 16-Oct-2009 17-Oct-2009 38.0 1 23-Oct-2009 28-Oct-2009 IΑ 28-Oct-2009 VAX Detail: Site Type Manufacturer Lot **Prev Doses** Route Other Vaccine

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cough, Dyspnoea, Ocular hyperaemia, Pyrexia

Symptom Text: Fever 102 degrees, cough, shortness of breath & red eyes.

Other Meds: CYMBALTA; Multivitamin

Lab Data: Influenza A antigen - negative; Influenza B antigen - negative

History: Fibromyalgia

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361848-1

Gender **Onset Date** Days Mfr Report Id <u>Age</u> **Vaccine Date Received Date Status Date** State **Last Edit Date** 41.0 19-Oct-2009 20-Oct-2009 20-Oct-2009 ОН Μ 1 22-Oct-2009 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500779P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia oral

Symptom Text: Awoke with numbness of upper lip states"like when you have dental work"

Other Meds:

<u>Lab Data:</u> unknown has not gotten medical attention at this time.

History: NONE
Prex Illness: NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361852-1

<u>Age</u>	<u>Gender</u>	Vaccine Da	ote Onset Date	Days	Received D	<u>ate</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
31.0	F	16-Oct-200	9 Unknown		20-Oct-200)9	03-Nov-2009	MA		03-Nov-2009
VAX Deta	ail: <u>Type</u>	<u>N</u>	<u>Manufacturer</u>		<u>Lot</u>	Prev Do	ses	<u>Site</u>	Route	Other Vaccine
	FLUN	N(H1N1) N	MEDIMMUNE VACCINES	, INC.	500761P	0	U	nknown	Unknown	
	FLU	S	SANOFI PASTEUR		U3185AA	0	U	nknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination

Symptom Text: Pt given live, attenuated nasal spray vaccine with PMH of positive HIV

Other Meds: LEVAQUIN; ZOMIG

Lab Data: HIV disease; CD8%=62; CD4=504; Viral load=pending

History: HIV+; migraine

Prex Illness: Cold sts

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361855-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 36.0 F 20-Oct-2009 IL 20-Oct-2009 0 20-Oct-2009 22-Oct-2009 22-Oct-2009 Site VAX Detail: Type <u>Lot</u> Prev Doses Manufacturer Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dysphagia, Pharyngeal oedema, Swollen tongue

Symptom Text: Swelling of throat and tongue, coughing, difficulty swallowing.

Other Meds: None

<u>Lab Data:</u> x-ray completed to check airway, soft tissue and wnl per Dr Othman Jibril.

History: Seasonal allergies

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361860-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 7.0 F 10-Oct-2009 21-Oct-2009 CA 18-Oct-2009 8 20-Oct-2009 21-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Parotid gland enlargement, Pyrexia, Salivary gland pain

Symptom Text: 36 hours ago PT began with (R) parotid swelling and pain, also has fever 102.2.

Other Meds:

Lab Data: Physical exam ENT referral pending

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361872-1

Onset Date Days **Received Date** Mfr Report Id <u>Age</u> Gender **Vaccine Date Status Date** State **Last Edit Date** 12-Oct-2009 15-Oct-2009 20-Oct-2009 22-Oct-2009 CA 9.0 Μ 3 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Swelling face

Symptom Text: SEVERE ALLERGIC REACTION ETIOLOGY UNKNOW. SEVERE SWELLING OF FACE. SEEN IN THE ER.

Other Meds:

Lab Data:noHistory:NONEPrex Illness:NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361876-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 35.0 F 12-Oct-2009 15-Oct-2009 20-Oct-2009 ΑZ 03-Nov-2009 3 03-Nov-2009 Site VAX Detail: Type Prev Doses **Other Vaccine** Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Tingling in hands and feet (interment)last sx 10/20/09

Other Meds: Lab Data:

History: shingles, Bell's Palsy
Prex Illness: Seasonal allergies

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361948-1

Vaccine Date Onset Date Received Date State Mfr Report Id **Last Edit Date** Age Gender Days **Status Date** F 6.0 13-Oct-2009 15-Oct-2009 2 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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: SHE GOT A FEVER ON 10/15. THE FEVER GOT UP TO 104. LASTED UNTIL 10/17. SHE WAS ADVISED TO GO TO THE EMERGENCY ROOM ON 10/17

BY DR., BUT HER FEVER RESOLVED LATER THAT DAY. SHE IS NOW AFEBRILE AS OF 10/17.

Other Meds:

Lab Data:

History: SHE WAS HEALTHY AT TIME OF H1N1 MIST.

Prex Illness: NONE

Prex Vax IIIns:

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

Page 101

Vaers Id: 361957-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F FL 3.0 19-Oct-2009 20-Oct-2009 1 21-Oct-2009 22-Oct-2009 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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash maculo-papular, Rash pruritic

Symptom Text: Itchy rash over entire body (maculopapular)Rx: Orapred 2 1/2 tsp day one, 1 1/2 tsp qd days 2 thru 5, Bendryl 1 tsp q4-6hrs for 24 hours, oatmeal baths

Other Meds:

Lab Data: None done

History: Milk allergy, rash from Zyrtec

Prex Illness: Finishing antibiotic for ecoli in urine?

VAERS Line List Report

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

Vaers Id: 361968-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 3.0 13-Oct-2009 13-Oct-2009 21-Oct-2009 PΑ 03-Nov-2009 Μ 0 03-Nov-2009 **Other Vaccine**

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P Unknown Unknown

NO CONDITIONS, NOT SERIOUS Seriousness:

Croup infectious, Pyrexia MedDRA PT

Symptom Text: Croup symptoms - 12 hr after MIST given with fever. Steroids given.

Other Meds:

Lab Data:

History: H/O croup **Prex Illness:** None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361970-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F CO 36.0 14-Oct-2009 14-Oct-2009 0 21-Oct-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500571P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Urticaria

Symptom Text: This health care worker developed small patches of hives on her arm app 4 hrs after receiving the flu mist-the next day hives were on her chest, thighs, neck,

back, face. Itching relieved with an anti-histamine-reddened areas remained.

Other Meds:

Lab Data:NoneHistory:NonePrex Illness:None

Prex Vax IIIns:

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

Vaers Id: 361987-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 5.0 F 06-Oct-2009 14-Oct-2009 21-Oct-2009 22-Oct-2009 OK 8 22-Oct-2009 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Wheezing

Symptom Text: Coughing and wheezing

Other Meds:

Lab Data:unknownHistory:nonePrex Illness:none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361988-1

<u>Age</u>	<u>Gender</u>	Vaccine D	Onset Date	<u>Days</u>	Received Da	ite Sta	tus Date	<u>State</u>	Mfr Report Id	Last Edit Date
2.0	M	13-Oct-20	09 18-Oct-2009	5	21-Oct-2009	9 22-0	Oct-2009	VT		22-Oct-2009
VAX Deta	ail: Type		<u>Manufacturer</u>		<u>Lot</u>	Prev Doses	v Doses Site		<u>Route</u>	Other Vaccine
	FLUN	N(H1N1)	MEDIMMUNE VACCINE	S, INC.	500759P	0	Unkn	own	Unknown	
	FLU		SANOFI PASTEUR		UT32531A	2	Left	leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Wheezing

Symptom Text: Awoke Wheezing with no previous hx. Given Albuterol Nebulizer treatment and sent home with a machine. Went to ER later that day with increased

symptoms

Other Meds:

Lab Data:

History: None Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 361993-1

Onset Date Received Date State Mfr Report Id Gender **Vaccine Date** Days **Status Date Last Edit Date** Age F SC 33.0 14-Oct-2009 14-Oct-2009 0 21-Oct-2009 22-Oct-2009 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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Headache, Heart rate increased, Pharyngeal oedema

Symptom Text: Client received H1N1 Nasal Mist in am. C/O swelling in throat, SOB, headache, heart beating fast. Advised to get someone to take her to ER. TC from client

@ 4pm - she went to ER, MD advised use of OTC Benadryl and return to ER if breathing worsened or swelling in throat increased. To be off work Wednesday

and Thursday.

Other Meds:

Lab Data: Heart Monitor @ ER

History: No. Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362036-1

State Gender **Vaccine Date Onset Date Days Received Date** Status Date Mfr Report Id **Last Edit Date** Age SC 31.0 M 14-Oct-2009 14-Oct-2009 0 21-Oct-2009 23-Oct-2009 23-Oct-2009 Site VAX Detail: **Type Prev Doses** Manufacturer Lot Route Other Vaccine

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dehydration, Dizziness, Flank pain, Headache, Nausea, Pain, Visual field defect, Vomiting

Symptom Text: Beginning with headache, progressing to severe headache with dizziness and c/o of bilateral flank pain. After 2 days patient returned to work on night shift and

symptoms returned and worsened over subsequent 2 nights of work. On 6th day after administration headache/dizziness was so severe patient experienced vomiting and loss of visual field. Pt was taken to ER by spouse. Treated for dehydration, nausea and pain. Returned home after treatment. Received

prescriptions for pain, dizziness and nausea. Instructed by ER to remain off work x 3 days.

Other Meds: Xanax

Lab Data:

History: OTC treatment of reflux.

Prex Illness: No illness, but patient was very fatigued for just switching to night shift. (Deputy Sheriff vaccinated after first night on du

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362053-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 15-Oct-2009 21-Oct-2009 23-Oct-2009 PΑ 1.1 Μ 15-Oct-2009 0 23-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Rash erythematous, Rash macular, Urticaria

Symptom Text: Very Large red blotchy Hives

Other Meds:

Lab Data: none to date (10/21/09)

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362059-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 30.0 16-Oct-2009 16-Oct-2009 0 21-Oct-2009 23-Oct-2009 TX 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(H1N1) MEDIMMUNE VACCINES, INC. 500756P Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Flushing, Immediate post-injection reaction, Paraesthesia

Symptom Text: C/O FACIAL FLUSHING IMMEDIATELY AFTER RECEIVING H1N1 FLUMIST. C/OLIGHTHEADEDNESS AND DIZZINESS FOR A FEW HOURS. ALSO C/O

TINGLING BEHIND EARS AND NECK AREA.

Other Meds:

Lab Data:NONEHistory:NONEPrex Illness:NONE

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362061-1

Mfr Report Id Gender **Vaccine Date Onset Date Days Received Date Status Date** State **Last Edit Date** Age F 39.0 15-Oct-2009 19-Oct-2009 4 21-Oct-2009 23-Oct-2009 IΑ 23-Oct-2009 VAX Detail: **Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Erythema, Pyrexia, Rash, Rash macular, Swelling face, Urticaria

Symptom Text: Symptoms first noted upon getting out of bed on 10/19/09. Symptoms were not present upon going to bed the night before. When I woke up on 10/19/09 I had

a rash to my face & neck. I also had facial swelling & urticaria. I was running a low grade fever (100 - 100.7). My face & neck felt like it was burning. It was very red & blotchy. I began taking Benadryl which did help alleviate some of the symptoms. On 10/20/09 I was given Kenalog 40 mg IM. As of today, I still

have some facial swelling & I still have the rash to my face & neck though it appears to be slowly resolving.

Other Meds: chlorpheniramine 4 mg daily Phentermine 37.5 mg daily

Lab Data:

History: none
Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362066-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 33.0 11-Oct-2009 11-Oct-2009 0 21-Oct-2009 23-Oct-2009 IN 23-Oct-2009 **VAX Detail: Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

500763P

Seriousness: ER VISIT, NOT SERIOUS

FLUN(H1N1)

MedDRA PT Computerised tomogram normal, Condition aggravated, Hypoaesthesia, Hypoaesthesia oral, Migraine, No reaction on previous exposure to drug, Visual field

defect, Visual impairment

Symptom Text: I am an RN & received the H1N1 Flumist vaccine while at work. Approx. 1 1/2 hrs after receiving vaccine, vision in my rt. eye was affected (wavy lines, loss of

peripheral vision, pieces of field of vision "missing"). This lasted for approx. 30 minutes. I went to the ER because I felt like I was going to lose vision in my rt. eye. Approx. an hour after vision issues resolved, my lips & rt. arm became completely numb; this lasted for several minutes then resolved. A head CT was done, which was normal, but no other treatment was necessary. In 2004, I was diagnosed with atypical migraine (no headache but had temporary stroke-like symptoms similar to this episode) but had had no issues in the last 5 years. I followed up with a neurologist on 10/20/09 & he believes I just had another atypical migraine, but with the length of time since the last episode & the timing of this episode so soon after receiving the vaccine, we felt it should be reported,

Unknown

Unknown

just in case. I typically receive the injectable seasonal flu vaccine & haven't had any issues.

MEDIMMUNE VACCINES, INC.

Other Meds: Ambien hs prn

Lab Data:

History: atypical migraine

Prex Illness: none

Prex Vax IIIns:

Page 111

FLU

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 112

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

Vaers Id: 362069-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 2.0 F 15-Oct-2009 23-Oct-2009 GΑ 15-Oct-2009 0 21-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Pyrexia

Symptom Text: Mother called clinic stating child has had diarrhea and fever since receiving H1N1 flu mist and seasonal flu vaccine on 10/15/09.

Other Meds:

Lab Data: none

History: ANAL STENOSIS

Prex Illness: NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362073-1

Mfr Report Id Gender **Vaccine Date Onset Date Days Received Date Status Date** State **Last Edit Date** Age F 26.0 15-Oct-2009 15-Oct-2009 0 21-Oct-2009 23-Oct-2009 MI 23-Oct-2009 VAX Detail: **Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Corneal abrasion, Eye irritation, Eye pain, Eye pruritus, Eye swelling, Headache, Ocular hyperaemia, Pyrexia

Symptom Text: Eyes were very irritated and they hurt. Took out contacts and eyes continued to hurt. Next am, eyes slightly swollen and very red. She did not wear her

contacts. She wore her glasses. While she was driving to work her eyes swelled shut. Had a severe HA and called her sister to get her and take her to urgent care. Was seen at Urgent care and was given Motrin 800 mg, and Nasocort nose spray. She had to have a patch because the itching was so intense that she scratched her cornea. By Oct 18th her symptoms subsided. She did say she had a fever of 101 in the urgent care. She did not have a fever before receiving

the vaccine. The doctor she saw said she may have had the H1N1 virus in her system and the vaccine made it worse.

Other Meds:

<u>Lab Data:</u> None <u>History:</u> None Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362084-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days 6.0 Μ 21-Oct-2009 21-Oct-2009 0 21-Oct-2009 23-Oct-2009 VA 23-Oct-2009

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.UNKNOWN0UnknownUnknownFLUN(H1N1)

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: PT RECEIVED SEASONAL FLUMIST IN OUR OFFICE ON 10-03-2009 AND RECEIVED THE H1N1 VACCINE AT THEIR SCHOOL TODAY 10/21/2009. NO

SYMPTOMS AS YET

Other Meds:NONELab Data:NONEHistory:NONEPrex Illness:NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362088-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 47.0 F 21-Oct-2009 23-Oct-2009 TN 09-Oct-2009 10-Oct-2009 1 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(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Ear pain, Headache, Oropharyngeal blistering, Oropharyngeal pain, Sinus headache

Symptom Text: Sore throat (blisters), ear and sinus pain, headache, cough.

Other Meds:

Lab Data: N/A
History: No
Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362091-1

Gender **Vaccine Date Onset Date Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** Days 41.0 F 19-Oct-2009 Unknown 21-Oct-2009 23-Oct-2009 CO 23-Oct-2009 **Other Vaccine**

VAX Detail: Site Type **Prev Doses** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P Unknown Unknown

NO CONDITIONS, NOT SERIOUS Seriousness:

MedDRA PT No adverse event

Symptom Text: None

Other Meds:

Lab Data:

NIDDM History:

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362097-1

Onset Date Received Date State Mfr Report Id Gender **Vaccine Date Days Status Date Last Edit Date** Age F 3.0 10-Oct-2009 16-Oct-2009 6 21-Oct-2009 23-Oct-2009 MA 23-Oct-2009 Site VAX Detail: **Type Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Back pain, Constipation, Vomiting

Symptom Text: Child vomitted on pillow in the middle of night, early morning started complaining of stomach ache. Next day, child still complained of stomach ache then

complained of back ache. Took child to the doctor on Monday, 10/19, doctor diagnosed stomach pain due to constipation prescribed enema and laxative.

Treatment administered but child still complaining of stomach pain, back pain and as of 10/20, knee pain on left knee.

Other Meds: None

Lab Data:

History: None known
Prex Illness: None known

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362103-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 39.0 Μ 21-Oct-2009 21-Oct-2009 21-Oct-2009 23-Oct-2009 CT 0 23-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: violent vomitting

Other Meds:

Lab Data:

History: hyperlipidemia, HTN

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362105-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 13.0 F 15-Oct-2009 21-Oct-2009 23-Oct-2009 WA 21-Oct-2009 6 23-Oct-2009 VAX Detail: Prev Doses Site Type Manufacturer Lot Other Vaccine Route FLU

FLU SANOFI PASTEUR U3212AA 1 Right arm Intramuscular FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: hives starting at wrists and then progressing through day to include arms, legs and neck. No respiratory difficulty or swellingof lips or tongue.

Other Meds:

Lab Data:

History: seasonal allergies

Prex Illness: no
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362107-1

Gender **Vaccine Date Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** 23-Oct-2009 3.0 Μ 20-Oct-2009 21-Oct-2009 21-Oct-2009 23-Oct-2009 UT 1 VAX Detail: Site Type **Other Vaccine**

 YAX Detail:
 Type
 Manufacturer
 Lot
 Prev Doses
 Site
 Route

 FLUN(H1N1)
 MEDIMMUNE VACCINES, INC.
 NULL
 0
 Unknown
 Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: rash on face

Other Meds: Floride

Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 121

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

Vaers Id: 362108-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days Age F ΑZ 26.0 17-Oct-2009 18-Oct-2009 1 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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dyspnoea, Fatigue, Rhinorrhoea

Symptom Text: Began on 10/18 as normal side effects (cough, runny nose). Slowly progressed into more severe symptoms during the next few days. As of 10/21/09,

symptoms include difficulty breathing accompanied by a cough as well as fatigue.

Other Meds:

Lab Data: Results known 10/22/09

<u>History:</u> No diagnosed allergies or health conditions

Prex Illness: Stomatitis of the mouth x 2 weeks prior to vaccination, no recent fever,

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362109-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 31.0 22-Oct-2009 22-Oct-2009 0 22-Oct-2009 23-Oct-2009 PΑ 23-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Balance disorder, Disorientation, Dizziness, Pallor

Symptom Text: light-headed, dizzy, slighty disoriented, pale, weak kneed, unbalanced. Began to diminish at 0440

Other Meds: zantac, lexapro, lamictal, clonazepam, wellbutrin XL

Lab Data:

History: OCD, depression, anxiety

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362168-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 31.0 F 20-Oct-2009 21-Oct-2009 22-Oct-2009 23-Oct-2009 TN 1 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(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Headache, Respiratory tract congestion

Symptom Text: Headache, severe congestion and cough

Other Meds:

Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report
Page 124

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

Vaers Id: 362187-1

State Gender **Vaccine Date Onset Date Days Received Date** Status Date Mfr Report Id **Last Edit Date** Age F 31.0 11-Oct-2009 11-Oct-2009 0 22-Oct-2009 23-Oct-2009 ΑZ 27-Oct-2009 **VAX Detail: Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Headache, No reaction on previous exposure to drug, Oropharyngeal pain, Palpitations, Rash, Rash erythematous, Sinus congestion, Urticaria,

Vaccination complication, Viral pharyngitis

Symptom Text: palpitations, urticaria to neck area, anxiety. 10/26/09 ED medical records received service date 10/11/09. Assessment: Adverse reaction H1N1 flu vaccination.

Patient presents with sudden onset of hives, anxiety, palpitations and an erythematous rash across the neck. No problems with other flu vaccinations. 10/23/09

PCP medical records service dates 10/08/09 to 10/23/09. (Includes additional ED visits.) Most recent assessment: Viral pharyngitis. Sorethroat, headache,

sinus congestion.

Other Meds: miracle mouthwash

Lab Data: EKG - normal

History: allergies to Vioxx, amoxicillin, flexril, tramadol, naproxyn. 10/23/09 PCP medical records service dates 10/08/09 to 10/23/09. Wound care - toenail avulsion.

Ingrown toenail. Injection of tendon sheath. Strapping of ankle. Viral pharyngitis. Viral enteritis. Acute sinusitis.

Prex Illness: None reported.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362194-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days MO 3.0 Μ 14-Oct-2009 18-Oct-2009 4 22-Oct-2009 23-Oct-2009 23-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Pyrexia

Symptom Text: Pt started with temperature of 101, then by Tuesday Am 10/20/09 fever up to 104.

Other Meds:

Lab Data: Pt parent took him to the Dr on Monday 10/19/09 and again on Tuesday 10/20/09

History: asthma and occas wheezing episodes

Prex Illness: no problems when being vaccinated

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362199-1

Onset Date Mfr Report Id Gender **Vaccine Date Days Received Date Status Date** State **Last Edit Date** Age CT 43.0 M 21-Oct-2009 21-Oct-2009 0 22-Oct-2009 23-Oct-2009 23-Oct-2009 VAX Detail: **Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental exposure, Lacrimation increased

Symptom Text: Nurse inadvertantly sprayed part of 2nd half dose of Monovalent Flu Mist onto the paitent's right side of face. Nurse told patient to immediately wash face.

Patient complied. Patient returned to work and changed his shirt. He also took out disposable contact lens, rinsed and replaced it. His eye then became teary. Patient reported it to his supervisor and then called us (the health department.) This morning about 10 AM, patient reports to having no problems. He reports

conjuctiva is not reddened or weepy. Patient was told to contact his eye doctor or his regular physician if he had any further problems.

Other Meds:

Lab Data: None

History: Wears Contact Lenses

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362230-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> F SC 10.0 13-Oct-2009 14-Oct-2009 1 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Pyrexia

Symptom Text: Patient received H1N1 flu nasal mist on 10/13/09 at 3:30pm. Patient developed a high fever of 104 degrees on 10/14/09 and was seen by the doctor on

10/14/09. Doctor prescribed CHILDRENS TYLENOL for fever. Fever did go away, but now the patient has developed a cough. Doctor is just monitoring the

cough.

Other Meds: STRATTERA-25mg/2 daily; CHILDRENS TYLENOL-as needed

Lab Data:

History: ADD
Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362260-1

Received Date Mfr Report Id <u>Age</u> Gender **Vaccine Date Onset Date Status Date** State **Last Edit Date** Days 52.0 22-Oct-2009 23-Oct-2009 WA Μ 21-Oct-2009 Unknown 23-Oct-2009 <u>Site</u> VAX Detail: Type <u>Lot</u> Prev Doses Manufacturer Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500739P 3 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: PT GIVEN H1N1 MIST THOUGH TOO OLD/NO KNOWN REACTION

Other Meds:

Lab Data:

History: NONE
Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362262-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received Da	ite S	atus Date	<u>State</u>	Mfr Report Id	Last Edit Date
5.0	M	21-Oct-2009	21-Oct-2009	0	22-Oct-2009	9 23	3-Oct-2009	IN		23-Oct-2009
VAX Detai	I: Type	<u>Manuf</u>	<u>Manufacturer</u>		<u>Lot</u>		<u>s</u>	<u>Site</u>	Route	Other Vaccine
	HEP	_	OSMITHKLINE IGICALS		AHBVB729AA	3	Le	eft leg	Intramuscular	

0

500762P

Unknown

Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pyrexia, Vomiting

FLUN(H1N1)

Symptom Text: severe headache, vomiting, fever 102.8. Sent to ER for assessment.

MEDIMMUNE VACCINES, INC.

Other Meds: none
Lab Data: none
History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362278-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 3.0 22-Oct-2009 GΑ Μ 21-Oct-2009 21-Oct-2009 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis

Symptom Text: Gave INFLUENZA A H1N1 vaccine nasal mist. Child was very calm. Nosebleed began within 30-60 sec after spray adm. Nosebleed stopped within 10 mins.

Other Meds: None
Lab Data: None
History: None
Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Page 131

Vaers Id: 362286-1

Gender **Vaccine Date Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Status Date** State **Last Edit Date** 21.0 F 22-Oct-2009 7747 22-Oct-2009 23-Oct-2009 PΑ 06-Aug-1988 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(H1N1) MEDIMMUNE VACCINES, INC. 500756P 1 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Syncope

Symptom Text: BECAME HOT AND DIZZY STOOD UP AND FAINTED

Other Meds:

Lab Data: UNKNOWN AT THIS TIME

History: None

Prex Illness: No illness reported

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 132

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

Vaers Id: 362287-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 30.0 19-Oct-2009 19-Oct-2009 0 22-Oct-2009 23-Oct-2009 PΑ 23-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Oropharyngeal pain, Pain, Respiratory tract congestion, Rhinorrhoea

Symptom Text: body ache same day as nose dose. followed in succesion by runny nose, conjestion, chills, sore throat, worse body aches

Other Meds:

Lab Data:

History: seasonal allergies

Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362298-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 44.0 F 15-Oct-2009 15-Oct-2009 22-Oct-2009 23-Oct-2009 0 23-Oct-2009 VAX Detail: Type Prev Doses Site **Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500756P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Heart rate increased

Symptom Text: SHRORTNESS OF BREATH AND RAPID HEARTBEAT

Other Meds: NONE
Lab Data: NONE
History: no
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362307-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 21.0 15-Oct-2009 15-Oct-2009 22-Oct-2009 23-Oct-2009 ΑZ Μ 0 23-Oct-2009 Site VAX Detail: Type Prev Doses Manufacturer Lot Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Rash generalised, Tonsillitis

Symptom Text: Tonsillitis, flu-like symptoms, generalized rash.

Other Meds:

Lab Data:

History: None Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362308-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 6.0 22-Oct-2009 22-Oct-2009 23-Oct-2009 IΑ Μ 21-Oct-2009 1 23-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500783P Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Urticaria

Symptom Text: Mother reports hives next day, hands and head. Itchy all over-given BENADRYL antihistamine and helped symptoms.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362309-1

Gender Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** Days 16.0 F 22-Oct-2009 23-Oct-2009 TN 21-Oct-2009 Unknown 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(H1N1) MEDIMMUNE VACCINES, INC. 50075P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: INFLUENZA A H1N1 mist vaccine given to pt who is pregnant.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362310-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 3.0 F TN 21-Oct-2009 Unknown 22-Oct-2009 23-Oct-2009 23-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500757P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination

Symptom Text: 2009 INFLUENZA A H1N1, live, attenuated by Medimmune Lot 500757P Exp. 1-25-10 was administered to child with history of VSD/pacemaker.

Other Meds:

Lab Data:

History: VSD/pacemaker

Prex Illness: Ventricular septal defect/pacemaker

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362312-1

Onset Date Mfr Report Id Gender **Vaccine Date Days Received Date Status Date** State **Last Edit Date** Age F 7.0 10-Oct-2009 19-Oct-2009 9 22-Oct-2009 23-Oct-2009 IL 27-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bacterial test negative, Urticaria, White blood cell count normal

Symptom Text: Hives on entire body - no place not covered with hives - treated initially with Benadryl at home without success and went to the ER on 10-20-09 at 8:30am

10/23/09 ED records received service date 10/20/09. Assessement: Urticaria. Patient presents with generalized hives.

Other Meds:

Lab Data: Blood tests done for mycoplasm, pneumonia and strep - all of which were negative. WBC count was within normal limits. Treated with steroids and

antihistamines. Contact made later with primary care physician. 10/23/09 ED records received

<u>History:</u> Eczema Prex Illness: No illness

Prex Vax Illns:

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

Vaers Id: 362324-1

Gender **Vaccine Date Onset Date Received Date** Status Date State Mfr Report Id **Last Edit Date** Age Days F 39.0 21-Oct-2009 21-Oct-2009 0 22-Oct-2009 23-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dysphagia, Dysphonia, Headache, Pyrexia, Skin warm, Throat tightness, Urticaria

Symptom Text: Patient receieved the Flu Mist around 4:45 PM approximately 15 minutes later stated that her head and face were hot and started tp break out in hives and

voice became Raspy. Hotness on head and face was coming and going along with hives. Approximately 9:30 Pm was starting to have difficulty with swalling and was light head and seek medical attention at ER. Patient was treated with Benadryl 50 mg and a injection of Solu-Medrol. Then sent home to rest. Patient was able to return to work on 10/22/09. 10/26/09: Emergency Department Records received for date of service 10/22/09. Assessment: Developed throat tightness and hives after nasal H1N1 flu vaccine. Presented to the ED with c/o fever, headache and hives as well as some residual throat tightness.

Medicated with Solumedrol IM. Discharged to home feeling better, will take Benadryl PRN.

Other Meds: None. 10/26/09: Emergency

Lab Data: 10/26/09: Emergency Department Records received for date of service 10/22/09. Labs and diagnostics: None.

History: Allergies to medications Reglan and Epi-Pen Allergy foods soy and ginger. Department Records received for date of service 10/22/09. PMH: Allergy to Reglan,

Dropelidol and Epinepherine.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362325-1

Gender **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date** State **Last Edit Date** Days 1.1 22-Oct-2009 23-Oct-2009 WA Μ 19-Oct-2009 Unknown 23-Oct-2009 <u>Site</u> VAX Detail: Type <u>Lot</u> Prev Doses Manufacturer Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: There has been NO ADVERSE EVENTS FROM THIS IMMUNIZATION.

Other Meds:NONELab Data:NONEHistory:NonePrex Illness:None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362330-1

Onset Date Gender **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** Days 33.0 F 20-Oct-2009 22-Oct-2009 23-Oct-2009 CT Unknown 23-Oct-2009 Site Other Vaccine

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteFLUN(H1N1)MEDIMMUNE VACCINES, INC.500757P0UnknownUnknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: NO ADVERSE EVENT

Other Meds: ALLEGRA, PRENATAL VITAMINS

Lab Data: N/A

History: PREGNANCY

Prex Illness: NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362333-1

Gender Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date Last Edit Date** 17.0 F 13-Oct-2009 14-Oct-2009 22-Oct-2009 23-Oct-2009 CA 1 23-Oct-2009 Site VAX Detail: Type **Prev Doses** Manufacturer Lot Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Cough, Fatigue, Oropharyngeal pain, Pyrexia

Symptom Text: Patient had acute cough, fever, sore throat, chills, and fatigue.

Other Meds:

Lab Data:noneHistory:nonePrex Illness:none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362338-1

State Mfr Report Id Gender **Vaccine Date Onset Date Days Received Date Status Date Last Edit Date** Age F 28.0 22-Oct-2009 22-Oct-2009 0 22-Oct-2009 23-Oct-2009 CO 03-Nov-2009 VAX Detail: **Prev Doses** Site **Type** Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy, No adverse event

Symptom Text: No adverse symptoms. Flumist given instead of injectable H1N1 to pregnant client H1N1 - pregnancy 11/2/09: Prenatal records received for dates of service

7/27/09 to 10/28/09. Dx: Pregnant pt. at 29 weeks gestation received LAIV H1N1 vaccine EDD: 1/5/10 Assessment: As above.

Other Meds:

Lab Data: 11/2/09: Prenatal records received for dates of service 7/27/09 to 10/28/09. Labs and Diagnostics: Fetal Heart Rate on 10/28/09 150.

History: pregnancy (2nd or 3rd trimester). 11/2/09: Prenatal records received for dates of service 7/27/09 to 10/28/09. PMH: Pregnancy, GDM, Depression, GBS+,

Abnormal PAP

Prex Illness:
Prex Vax Illns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 144

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

Vaers Id: 362343-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received I	Date S	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
2.0	M	22-Oct-2009	22-Oct-2009	0	22-Oct-20	009 2	3-Oct-2009	OR		23-Oct-2009
VAX Detai	il: Type	<u>Man</u>	<u>ufacturer</u>		<u>Lot</u>	Prev Dose	es Sit	<u>e</u>	<u>Route</u>	Other Vaccine
	HIBV	SAN	OFI PASTEUR		UF696AB	3	Left I	eg	Intramuscular	
	FLU	SAN	OFI PASTEUR		U3263CA	2	Left I	eg	Intramuscular	
	FLUN	(H1N1) MFD	IMMUNE VACCINES	INC	500751P	0	Unkno	own	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia

Symptom Text: unable to walk

Other Meds: Fluoride

Lab Data: child has been referred to ER at the time of this reporting so I am not able to determine what his final outcome is at this time. parent was advised to call 911

and have the ambulance transport them to hospital.

History: history of intussusception history of infectious enteritis

Prex Illness: none reported by mother

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362345-1

Mfr Report Id <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** Days 22.0 F IL 22-Oct-2009 22-Oct-2009 0 22-Oct-2009 23-Oct-2009 IL 23-Oct-2009 VAX Detail: <u>Lot</u> Site Type Manufacturer **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: dizziness, bad headache that lasted all day

Other Meds: neurontin, baclofen, zoloft, ditropan xl, elavil, microgestin, daily multi-vitamin, cranberry pills

Lab Data:

History: C5/C6 incomplete quadriplegic. allergic to bactrim and latex.

Prex Illness: no
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362354-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received	<u>Date</u>	Status I	Date S	State	Mfr Report Id	Last Edit Date
14.0	F	07-Oct-2009	12-Oct-2009	5	22-Oct-2	009	23-Oct-2	2009	CA		23-Oct-2009
VAX Detai	I: Type	<u>Manuf</u>	acturer		<u>Lot</u>	Prev	Doses	<u>Site</u>		Route	Other Vaccine
	FLU	SANO	FI PASTEUR		43212AA		1	Unknown		Intramuscular	

500759F

0

Unknown

Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MEDIMMUNE VACCINES, INC.

FLUN(H1N1)

MedDRA PT Urticaria

Symptom Text: Hives on face.

Other Meds:

Lab Data: None
History: None
Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362355-1

Gender **Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date Vaccine Date Days** Age F 26.0 10-Oct-2009 20-Oct-2009 10 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Petechiae

Symptom Text: On 10/20/09, patient reported that she had noted petechiae on her abdomen & upper chest while showering (before coming to work). She contacted facility &

was advised to seek medical care from her physician. Saw patient on 10/21 & again told to pursue care through her physician. She works as RN on pediatric

unit, received H1N1 vaccine as part of campaign for health care workers.

Other Meds:

Lab Data: None available to nurse.

History: None known (for allergies) per patient

Prex Illness: None

Prex Vax Illns:

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

Vaers Id: 362357-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received D	Date St	atus Date	<u>State</u>	Mfr Report Id	Last Edit Date
34.0	M	21-Oct-2009	21-Oct-2009	0	22-Oct-20	09 23	-Oct-2009	WA		30-Oct-2009
VAX Deta	ail: Type	<u>Ma</u>	<u>nufacturer</u>		<u>Lot</u>	Prev Doses	<u>s</u> <u>S</u>	<u>Site</u>	Route	Other Vaccine
	FLUI	N(H1N1) ME	EDIMMUNE VACCINES	S, INC.	500764P	0	Unk	nown	Unknown	FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT

Allergy to vaccine, Anaphylactic reaction, Anxiety, Balance disorder, Chest discomfort, Dyspnoea, Gait disturbance, Immediate post-injection reaction, Muscular International Company of the C

Musculoskeletal discomfort, Oxygen saturation decreased, Sinusitis, Speech disorder, Tachycardia, Throat tightness, Vomiting

Symptom Text: 5 minutes after administration of nasal monovalent H1N1, developed imbalance gait, tachycardia, increased BP, decreased PO2 (90-92%), tightening of throat,

decreased ability to speak. RX in ER-IV BENADRYL, ranitidine, PREDNISONE PO. 10/27/09 Dermatology consult (includes dermatology ER visit) received service dates 1/1/94 to 10/27/09. Assessment: Allergic to Nasal H1N1 flu vaccine. Anaphylaxis. Sinusitis. Patient c/o throat tightness, lost balance, anxious. Tightness in shoulders, vomited. 10/29/09 ED records received service date 10/21/09. Assessment: Allergic to Nasal H1N1 flu vaccine. Anaphylaxis. Sinusitis.

Patient presents with shortness of breath and chest tightness which began within 10 minutes of vaccination.

Other Meds:

Lab Data: EKG done. BP 149/90, (N. 123/74)

History: Herpes stomatitis. Mouth and throat pain with fevers and sore throat. Tightness around head, cough, sinus pressure, bronchitis. Chronic hand dermatitis.

Chronic paronychia. Childhood asthma.

Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 149

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

Vaers Id: 362359-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 4.0 F 13-Oct-2009 16-Oct-2009 22-Oct-2009 23-Oct-2009 ΑZ 3 25-Oct-2009 Site VAX Detail: Type Prev Doses **Other Vaccine** Manufacturer Lot Route

Unknown

Unknown

500760P

MEDIMMUNE VACCINES, INC.

<u>Seriousness:</u> NO CONDITIONS, NOT SERIOUS

Vomiting

FLUN(H1N1)

Symptom Text: Vomited x1. "Appears to be recovering" per mother.

Other Meds: None

Lab Data:

MedDRA PT

History: None known

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362360-1

Gender **Onset Date** Days State Mfr Report Id <u>Age</u> **Vaccine Date Received Date Status Date Last Edit Date** 24.0 F 13-Oct-2009 16-Oct-2009 22-Oct-2009 23-Oct-2009 ΑZ 3 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(H1N1) MEDIMMUNE VACCINES, INC. 5007609P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Vomiting

Symptom Text: Vomiting-Saturday 3/17 x2 in AM. Diarrhea since Friday PM (denies blood in stool).

Other Meds: None

Lab Data:

History: None known

Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Vaers Id: 362397-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> F 49.0 20-Oct-2009 20-Oct-2009 0 23-Oct-2009 23-Oct-2009 IN 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(H1N1) MEDIMMUNE VACCINES, INC. 500763P Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure increased, Body temperature increased, Hyperhidrosis, Tremor

Symptom Text: Arms and hands started shaking 15 minutes later. Started sweating, started at 4:00ish. BP elevated, increased temp. Seen ER - BENADRYL given IV helped.

Other Meds: DARVOCET prn not taken in 2 weeks

Lab Data: Cardiac markers x2; EKG x2

History: No x-ray dye had reaction; NKDA; disc disease

Prex Illness: None noted

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362403-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 20-Oct-2009 23-Oct-2009 23-Oct-2009 23-Oct-2009 CA 3.0 Μ 3 23-Oct-2009

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

FLU UNKNOWN MANUFACTURER NULL Unknown Unknown FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown

 $\underline{\textbf{Seriousness:}} \qquad \text{NO CONDITIONS, NOT SERIOUS}$

MedDRA PT Body temperature increased, Pyrexia

Symptom Text: FEVER, RUSH IN THE BODY. NEO-MELUBRINA

Other Meds:

Lab Data:

History: NONE
Prex Illness: NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362411-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 65.0 F 23-Oct-2009 23-Oct-2009 OR 20-Oct-2009 Unknown 25-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Patient received the H1N1 live virus through the nose. She is 65 year of age with a long term health problem.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362412-1

Gender Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** Days 64.0 F 23-Oct-2009 23-Oct-2009 OR 20-Oct-2009 Unknown 25-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Patient received the H1N1 live virus through the nose. She is 64 years of age with a long term health problem.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362418-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** F 15-Oct-2009 23-Oct-2009 23-Oct-2009 WI 29.0 18-Oct-2009 3 25-Oct-2009 VAX Detail: Type Site Manufacturer **Prev Doses** Other Vaccine Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

<u>MedDRA PT</u> Chest pain, Chills, Dizziness, Fatigue, Myalgia, Pleuritic pain, Pyrexia, Syncope

Symptom Text: Fatigue, Dizzy, syncope x 3, pleuritic chest pain, chills, fever 99.7 and myalgias

Other Meds:

Lab Data: none

History: Mild asthma

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362423-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 37.0 F 20-Oct-2009 20-Oct-2009 0 23-Oct-2009 23-Oct-2009 ΤN 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(H1N1) MEDIMMUNE VACCINES, INC. 500754P 1 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Panic attack, Syncope

Symptom Text: taken to local E.R. after receiving HINI nasal mist.syncope episode @ home.discharged home the same day.clinical impression @ hospital panic

attack, episode of dyspnea, syncope.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362430-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 6.0 F 21-Oct-2009 23-Oct-2009 23-Oct-2009 NC 21-Oct-2009 0 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(H1N1) MEDIMMUNE VACCINES, INC. 500745P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis

Symptom Text: Child had a spontaneous bloody nose on the way home from the clinic.

Other Meds:

Lab Data:

History: None
Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362447-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 43.0 F 23-Oct-2009 23-Oct-2009 23-Oct-2009 23-Oct-2009 SC 0 25-Oct-2009 Site VAX Detail: Type <u>Lot</u> Prev Doses Manufacturer Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Rash upper left chest and bilateral ears with itching.

Other Meds:

<u>Lab Data:</u> Received Claritin 10 PO in Employee Health

History: None Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362517-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 34.0 Μ 21-Oct-2009 21-Oct-2009 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Hyperhidrosis, Hypertension, Palpitations, Tachycardia, Vomiting

Symptom Text: Plae, lightheadness, diaphoretic, dizzy, difficulty breathing, heart palpitations, tachycardia, hypertension, vomiting

Other Meds:

Lab Data: CBC and Chem 7

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362520-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 25.0 F 22-Oct-2009 22-Oct-2009 0 23-Oct-2009 23-Oct-2009 ОН 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(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous, Rash papular, Rash pruritic, Skin irritation

Symptom Text: Small, Red, rash from head to toe. Some spots are slightly raised. It does itch in spots, but not all over all the time. Skin seems to be somewhat hypersensitive.

PO benadryl didn't help

Other Meds: Augmentin for x2wks for bacterial cold

Lab Data:

History: None

Prex Illness: minor cold

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362527-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 34.0 F WI 23-Oct-2009 23-Oct-2009 0 23-Oct-2009 23-Oct-2009 25-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial pain, Swelling face

Symptom Text: Swelling in both cheeks and soreness about 15 minutes after H1N1 Flu Mist. Started resolving within 15 minutes. Took 50 mg oral benadryl and reported event

to Employee Health Services

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362574-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 2.0 Μ 21-Oct-2009 23-Oct-2009 2 23-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500765P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Pyrexia, Rash, Respiratory rate increased

Symptom Text: short fast breathing, temperature 100, small patches of rash on skin. Gave Motrin and fever reduced. Fever did come back at about 11:30 AM. Called Dr office

for suggestion but no response yet

Other Meds:

Lab Data:

History: no Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362585-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> 11.0 F 17-Oct-2009 17-Oct-2009 0 23-Oct-2009 26-Oct-2009 NJ 27-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tongue disorder, Urticaria

Symptom Text: Approx. 1.5 hours after administration, child a red tongue and hives on tongue. Parent consulted with private physician who advised anbesol topically. The

next morning, approx. 18 hours after intra-nasal administration, signs and symptoms were gone. Parent notified our department today, 10/23/2009.

Other Meds:

Lab Data:NoneHistory:NoPrex Illness:No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362590-1 (S)

Onset Date Received Date Status Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days State Age GΑ 9.0 Μ 14-Oct-2009 21-Oct-2009 7 23-Oct-2009 28-Oct-2009 29-Oct-2009 VAX Detail: **Type** Site **Prev Doses** Other Vaccine Manufacturer Lot Route

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Blood creatine phosphokinase increased, Body temperature increased

Symptom Text: Infection control nurse from hosp reported child admitted 10/22/09 temp 99.6, unable to walk, CPK - 3362. Reports 10/23 temp 99.3, CPK - 1165, moving all

extremities (states she is unaware of ambulatory status).

Other Meds:

Lab Data: See CPK results above.

History: None known

Prex Illness: None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362595-1 Gender **Vaccine Date Onset Date Received Date** Status Date State Mfr Report Id **Last Edit Date** Age Days 12.0 M 22-Oct-2009 1 23-Oct-2009 26-Oct-2009 FL 27-Oct-2009 21-Oct-2009 **VAX Detail: Prev Doses** Site **Type** Manufacturer Lot Route Other Vaccine HEPA **GLAXOSMITHKLINE** AHAVB312AA 0 Right arm Intramuscular **BIOLOGICALS** VARCEL MERCK & CO. INC. 09997Y Left arm Subcutaneously 1 FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500776P Unknown Unknown **TDAP GLAXOSMITHKLINE** AC52B037AA 0 Left arm Intramuscular **BIOLOGICALS** MNQ SANOFI PASTEUR U3012AA 0 Right arm Intramuscular

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site erythema, Injection site pain

MOTHER REPORTS SON PRESENTED COMPLAINTS OF TENDERNESS OF LDT WITH REDNESS MEASURING APPROX AT TIME OF REPORTING 30 Symptom Text:

MM X 40 MM SURROUNDED BY LARGE REDDNESS AREA. NO OPEN AREAS NOTED. MOTHER/CHILD DENIES ANY SOB OR DYSPNEA; OR CHEST PAIN. NO HISTORY OF ASTHMA. MOTHER REPORTS THAT SHE GAVE CHILD 1 ALEVE FOR COMPLAINT OF HEADACHE ON 10/22/09 AT APPROX 4 PM AFTER RETURN FROM SCHOOL. CHILD RECEIVED VZV ON 10/21 AND WAS INSTRUCTED NOT AVOID USE OF ASA OR MOTRIN PRODUCT BY

VACCINE ADMINISTRATOR, RN AT TIME OF ADMINISTRATION. MOTHER REPORTS REDNESS TO BEGIN YESTERDAY EVENING

NO MEDICATIONS AT TIME OF VACCINATION Other Meds:

Lab Data: NONE

History: MOTHER REPORTS HISTORY OF ALLERGY TO POLLEN AND DUST.

Prex Illness: MOTHER DENIES ANY CONCURRENT ILLNESS AT TIME OF VACCINATION

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362604-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 32.0 F MO 23-Oct-2009 23-Oct-2009 0 23-Oct-2009 26-Oct-2009 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Pruritus, Swollen tongue, Urticaria

Symptom Text: Hives over entire body, around eyes, pale. Intense itching. Tongue swollen. She chose to take 75mg of diphenhydramine without our knowledge.

Other Meds: Note: Patient received seasonal LAIV on 09/21/2009 without incident.

Lab Data:

History: Allergies
Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362605-1

Onset Date Received Date Mfr Report Id Gender **Vaccine Date Days Status Date** State **Last Edit Date** Age F 46.0 22-Oct-2009 22-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Malaise, Nausea

Symptom Text: By 2:30 she was developing a HA which continued to worsen despite lying down and taking 2 Advil. Within an hour HA rated up to a 10 and she developed

chills and nausea. Contacted the nurse Advisor Line. Took 12.5 mg oral benadryl and able to sleep a little. By 7:00pm starting to improve. Took another Advil and went to bed. Up at 5:am this morning and feeling fine. She reports has not gotten any flu vaccine for last 15 years when she had an injectable vaccine

and 2 days later had fever and chills and malaise lasting 4 days.

Other Meds:

Lab Data:

<u> History:</u>

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362609-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** F 23-Oct-2009 26-Oct-2009 CA 26.0 19-Oct-2009 19-Oct-2009 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Lymphadenopathy, Pruritus, Rash

Symptom Text: headache, rash on face/itching, Rt side lympnode below ear swelling. Pt. does not has history of egg allergy

Other Meds:

Lab Data:

History: No Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362610-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F DC 28.0 21-Oct-2009 21-Oct-2009 0 23-Oct-2009 26-Oct-2009 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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Urticaria

Symptom Text: patient informed this office of an allergic reaaction on 10/23/09. She reported mild hives. She was given allegra-D by her own MD. On 10/23/09 she was

examined and she still had hives present. She was instructed to continue Allegra-D in the am and Benedryl hs. She will follow in 2 days

Other Meds:

Lab Data:

History: PCN, Amoxicillin, cipro

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362615-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 4.0 F 20-Oct-2009 20-Oct-2009 23-Oct-2009 26-Oct-2009 CA 27-Oct-2009 0 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500776P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Pharyngitis, Pyrexia

Symptom Text: high fever/cough/pharyngitis/treated with tamiflu

Other Meds:

Lab Data:noneHistory:noPrex Illness:noPrex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362616-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 9.0 F 20-Oct-2009 20-Oct-2009 23-Oct-2009 26-Oct-2009 CA 27-Oct-2009 0 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500776P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Pyrexia

Symptom Text: high fever/cough/tamiflu given/zithromax given

Other Meds:

Lab Data:noneHistory:noPrex Illness:noPrex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362617-1

<u>Age</u>	<u>Gender</u>	Vaccine Da	ate Onset Date	Days	Received Da	<u>ite</u> <u>Statu</u>	s Date	<u>State</u>	Mfr Report Id	Last Edit Date
5.0	F	23-Oct-200	09 23-Oct-2009	0	23-Oct-2009	9 26-Od	t-2009	OR		27-Oct-2009
VAX Deta	ail: Type	<u> </u>	<u>Manufacturer</u>		<u>Lot</u>	Prev Doses	<u>Site</u>		<u>Route</u>	Other Vaccine
	FLUI	N(H1N1) I	MEDIMMUNE VACCINES	S, INC.	500760P	0	Unknow	า	Unknown	
	FLU	;	SANOFI PASTEUR		U3177BA	0	Left arm		Intramuscular	

NO CONDITIONS, NOT SERIOUS Seriousness:

MedDRA PT Epistaxis

Symptom Text: Bloody nose within 15 minutes of administration

Other Meds: Lab Data: None

History: Still's heart murmur, seasonal allergies

Prex Illness: No

Prex Vax IIIns:

Page 172

VAERS Line List Report

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

Vaers Id: 362621-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 13.0 F 15-Oct-2009 16-Oct-2009 23-Oct-2009 26-Oct-2009 WA 1 27-Oct-2009 Site VAX Detail: Type **Prev Doses** Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Intramuscular

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Headache, Oropharyngeal pain, Pyrexia

Symptom Text: fever to 101.1, head ache, sore throat, cough

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362626-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date Days Status Date** State Age CO 3.0 M 19-Oct-2009 21-Oct-2009 2 23-Oct-2009 26-Oct-2009 CO 27-Oct-2009 VAX Detail: Type **Prev Doses** Site Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Crying, Hypersomnia

Symptom Text: 10/21 - Happy then sudden, inconsolable, and persistent crying for no apparent reason for 1 hour in the afternoon which is unlike his normal, calm behavior.

When he does cry, it is for very short periods and can be easily consoled. Long nap this day (2.5-3 hours). 10/23 - Repeat of 10/21, except in the evening. Happy, then in consolable crying during dinner. Put in a time out for 3 minutes at an attempt to console crying. Normally, he will stop crying within 1 minute during time out. Cried for full 3 minutes until I finally went to him to console him. Very unlike usual behavior. Also took 3-hour nap earlier today. Normal is 1.5-2

hours.

Other Meds:

Lab Data:

History: No Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362627-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F OR 26.0 23-Oct-2009 23-Oct-2009 0 24-Oct-2009 26-Oct-2009 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Visual impairment

Symptom Text: Visual disturbance for less than 1 minute. Headache that lasted several hours (can not directly correlate headache to vaccine - could have been limited caffeine

intake that morning)

Other Meds: oral contraceptive; lovastatin; multivitamin; topical

Lab Data:

History: Seasonal Allergies

Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362647-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 24-Oct-2009 ОН 26.0 23-Oct-2009 24-Oct-2009 1 26-Oct-2009 26-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Headache, Myalgia, Oropharyngeal pain, Respiratory tract congestion

Symptom Text: Headache, congestion, sore throat initially. Within 12 hours, experiencing muscle pain all over body and weakness.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362648-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 3.0 24-Oct-2009 27-Oct-2009 Μ 21-Oct-2009 23-Oct-2009 2 MD MD27-Oct-2009 VAX Detail: Type Site Manufacturer Lot **Prev Doses** Route Other Vaccine

Unknown

Unknown

500754P

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Vomiting

FLUN(H1N1)

Symptom Text: Vomiting, with no associated fever, headache, nausea or chills. Also decreased appetite.

MEDIMMUNE VACCINES, INC.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362649-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 21.0 F 22-Oct-2009 24-Oct-2009 2 24-Oct-2009 26-Oct-2009 ΜI MI 26-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Route Other Vaccine Lot

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: 10 or so vomiting spells, unable to keep anything down liquid or solid since the onset of the symptoms. If situation remains the same by tomorrow at noon, I

will be taking her to the hospital.

Other Meds: Ametryptolin

Lab Data:
History:
Prex Illness:
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362650-1

State Mfr Report Id Gender **Vaccine Date Onset Date Received Date Status Date Last Edit Date** Age Days F 8.0 22-Oct-2009 23-Oct-2009 24-Oct-2009 26-Oct-2009 FL 26-Oct-2009 1

<u>VAX Detail:</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. 500776P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Headache, Heart rate increased, Malaise, Pyrexia

Symptom Text: COMPLAINT TO PARENT OF HEART BEATING FAST & CHEST PAIN. NO DOCUMENTED FEVER AT ONSET OF SYMPTOMS PER PARENTS. DID

DEVELOP FEVER WITHIN 4-6 HOURS OF ONSET OF SYMPTOMS. 10/24/09 FOLLOW UP:HAD FEVER THROUGHOUT EVENING 10/23 AND EARLY AM

HOURS. STILL WITH RECURRING FEVER, GENERAL MALAISE AND HEADACHE ON/OFF AS OF 9:00AM.

Other Meds: NONE

Lab Data: CHEST XRAY- NEG EKG PRELIMINARY REPORT- NORMAL (PENDING FINAL READING BY CARDIOLOGIST)

History: BRONCHIOLITIS DURING INFANCY/ EARLY CHILDHOOD. LAST DOCUMENTED EPISODE: 2004

Prex Illness: IN OFFICE FOR A WELL VISIT

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362654-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 8.0 F 21-Oct-2009 23-Oct-2009 24-Oct-2009 26-Oct-2009 NE 2 26-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Oropharyngeal pain, Pyrexia

Symptom Text: Fever, sore throat and cough

Other Meds:

Lab Data:

History: Rheumatoid arthritis

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362663-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 22.0 F 15-Oct-2009 15-Oct-2009 25-Oct-2009 26-Oct-2009 0 NH 26-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Lethargy, Rhinorrhoea

Symptom Text: Temp of 102F, runny nose, lethary for four days.

Other Meds:

Lab Data:

History: Allergy to sulfa

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362664-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 30.0 20-Oct-2009 21-Oct-2009 1 25-Oct-2009 26-Oct-2009 NJ 26-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Myalgia, Pyrexia

Symptom Text: muscle aches, chills, fever, headache; all still persisting today (10/25)

Other Meds: prenatal vitamin

Lab Data:

History: -had seasonal flu shot (Fluvirin) the previous week -gave birth 6 weeks before this vaccination

Prex Illness: no
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362666-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 45.0 F 21-Oct-2009 21-Oct-2009 0 25-Oct-2009 26-Oct-2009 VA 26-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Nausea, Palpitations

Symptom Text: blood presure went 154/104 rapid heart palpitations, diziness and weakness. Nausea. After 15 minutes I was rush to the Emergency room

Other Meds: none

Lab Data: EKG, blood work to check heart attack, chest X ray. Came all negative

History: none
Prex Illness: none

Prex Vax IIIns: none~ ()~~0.00~Patient

VAERS Line List Report

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

Vaers Id: 362667-1

Gender Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date Last Edit Date** 17-Oct-2009 24-Oct-2009 25-Oct-2009 26-Oct-2009 FL 8.0 Μ 7 26-Oct-2009 Site VAX Detail: Type Other Vaccine

 /AX Detail:
 Type
 Manufacturer
 Lot
 Prev Doses
 Site
 Route
 C

 FLUN(H1N1)
 MEDIMMUNE VACCINES, INC.
 NULL
 0
 Unknown
 Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Feeling abnormal, Pain, Pyrexia, Vomiting

Symptom Text: Fever, Coughing, Vomiting, body aches, general feeling of yuckiness.

Other Meds:

Lab Data:

History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362679-1

Onset Date Received Date Status Date State Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days <u>Age</u> 40.0 Μ 24-Oct-2009 25-Oct-2009 1 25-Oct-2009 26-Oct-2009 DE 26-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Dysgeusia, Oropharyngeal pain, Productive cough

Symptom Text: lungs feel tight, productive cough with severe burning sensation in lungs; mild sore throat; no fever; note: when instructed to sniff in when vaccine

administered, I sniffed strongly, had funny taste in throat and back of mouth 15 minutes after.

Other Meds:

Lab Data:

History: no Prex Illness: no

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report
Page 186

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

Vaers Id: 362688-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days CA 8.0 Μ 24-Oct-2009 24-Oct-2009 0 25-Oct-2009 26-Oct-2009 26-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500779P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate increased, Pyrexia

Symptom Text: High fever (103 degree), fast heart rate (120-130 heart beat per min). Mortrim administered but the fevel continues. Mortrim is able to lower the temp to 101

degrees. Heart rate continues to be fast. Have contacted doctor and waiting to go emergency visit tonight or going to see doctor tomorrow.

Other Meds:

Lab Data:

History: No Prex Illness: No

VAERS Line List Report

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

Vaers Id: 362692-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 4.0 Μ 22-Oct-2009 23-Oct-2009 1 23-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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash-uncertain in description, appeared around nostrils this morning. Father uncertain if red or hives. Person at facility notified. Rash had subsided by mid-

norning.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362710-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days OR 29.0 Μ 20-Oct-2009 21-Oct-2009 1 25-Oct-2009 26-Oct-2009 26-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cough, Pyrexia

Symptom Text: Started with deep hollow cough from the lungs, not bad at first, has gotten worse since, now I have a fever and weakness, I think the vaccine gave me the

illness.

Other Meds:

Lab Data:

History: None Prex Illness: No

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362713-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 9.0 F 16-Oct-2009 24-Oct-2009 25-Oct-2009 26-Oct-2009 CA 8 26-Oct-2009 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. UNKNOWN 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis, Headache

Symptom Text: Headache and Bloody Nose

Other Meds:

Lab Data:NONEHistory:nonePrex Illness:none

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 190

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

Vaers Id: 362781-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> IL 11.0 Μ 22-Oct-2009 25-Oct-2009 3 26-Oct-2009 26-Oct-2009 26-Oct-2009 VAX Detail: Site Type **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Cough, Decreased appetite, Nausea, Oropharyngeal pain, Pyrexia

Symptom Text: Fever of 102, coughing, sore throat, feeling like she is going to vomit, loss of appetite.

Other Meds: None

Lab Data:

History: None

Prex Illness: Patient had a mild cough and an on an off mild sore throat but no fever in the days leading up to vaccination.

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Page 191

Vaers Id: 362781-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> IL 11.0 Μ 22-Oct-2009 25-Oct-2009 3 26-Oct-2009 26-Oct-2009 26-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Cough, Decreased appetite, Nausea, Oropharyngeal pain, Pyrexia

Symptom Text: Fever of 102, coughing, sore throat, feeling like she is going to vomit, loss of appetite.

Other Meds: None

Lab Data:

History: None

Prex Illness: Patient had a mild cough and an on an off mild sore throat but no fever in the days leading up to vaccination.

Report run on: 04 NOV 2009 10:32 VAERS Line List Report
Page 192

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

Vaers Id: 362781-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> IL 11.0 Μ 22-Oct-2009 25-Oct-2009 3 26-Oct-2009 26-Oct-2009 26-Oct-2009 VAX Detail: Site Type **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Cough, Decreased appetite, Nausea, Oropharyngeal pain, Pyrexia

Symptom Text: Fever of 102, coughing, sore throat, feeling like she is going to vomit, loss of appetite.

Other Meds: None

Lab Data:

History: None

Prex Illness: Patient had a mild cough and an on an off mild sore throat but no fever in the days leading up to vaccination.

VAERS Line List Report

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

Vaers Id: 362792-1

Gender **Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date Vaccine Date** Days <u>Age</u> 48.0 F 23-Oct-2009 24-Oct-2009 1 26-Oct-2009 26-Oct-2009 NV 26-Oct-2009 VAX Detail: **Type** Site **Prev Doses** Other Vaccine Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphonia, Dysphonia, Oropharyngeal pain

Symptom Text: Started with a sore throat and on the morning of the 25th I became very hoarse eventually losing my voice all together. I used cloroseptic and some percocet

for the pain, and rested my voice. Am still slightly hoarse.

Other Meds: Percocet for back pain and xanax for panic attacks.

Lab Data:noneHistory:NOPrex Illness:NO

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362792-1

Gender **Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date Vaccine Date** Days <u>Age</u> 48.0 F 23-Oct-2009 24-Oct-2009 1 26-Oct-2009 26-Oct-2009 NV 26-Oct-2009 **Type** Site VAX Detail: **Prev Doses** Other Vaccine Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphonia, Dysphonia, Oropharyngeal pain

Symptom Text: Started with a sore throat and on the morning of the 25th I became very hoarse eventually losing my voice all together. I used cloroseptic and some percocet

for the pain, and rested my voice. Am still slightly hoarse.

Other Meds: Percocet for back pain and xanax for panic attacks.

Lab Data:noneHistory:NOPrex Illness:NO

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362794-1

Gender **Onset Date Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** Days 10.0 F 15-Oct-2009 26-Oct-2009 26-Oct-2009 IN Unknown 26-Oct-2009 Site VAX Detail: Type

/AX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500751P1UnknownUnknownFLU

Seriousness: NOT SERIOUS, NO CONDITIONS

MedDRA PT No adverse event

Symptom Text: Patient was given H1N1 Flu Mist on 10-15-09 after receiving Seasonal Flu Mist on 9-22-09.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362794-1

Gender **Onset Date Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** Days 10.0 F 15-Oct-2009 26-Oct-2009 26-Oct-2009 IN Unknown 26-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 1 Unknown Unknown FLU

Seriousness: NOT SERIOUS, NO CONDITIONS

MedDRA PT No adverse event

Symptom Text: Patient was given H1N1 Flu Mist on 10-15-09 after receiving Seasonal Flu Mist on 9-22-09.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362855-1 (D)

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received	<u>Date</u>	Status Da	ate S	tate	Mfr Report Id	Last Edit Date
35.0	F	22-Oct-2009	25-Oct-2009	3	26-Oct-20	009	27-Oct-20	09 C	OR .		02-Nov-2009
VAX Deta	ail: Type	<u>Man</u>	ufacturer		<u>Lot</u>	Prev l	Doses	<u>Site</u>		Route	Other Vaccine
	FLUI	N(H1N1) MED	DIMMUNE VACCINES	S, INC.	500765P)	Unknown		Unknown	FLU

Seriousness: DIED, ER VISIT, HOSPITALIZED, SERIOUS

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

Vomiting

Symptom Text: Patient got sick with flu like symptoms on 10/24 around 1PM, went to hospital with trouble breathing around 9PM, was pronounced deceased at 1AM on 10/25.

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

Flu vaccine given.

Other Meds: none known

Lab Data: /27/09 ER and hospital records received service date 10/25/09. LABS and DIAGNOSTICS: ECG - Abnormal, sinus tachycardia, Nonspecific ST and T wave

abnormality. Arterial Blood gases: pCO2 50 mmHg (H) O2 Sat 83% (L) Bicarb 8.0 mmol/L (L) Base

History: none. /27/09 ER and hospital records received service date 10/25/09. Splenectomy. Appendectomy. 11/02/09: Primary Care Records received for date of

service 10/9/09. PMH: Heriditary spherocytosis with splenectomy, D&C, L ACL Repair, L arthroscopic knee surgery.

Prex Illness: spherocytosis, hemolitic onemica

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 362855-1 (D)

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days 35.0 F 25-Oct-2009 3 26-Oct-2009 27-Oct-2009 OR 02-Nov-2009 22-Oct-2009 **VAX Detail: Type Prev Doses** Site Manufacturer Lot Route Other Vaccine FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500765P Unknown Unknown FLU

Seriousness: DIED, ER VISIT, HOSPITALIZED, SERIOUS

Abdominal pain upper, Acidosis, Acute respiratory distress syndrome, Asplenia, Brain injury, Cardiac arrest, Chills, Cyanosis, Death, Diarrhoea, Dyspnoea, Electromechanical dissociation, Endotracheal intubation, Hyperhidrosis, Hypotension, Infection, Influenza like illness, Intensive care, Livedo reticularis, Lung influenza like illness, Page absent, Pag

infiltration, Nausea, Pulse absent, Renal disorder, Respiratory arrest, Resuscitation, Sepsis, Septic shock, Tachycardia, Tachypnoea, Vaginal haemorrhage,

Vomiting

Symptom Text: Patient got sick with flu like symptoms on 10/24 around 1PM, went to hospital with trouble breathing around 9PM, was pronounced deceased at 1AM on 10/25.

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

Flu vaccine given.

Other Meds: none known

Lab Data: /27/09 ER and hospital records received service date 10/25/09. LABS and DIAGNOSTICS: ECG - Abnormal, sinus tachycardia, Nonspecific ST and T wave

abnormality. Arterial Blood gases: pCO2 50 mmHg (H) O2 Sat 83% (L) Bicarb 8.0 mmol/L (L) Base

History: none. /27/09 ER and hospital records received service date 10/25/09. Splenectomy. Appendectomy. 11/02/09: Primary Care Records received for date of

service 10/9/09, PMH: Heriditary spherocytosis with splenectomy, D&C, L ACL Repair, L arthroscopic knee surgery.

Prex Illness: spherocytosis, hemolitic onemica

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362878-1

Onset Date Received Date Mfr Report Id Gender **Vaccine Date Days Status Date** State **Last Edit Date** Age F 7.0 22-Oct-2009 23-Oct-2009 1 26-Oct-2009 27-Oct-2009 ΤX 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500576P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchospasm, Caesarean section, Dyspnoea, Oxygen saturation decreased, Pyrexia, Wheezing

Symptom Text: Acute onset of bronchospasm within 24 hours of H1N1 flumist. 10/28/09 and 10/29/9 Medical records received for DOS 10/23. C/O Trouble breathing.

Child developed SOB /wheeze. On PE mild exp wheeze bilat 1 day s/p vaccine. Fever 99.3. O2 sat 89% (at school). Nebulized x3 at school. Discharged to

home. Routine care. RTC as needed.

Other Meds:

Lab Data:

History: PMH: Was term C-section deliv. 8.4lbs. Allergies: None/dsb

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362891-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 9.0 15-Oct-2009 17-Oct-2009 2 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Rash, Rash pruritic

Symptom Text: Pt received the H1N1 mist at our office on 10-15-09. 2 days later had a red bump then spread into a rash that hurt and itched. Mom waited until 10-23-09 to

report to us. Told pt to use BENADRYL q 8 hrs. Mom answered no to all guestions.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report
Page 201

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

Vaers Id: 362891-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 9.0 15-Oct-2009 17-Oct-2009 2 26-Oct-2009 27-Oct-2009 IN 27-Oct-2009 VAX Detail: **Type** Site **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Rash, Rash pruritic

Symptom Text: Pt received the H1N1 mist at our office on 10-15-09. 2 days later had a red bump then spread into a rash that hurt and itched. Mom waited until 10-23-09 to

report to us. Told pt to use BENADRYL q 8 hrs. Mom answered no to all questions.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362893-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 41.0 22-Oct-2009 WA Μ 21-Oct-2009 1 26-Oct-2009 27-Oct-2009 28-Oct-2009 VAX Detail: **Type** Site Manufacturer Lot **Prev Doses** Other Vaccine Route FLU **NOVARTIS VACCINES AND** 98441P1 Unknown Intramuscular

DIAGNOSTICS

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Pt is experiencing swollen, hard glands under the armpits. Pt says his lymph nodes are going "nuts."

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362893-1

Age	Gender	Vaccine Date	Onset Date	<u>Days</u>	Received I	<u>Date</u>	Status Dat	e State	Mfr Report Id	Last Edit Date
41.0	M	21-Oct-2009	22-Oct-2009	1	26-Oct-20	009	27-Oct-200	9 WA		28-Oct-2009
VAX Deta	ail: Type	<u>Manu</u>	facturer		<u>Lot</u>	Prev D	oses	<u>Site</u>	Route	Other Vaccine
	FLU		RTIS VACCINES A NOSTICS	ND	98441P1	0		Unknown	Intramuscular	

0

500764P

Unknown

Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

FLUN(H1N1)

MedDRA PT Lymphadenopathy

Symptom Text: Pt is experiencing swollen, hard glands under the armpits. Pt says his lymph nodes are going "nuts."

MEDIMMUNE VACCINES, INC.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362894-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 35.0 F 23-Oct-2009 23-Oct-2009 26-Oct-2009 27-Oct-2009 VA 0 28-Oct-2009 Site VAX Detail: Type Prev Doses **Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on arms with urticaria.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362894-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 35.0 F 23-Oct-2009 23-Oct-2009 26-Oct-2009 27-Oct-2009 VA 0 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. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on arms with urticaria.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362895-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received D	Date S	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
14.0	M	21-Oct-2009	22-Oct-2009	1	26-Oct-20	09 2	27-Oct-2009	CA		28-Oct-2009
VAX Deta	il: Type	<u>Manu</u>	<u>facturer</u>		<u>Lot</u>	Prev Dos	es	<u>Site</u>	Route	Other Vaccine
	FLU	SANO	FI PASTEUR		U3212AA	0	Le	eft arm	Unknown	

Unknown

Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MEDIMMUNE VACCINES, INC.

FLUN(H1N1)

MedDRA PT Dyspnoea

Symptom Text: Mother of pt. That pt on 10/22/09-son states he had two random occasions at school that he found it harder to breathe, causing him to pause and put effort into

ea breath. States instances were brief and not to extent that he was alarmed enough to seek medical care-no other episodes to date.

500760P

Other Meds:

Lab Data:NoneHistory:NonePrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362895-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received D	<u>Date</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
14.0	M	21-Oct-2009	22-Oct-2009	1	26-Oct-20	09	27-Oct-2009	CA		28-Oct-2009
VAX Deta	il: Type	<u>Manu</u>	<u>facturer</u>		<u>Lot</u>	Prev Dos	ses	<u>Site</u>	Route	Other Vaccine
	FLU	SANO	FI PASTEUR		U3212AA	0	Le	eft arm	Unknown	

Unknown

Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MEDIMMUNE VACCINES, INC.

FLUN(H1N1)

MedDRA PT Dyspnoea

Symptom Text: Mother of pt. That pt on 10/22/09-son states he had two random occasions at school that he found it harder to breathe, causing him to pause and put effort into

ea breath. States instances were brief and not to extent that he was alarmed enough to seek medical care-no other episodes to date.

500760P

Other Meds:

Lab Data:NoneHistory:NonePrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362896-1

Onset Date Received Date Status Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days State Age F 4.0 22-Oct-2009 23-Oct-2009 1 26-Oct-2009 27-Oct-2009 IΑ 28-Oct-2009 **Type** Site VAX Detail: **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fluid intake reduced, Vomiting

Symptom Text: Per TC 9:35 AM 10/23/09 from grandmother caring for child. Relates began vomiting at 1:00 AM. Vomited 3 times during the night and now 3 times this

morning. Unable to keep liquids down. Had called physician and was told to call vaccine administrator. Instructed to recall physician and ask if needs to go to

the ER. TC to caretaker 10:10-to see doctor at 11:10 today.

Other Meds: None

Lab Data:

History: Allergies-PCN, AMOXICILLIN, no medical conditions

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362896-1

Onset Date Received Date Status Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days State Age F 4.0 22-Oct-2009 23-Oct-2009 1 26-Oct-2009 27-Oct-2009 IΑ 28-Oct-2009 **Type** Site VAX Detail: **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fluid intake reduced, Vomiting

Symptom Text: Per TC 9:35 AM 10/23/09 from grandmother caring for child. Relates began vomiting at 1:00 AM. Vomited 3 times during the night and now 3 times this

morning. Unable to keep liquids down. Had called physician and was told to call vaccine administrator. Instructed to recall physician and ask if needs to go to

the ER. TC to caretaker 10:10-to see doctor at 11:10 today.

Other Meds: None

Lab Data:

History: Allergies-PCN, AMOXICILLIN, no medical conditions

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362905-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 5.0 F 25-Oct-2009 27-Oct-2009 MO 23-Oct-2009 2 26-Oct-2009 27-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 1 Unknown Unknown

<u>Seriousness:</u> NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash generalised

Symptom Text: Red rash spreading all over body. Itchy

Other Meds:

Lab Data:

History: Asthma

Prex Illness: No illness at time of vaccine. Started a red rash over a day later. Started on arm and has been spreading ever since. Itchy.

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 211

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

Vaers Id: 362905-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 5.0 F 25-Oct-2009 27-Oct-2009 MO 23-Oct-2009 2 26-Oct-2009 27-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash generalised

Symptom Text: Red rash spreading all over body. Itchy

Other Meds:

Lab Data:

History: Asthma

Prex Illness: No illness at time of vaccine. Started a red rash over a day later. Started on arm and has been spreading ever since. Itchy.

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 212

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

Vaers Id: 362910-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 27.0 F ΑZ 24-Oct-2009 24-Oct-2009 0 26-Oct-2009 27-Oct-2009 27-Oct-2009 VAX Detail: **Type** Site **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 100739 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Unevaluable event

Symptom Text: Patient indicated on the consent that she was not pregnant by checking the "no" box. After the nurse administered H1N1 LAIV she learned that the patient was

in fact pregnant. She was given a note to take to her health care provider indicating that she had been given LAIV.

Other Meds:

Lab Data: NA

History: None known
Prex Illness: None known

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 362910-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 27.0 F ΑZ 24-Oct-2009 24-Oct-2009 0 26-Oct-2009 27-Oct-2009 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 100739 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Unevaluable event

Symptom Text: Patient indicated on the consent that she was not pregnant by checking the "no" box. After the nurse administered H1N1 LAIV she learned that the patient was

in fact pregnant. She was given a note to take to her health care provider indicating that she had been given LAIV.

Other Meds:

Lab Data: NA

History: None known
Prex Illness: None known

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362915-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 7.0 24-Oct-2009 25-Oct-2009 26-Oct-2009 27-Oct-2009 GΑ Μ 1 27-Oct-2009 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Headache, Nausea, Pyrexia

Symptom Text: Slight Fever, headaches, cough, nausea

Other Meds: Lab Data:

History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362915-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 7.0 24-Oct-2009 25-Oct-2009 26-Oct-2009 27-Oct-2009 GΑ Μ 1 27-Oct-2009 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown FLU

<u>Seriousness:</u> NO CONDITIONS, NOT SERIOUS

<u>MedDRA PT</u> Cough, Headache, Nausea, Pyrexia

Symptom Text: Slight Fever, headaches, cough, nausea

Other Meds: Lab Data:

History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362916-1

Gender **Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** State 11.0 22-Oct-2009 25-Oct-2009 26-Oct-2009 27-Oct-2009 WA 27-Oct-2009 Μ 3 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Vomiting

Symptom Text: Vomiting and diarrhea

Other Meds: Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362916-1

Gender **Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** State 11.0 22-Oct-2009 25-Oct-2009 26-Oct-2009 27-Oct-2009 WA 27-Oct-2009 Μ 3 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

<u>MedDRA PT</u> Diarrhoea, Vomiting

Symptom Text: Vomiting and diarrhea

Other Meds: Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 362920-1

Gender **Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Vaccine Date Days 23.0 F 22-Oct-2009 26-Oct-2009 27-Oct-2009 ОН 27-Oct-2009 21-Oct-2009 1 **VAX Detail: Type** Site Manufacturer Lot **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Body temperature increased, Decreased appetite, Dehydration, Diarrhoea, Fatigue, Haemorrhoids, Headache, Migraine,

Occult blood, Pyrexia

Symptom Text: Patient received nasal swine flu vaccine at 4pm Wednesday 10/21. On 10/22 and 10/23 patient noticed unusual fatigue considering she had slept 9 hours

each night and was on 200 mg/day Provigil for narcolepsy and had not experienced daytime fatigue since beginning that medication several months ago. On Saturday 10/24, patient awoke at 8am with a basal body temperature of 98.9 (normal temp 97.8) which rose to 99.9 for the next 24 hours. Patient also experienced multiple loose stools, and by midafternoon patient experienced five hours of severe watery diarrhea, to the point of producing external hemorrhoids (and potentially internal as well since both bright and occult blood were noted in the stool for the next 24 hours). The diarrheal symptoms decreased in frequency after the first five hours from bowel movements every 10-15 minutes to every few hours. Patient also complained of appetite loss and severe headaches, though noted that dehydration is her usual migraine trigger. Fever, diarrhea, tiredness, and headaches resolved by the evening of 10/25. The

patient lost 1.5 work days due to the severity of her GI symptoms.

Other Meds: Provigil, 200 mg/day Imitrex, 50 mg as needed

Lab Data:

<u>History:</u> narcolepsy

Prex Illness: no

Prex Vax Illns: infant lethargic and difficult to rouse for 36 hours after vaccine administration~DTP (no brand name)~1~2.00~Patient

VAERS Line List Report

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

Page 219

Vaers Id: 362920-1

Gender **Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Vaccine Date Days 23.0 F 22-Oct-2009 26-Oct-2009 27-Oct-2009 ОН 27-Oct-2009 21-Oct-2009 1 **VAX Detail: Type** Site Manufacturer Lot **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Body temperature increased, Decreased appetite, Dehydration, Diarrhoea, Fatigue, Haemorrhoids, Headache, Migraine,

Occult blood, Pyrexia

Symptom Text: Patient received nasal swine flu vaccine at 4pm Wednesday 10/21. On 10/22 and 10/23 patient noticed unusual fatigue considering she had slept 9 hours

each night and was on 200 mg/day Provigil for narcolepsy and had not experienced daytime fatigue since beginning that medication several months ago. On Saturday 10/24, patient awoke at 8am with a basal body temperature of 98.9 (normal temp 97.8) which rose to 99.9 for the next 24 hours. Patient also experienced multiple loose stools, and by midafternoon patient experienced five hours of severe watery diarrhea, to the point of producing external hemorrhoids (and potentially internal as well since both bright and occult blood were noted in the stool for the next 24 hours). The diarrheal symptoms decreased in frequency after the first five hours from bowel movements every 10-15 minutes to every few hours. Patient also complained of appetite loss and severe headaches, though noted that dehydration is her usual migraine trigger. Fever, diarrhea, tiredness, and headaches resolved by the evening of 10/25. The

patient lost 1.5 work days due to the severity of her GI symptoms.

Other Meds: Provigil, 200 mg/day Imitrex, 50 mg as needed

Lab Data:

History: narcolepsy

Prex Illness: no

Prex Vax Illns: infant lethargic and difficult to rouse for 36 hours after vaccine administration~DTP (no brand name)~1~2.00~Patient

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Vaers Id: 362926-1 (S)

Onset Date Mfr Report Id Gender **Vaccine Date Days Received Date Status Date** State **Last Edit Date** Age 3.0 Μ 26-Oct-2009 26-Oct-2009 0 26-Oct-2009 27-Oct-2009 LA 03-Nov-2009

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

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

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Cough, Eye rolling, Grand mal convulsion, Incontinence, Pruritus, Rhinorrhoea

Symptom Text: Generalized Tonic-Clonic Seizure for 30 seconds. No treatment needed. Afebrile. No trauma. 10/28/2009 ED records from 10/26/2009. Patient with tonic-

clonic seizure activity, eyes rolled back, incontinence, itching, runny nose and cough. Neuro exam WNL, no repeat seizure activity, no tx noted. DC DX New

Onset Seizure? related to H1N1 vaccine.

Other Meds: None

Lab Data: CBC,CMP, UA, and Tox Screen were normal/negative. Labs: CBC, CMP, Tox screen, UA normal

History: Reactive Airway Disease No history of Seizures NKDA PMH RAD Allergies: NKDA

Prex Illness: No

Prex Vax Illns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 221

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

Vaers Id: 362926-1 (S)

Onset Date **Received Date** Mfr Report Id Gender **Vaccine Date Days Status Date** State **Last Edit Date** Age 3.0 Μ 26-Oct-2009 26-Oct-2009 0 26-Oct-2009 27-Oct-2009 LA 03-Nov-2009 **Type** Site VAX Detail: **Prev Doses** Manufacturer Lot Route Other Vaccine

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

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Cough, Eye rolling, Grand mal convulsion, Incontinence, Pruritus, Rhinorrhoea

Symptom Text: Generalized Tonic-Clonic Seizure for 30 seconds. No treatment needed. Afebrile. No trauma. 10/28/2009 ED records from 10/26/2009. Patient with tonic-

clonic seizure activity, eyes rolled back, incontinence, itching, runny nose and cough. Neuro exam WNL, no repeat seizure activity, no tx noted. DC DX New

Onset Seizure? related to H1N1 vaccine.

Other Meds: None

Lab Data: CBC,CMP, UA, and Tox Screen were normal/negative. Labs: CBC, CMP, Tox screen, UA normal

History: Reactive Airway Disease No history of Seizures NKDA PMH RAD Allergies: NKDA

Prex Illness: No

Prex Vax Ilins:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report

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

Page 222

Vaers Id: 363009-1

Mfr Report Id Gender **Vaccine Date Onset Date Days Received Date Status Date** State **Last Edit Date** Age F 20.0 23-Oct-2009 24-Oct-2009 1 27-Oct-2009 27-Oct-2009 PΑ 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Chills, Dizziness, Fatigue, Headache, Heart rate increased, Hypersomnia, Pallor, Pyrexia, Vomiting

Symptom Text: Around 9 AM, I started getting chills, fever, headache, extreme tiredness,& some abdominal pain. I was also told that I was very pale throughout my face. As

the day went on, my fever would come and go, however, my headache only worsened. Also, at times, I had a lot of abdominal pain, to the point where I thought I could not eat or else I would throw up. I probably slept a total of 15 to 16 hours that day. The next day (10/25), I was experiencing my pronlonged headache,

as well as dizzyness for the majority of the day. I felt weak and tired. At times, my heart seemed to be beating faster than usual.

Other Meds: Synthroid

Lab Data:

History: Hypothyroidism

Prex Illness:
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363011-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 35.0 F ОН 23-Oct-2009 23-Oct-2009 0 27-Oct-2009 27-Oct-2009 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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Heart rate increased, Memory impairment, Paraesthesia

Symptom Text: heart was beating fast, light-headed, foggy brain, body felt tingly, trouble remembering things

Other Meds:

Lab Data:

History: allergic to Tertracyclin

Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363020-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 2.0 26-Oct-2009 26-Oct-2009 27-Oct-2009 27-Oct-2009 TX Μ 0 27-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500776P Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Heart rate increased, Wheezing

Symptom Text: Wheezing ,Chills,and Rapid heart beat

Other Meds: Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363021-1

Onset Date Received Date Mfr Report Id Gender **Vaccine Date Days Status Date** State **Last Edit Date** Age 4.0 Μ 22-Oct-2009 22-Oct-2009 0 27-Oct-2009 27-Oct-2009 27-Oct-2009 Site VAX Detail: **Type Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Pruritus, Rash erythematous, Rash macular

Symptom Text: red splotches to posterior torso within 5-6 minutes after administration of vaccine. Patient denies pain, c/o itching. T 99.3, 52.5 lbs, HR 92, BP 106/64. Treated

with 29 mg Benadryl IM LDT and observed for 30 minutes. No s/s of deterioration during observation period. VS after 30 minutes: T98.7 F, BO 100/62, R24, HR

93. No redness on posterior torso. Pt discharged home with instructions to go to ER for any S/S of detioration of condition.

Other Meds:

Lab Data:

History: na Prex Illness: na

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363022-1

Gender Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date** State **Last Edit Date** 4.0 F 24-Oct-2009 27-Oct-2009 27-Oct-2009 ID 24-Oct-2009 0 27-Oct-2009 Site VAX Detail: Type Manufacturer Lot **Prev Doses** Route Other Vaccine

Unknown

Unknown

NULL

Seriousness: NO CONDITIONS, NOT SERIOUS

FLUN(H1N1)

MedDRA PT Abdominal pain upper, Pyrexia, Vomiting

Symptom Text: vomiting/stomach ache/fever

Other Meds:

Lab Data:

History: born premature at 28 weeks/ mild cerebral palsy

MEDIMMUNE VACCINES, INC.

Prex Vey Illes

Prex Vax IIIns:

Page 226

FLU

VAERS Line List Report

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

Vaers Id: 363031-1

Gender **Vaccine Date Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** 9.0 F 23-Oct-2009 24-Oct-2009 27-Oct-2009 28-Oct-2009 TX 28-Oct-2009 1 **Other Vaccine**

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteFLUN(H1N1)MEDIMMUNE VACCINES, INC.500756P0UnknownUnknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: HIVES ALL OVER BODY

Other Meds:

Lab Data:

History: NONE
Prex Illness: NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363032-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Age Gender **Vaccine Date** Days **Status Date** State 7.0 Μ 15-Oct-2009 18-Oct-2009 3 27-Oct-2009 28-Oct-2009 MO MO-2009-21 28-Oct-2009 VAX Detail: **Type** Site **Prev Doses Other Vaccine** Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Cough, Headache, Oropharyngeal pain, Pain, Pyrexia, Tremor

Symptom Text: 10/18/09 Cough and headache and sore throat, fever 101 and achiness continued same symptoms with increase 10/20/09 of shakiness, chills, 103. 10/27/09

f/u with mother - cough persists - has twin sister with s/s

Other Meds:

Lab Data: none

History:

Prex Illness:

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 229

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

Vaers Id: 363038-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 3.0 22-Oct-2009 24-Oct-2009 2 27-Oct-2009 28-Oct-2009 UT Μ 28-Oct-2009 Site VAX Detail: Type **Prev Doses** Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Nasal congestion, Pyrexia, Respiratory tract congestion

Symptom Text: stuffy nose, cough, congestion, fever

Other Meds: Lab Data:

History: none Prex Illness: none

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 363043-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 52.0 F 24-Oct-2009 27-Oct-2009 28-Oct-2009 ID 24-Oct-2009 0 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. 500781 P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Lymphadenopathy, Pruritus

Symptom Text: Swollen lymph nodes on neck. Ichy upper back, possible hives. No fever.

Other Meds:

Lab Data:

History: No Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363165-1

<u>Age</u>	<u>Gender</u>	Vaccine Da	ate Onset Date	<u>Days</u>	Received D	ate S	tatus Date	<u>State</u>	Mfr Report Id	Last Edit Date
31.0	F	21-Oct-200	09 21-Oct-2009	0	27-Oct-200	09 28	3-Oct-2009	WA		28-Oct-2009
VAX Deta	ail: Type	<u> </u>	<u>Manufacturer</u>		<u>Lot</u>	Prev Dose	<u>s</u>	<u>Site</u>	Route	Other Vaccine
	FLUI	N(H1N1) I	MEDIMMUNE VACCINE	S, INC.	500759P	0	Un	known	Unknown	
	FLU(H1N1) l	UNKNOWN MANUFACT	URER	UP002AA	0	Rig	ght 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 IIIns:

VAERS Line List Report

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

Vaers Id: 363167-1

<u>Age</u>	<u>Gender</u>	Vaccine D	Oate Onset Date	<u>Days</u>	Received	<u>Date</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
11.0	M	21-Oct-20	009 Unknown		27-Oct-2	009	28-Oct-2009	WA		28-Oct-2009
VAX Det	ail: Typ	<u>e</u>	<u>Manufacturer</u>		<u>Lot</u>	Prev D	oses	<u>Site</u>	Route	Other Vaccine
	FLU	N(H1N1)	MEDIMMUNE VACCINE	S, INC.	500759P	0	U	nknown	Unknown	

UP002AA

Right arm

Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered

FLU(H1N1)

Symptom Text: H1N1 mist and H1N1 inj given at same time.

SANOFI PASTEUR

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363188-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 7.0 DC Μ 24-Oct-2009 25-Oct-2009 1 27-Oct-2009 28-Oct-2009 29-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500781P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphonia, Eye infection, Lacrimation increased, Sinusitis

Symptom Text: Hoarseness, eye tearing initially, then turned into an eye infection and sinus infection. Given antibiotics by pediatrician.

Other Meds: Allegra allergy liquid medicine 2 tsp. per day.

Lab Data:

<u>History:</u> seasonal allergies including hayfever, mold, etc. takes Allegra.

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363194-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days State 7.0 F 15-Oct-2009 18-Oct-2009 3 27-Oct-2009 28-Oct-2009 MO MO-2009-22 28-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses Other Vaccine** Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Malaise, Pyrexia

Symptom Text: 10/18/09 Primarily fever and headache (101) Continued ill with highest 102. She is improving this am. 10/27/09 F/U with mom - fully recovered - twin brother

with similar s/s

Other Meds: none Lab Data: none

History: High prevalence of Influenza in school, especially this class

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363237-1

Gender Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date Last Edit Date** 9.0 F 25-Oct-2009 27-Oct-2009 28-Oct-2009 KS 21-Oct-2009 4 28-Oct-2009 Site VAX Detail: Type Manufacturer Lot **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Headache, Pain, Pyrexia, Vomiting

Symptom Text: Fever 103, Intense headache, body aches, vomiting, mild cough

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363259-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received I	<u>Date</u>	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
10.0	F	26-Oct-2009	26-Oct-2009	0	27-Oct-20	009	28-Oct-2009	NC		28-Oct-2009
VAX Detai	il: Type	<u>Man</u>	<u>ufacturer</u>		<u>Lot</u>	Prev Dos	ses S	<u>Site</u>	Route	Other Vaccine
	FLU	_	ARTIS VACCINES A SNOSTICS	ND	98442P1B	0	Rigl	nt arm	Intramuscular	
	FLUN	(H1N1) MED	IMMUNE VACCINES	S, INC.	5007769	0	Unk	nown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Cough, Ear discomfort, Pain

Symptom Text: Cough worsen 10-26-09 at 8:30. On 10-27-09 noted temp 101.6, body aches, bilateral ear popping at 7:00 am. Pt seen by Dr. Benton this am and ordered

Tamiflu and Phenergan.

Other Meds: No

None

Lab Data:

History: No allergies to meds and heart murmur noted after birth. **Prex Illness:** sinus pressure and cough - nonproductive. No fever.

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363260-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 17.0 F 26-Oct-2009 27-Oct-2009 27-Oct-2009 28-Oct-2009 GΑ 1 28-Oct-2009 Site VAX Detail: Type Prev Doses Manufacturer Lot Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Swelling face, Urticaria

Symptom Text: Urticarial rash with facial swelling

Other Meds: Ocella Birth Control Pills

Lab Data:

History: Menorrhagia, Herpetic Vulvitis, Depression

Prex Illness: No

Prex Vax IIIns:

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

Page 238

Vaers Id: 363268-1 (S)

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days 7.0 М 22-Oct-2009 25-Oct-2009 3 27-Oct-2009 29-Oct-2009 OK 03-Nov-2009 **VAX Detail:** Site **Type** Manufacturer Lot **Prev Doses** Route Other Vaccine

Seriousness: HOSPITALIZED, SERIOUS

FLUN(H1N1)

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

500758P

Symptom Text: Pt. had bilateral lower extremity pain and weakness; he also had abdominal pain and low back pain. Tmax 103 degrees. 10/28/09: Hospital Record and

Discharge Summary received for Dates of Service 10/25/09 to 10/27/09. Final DX: Ataxia, Bilateral lower extremity weakness and pain, Abdominal pain, rule out Guillain-Barre Syndrome. Assessment: Presented to the ED with fever of 103, chills, recent HA's, pain and weakness in the bilateral LE's, pain in the abdomen on the left and pain in the low back on the left. Also, one episode of nausea and vomiting as well as cough and headache. Decreased patellar reflex

Unknown

Unknown

and difficulty walking. Patient discharged to home to follow up in 5 days. 10/29/09: Vaccine record received. No lot number included.

Other Meds: Multivitamin

Lab Data: Abdominal CT: mesenteric adenitis; CBC, 12.3; CRP, 6.32. 10/28/09: Hospital Record and Discharge Summary received for Dates of Service 10/25/09 to

10/27/09. Labs and Diagnostics: Rapid strep-Negative, CBC; WBC's 12.3 (H), Abs. Neut. 9.

MEDIMMUNE VACCINES, INC.

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

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363270-1

Gender Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date Last Edit Date** 6.0 F 16-Oct-2009 20-Oct-2009 27-Oct-2009 28-Oct-2009 CA 4 28-Oct-2009 Site VAX Detail: Type <u>Lot</u> Prev Doses Manufacturer Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Pyrexia, Vomiting

Symptom Text: Fever 102, cough, vomiting. Onset about 96 h after administration of LAIV H1N1.

Other Meds: None
Lab Data: None
History: None
Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363273-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 16.0 F 21-Oct-2009 26-Oct-2009 27-Oct-2009 28-Oct-2009 NJ 5 28-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Received nasal spray H1N1 vaccine on 10/21. Developed hives 10/26.

Other Meds: Minocycline

Lab Data:

History: No Prex Illness: No

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Vaers Id: 363286-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 25-Oct-2009 27-Oct-2009 1.6 Μ 22-Oct-2009 3 28-Oct-2009 TX 28-Oct-2009 VAX Detail: Prev Doses Site Type Manufacturer Other Vaccine Lot Route FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500759P Unknown Unknown

U2807AA

0

Right leg

Intramuscular

<u>Seriousness:</u> ER VISIT, NOT SERIOUS

MedDRA PT Chills, Cough, Pyrexia

FLU

Symptom Text: Fever, chills, cough. Prescribed Tamiflu and advised fluid/fever control.

SANOFI PASTEUR

Other Meds:

<u>Lab Data:</u> Rapid Flu test came back negative. Patient presented with flu-like symptoms.

History: No known allergies.

Prex Illness: No.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363287-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> F 40.0 08-Oct-2009 08-Oct-2009 0 27-Oct-2009 28-Oct-2009 IN 28-Oct-2009 VAX Detail: Site Type **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Headache, Malaise, Myalgia, Oropharyngeal pain, Paraesthesia, Pyrexia

Symptom Text: Headache, muscle aches and tingling in hands that eve. Headache the next day. 4 days later became very ill for 1 week with fever for 4 days, sore throat,

severe cough, headache and muscle aches.

Other Meds: Synthroid 15mcg

Lab Data:

History: Hypothyroid

Prex Illness: No.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363297-1

Onset Date Received Date Status Date State Mfr Report Id **Last Edit Date** Age Gender **Vaccine Date** Days F DC 5.0 27-Oct-2009 27-Oct-2009 0 27-Oct-2009 28-Oct-2009 28-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500781P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: child vomited. not accompanied by fever. still monitoring for fever or additional problems. Gave her water to drink and nothing else. put her to bed for rest.

Other Meds:

<u>Lab Data:</u> still monitoring situation. Only been 1 1/2 hours since vomiting. Waiting for morning to contact doctor if necessary and follow up.

History: No

Prex Illness: Prior to vaccination, daughter did say her tummy ached, like she had to go to the bathroom and passed gas but she showed no othe

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363374-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 9.0 F 26-Oct-2009 27-Oct-2009 28-Oct-2009 28-Oct-2009 NC 1 28-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Vomiting

Symptom Text: Throwing up bad stomach cramps

Other Meds:

Lab Data:

History: NONE
Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363374-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 9.0 F 26-Oct-2009 27-Oct-2009 28-Oct-2009 28-Oct-2009 NC 1 28-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Vomiting

Symptom Text: Throwing up bad stomach cramps

Other Meds:

Lab Data:

History: NONE
Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363376-1

Gender **Onset Date Days Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 5.0 F 16-Oct-2009 18-Oct-2009 28-Oct-2009 28-Oct-2009 NC 2 28-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Vomiting

Symptom Text: Throwing up stomach cramps and pain

Other Meds:

Lab Data:

History: NONE
Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363376-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** 5.0 F 16-Oct-2009 18-Oct-2009 28-Oct-2009 28-Oct-2009 NC 2 28-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Vomiting

Symptom Text: Throwing up stomach cramps and pain

Other Meds:

Lab Data:

History: NONE
Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363400-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 39.0 F 26-Oct-2009 26-Oct-2009 28-Oct-2009 29-Oct-2009 KS 30-Oct-2009 0 **Other Vaccine**

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteFLUN(H1N1)MEDIMMUNE VACCINES, INC.500759P1UnknownUnknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash across truck of body

Other Meds:

Lab Data:noneHistory:nonePrex Illness:none

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 249

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

Vaers Id: 363400-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 39.0 F 26-Oct-2009 26-Oct-2009 28-Oct-2009 29-Oct-2009 KS 30-Oct-2009 0

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500759P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash across truck of body

Other Meds:

Lab Data:noneHistory:nonePrex Illness:none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363403-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 26.0 F 15-Oct-2009 28-Oct-2009 13 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: No adverse reaction, patient received H1N1 flu mist and later found out she was pregnant

Other Meds:

Lab Data: Referral to OB for further evaluation

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363403-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 26.0 F 15-Oct-2009 28-Oct-2009 28-Oct-2009 13 29-Oct-2009 IN 29-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: No adverse reaction, patient received H1N1 flu mist and later found out she was pregnant

Other Meds:

Lab Data: Referral to OB for further evaluation

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363417-1

Gender Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** Days 0.7 28-Oct-2009 29-Oct-2009 Μ 19-Oct-2009 Unknown ME 29-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500757P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Called father and mother. Both stated "no reactions".

Other Meds:

Lab Data:

History: No Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363417-1

Gender **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date** State **Last Edit Date** Days 0.7 28-Oct-2009 29-Oct-2009 Μ 19-Oct-2009 Unknown ME 29-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500757P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Called father and mother. Both stated "no reactions".

Other Meds:

Lab Data:

History: No Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363419-1 (S)

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 5.0 20-Oct-2009 22-Oct-2009 2 28-Oct-2009 29-Oct-2009 WI 29-Oct-2009

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

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Influenza like illness, Pain, Pyrexia, Rash, Urticaria

Symptom Text: (REPORTED BY HOSPITAL) 104-105 FEVERS, BODY ACHES AND OTHER FLU LIKE SYMPTOMS. HIVE LIKE RASH TO FACE

Other Meds:

<u>Lab Data:</u> RAPID INFLUENZA POSITIVE REPORTED THAT A COLLECTION WOULD BE SENT TO STATE LAB.

History: NONE REPORTED

Prex Illness: NONE

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report

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

Vaers Id: 363419-1 (S)

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 5.0 20-Oct-2009 22-Oct-2009 2 28-Oct-2009 29-Oct-2009 WI 29-Oct-2009

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

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Influenza like illness, Pain, Pyrexia, Rash, Urticaria

Symptom Text: (REPORTED BY HOSPITAL) 104-105 FEVERS, BODY ACHES AND OTHER FLU LIKE SYMPTOMS. HIVE LIKE RASH TO FACE

Other Meds:

Lab Data: RAPID INFLUENZA POSITIVE REPORTED THAT A COLLECTION WOULD BE SENT TO STATE LAB.

History: NONE REPORTED

Prex Illness: NONE

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363427-1

<u>Gender</u> **Onset Date** Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Status Date Last Edit Date** Unknown F 15-Oct-2009 17-Oct-2009 2 28-Oct-2009 29-Oct-2009 29-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown
FLU UNKNOWN MANUFACTURER NULL Unknown Intramuscular

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: 48 hours after H1N1 LAIV.

Other Meds: Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363437-1

<u>Age</u> **Onset Date Received Date** Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State 2.0 Μ 28-Oct-2009 28-Oct-2009 0 28-Oct-2009 29-Oct-2009 29-Oct-2009 VAX Detail: **Type** Site **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500780P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dark circles under eyes, Lethargy, Nasopharyngitis, Pallor, Pyrexia

Symptom Text: After H1N1 mist patient left office and was pale, dark circles under eyes, weak and lethargic. fell asleep and woke 1.5 hours later with a fever of 102. patient

came back to office and looked fine except for cold and temp was 99

Other Meds:

Lab Data:

History: none

Prex Illness: cold for a few days, no fever

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Vaers Id: 363450-1

Onset Date Mfr Report Id Gender **Vaccine Date Days Received Date Status Date** State **Last Edit Date** Age 2.0 Μ 24-Oct-2009 24-Oct-2009 0 28-Oct-2009 29-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Fatigue, Headache, Irritability, Opisthotonus

Symptom Text: Child received H1N1 LAIV in AM. "Headache" (frontal lobe and temples) began the same evening. No symptoms Sunday but headache, as well as a "stomach

ache", resumed Sunday evening, all day and evening Monday. Better Tuesday but symptoms resumed Tuesday evening. Mother states that the child has

been very tired and uncharacteristically irritable: stomping feet, arching back, slapping sibling, and flailing about.

Other Meds: Zyrtec Multivitamin with iron

Lab Data: None. Instructed by office of PCP to bring the child in if symptoms worsened.

History: Seasonal allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363452-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 51.0 F 26-Oct-2009 27-Oct-2009 28-Oct-2009 29-Oct-2009 1 MN 29-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500783P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Noted that Flumist vaccine had been administered to person over the age of 49.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363460-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days CA 4.0 Μ 26-Oct-2009 26-Oct-2009 0 28-Oct-2009 29-Oct-2009 29-Oct-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Body temperature increased, Headache, Nausea

Symptom Text: Temp to 103, headache, stomach ache and nausea-onset 4 hrs. after H1N1 nasal mist.

Other Meds: None Lab Data: None

History: AMOXICILLIN; BACTRIM

Prex Illness: None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 363466-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 33.0 F 20-Oct-2009 20-Oct-2009 0 28-Oct-2009 29-Oct-2009 WA 29-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Laryngitis, Pain, Pyrexia

Symptom Text: Developed fever, body aches and cough within several hours of receiving vaccine; this continued into fever of greater than 102, intractable cough, body aches

and laryngitis.

Other Meds: Insulin Lab Data: None

History: Diabetes; hypertension

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363471-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 29.0 F 27-Oct-2009 KS 27-Oct-2009 0 28-Oct-2009 29-Oct-2009 29-Oct-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear pain, Myalgia, Pharyngeal hypoaesthesia

Symptom Text: 10/27/2009 R ear pain for 1 hour after administration, throat numbness for 1 hour, a lot of muscle aches.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report

500759P

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

Page 263

Vaers Id: 363495-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received Da	ate State	us Date	<u>State</u>	Mfr Report Id	Last Edit Date
9.0	F	14-Oct-2009	14-Oct-2009	0	28-Oct-200	9 30-0	ct-2009	CA		30-Oct-2009
VAX Deta	il: Type	<u>Manuf</u>	<u>acturer</u>		<u>Lot</u>	Prev Doses	<u>s</u>	<u>Site</u>	<u>Route</u>	Other Vaccine
	FLU	SANOI	FI PASTEUR		U3186AA	0	Left	arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

FLUN(H1N1)

MedDRA PT Headache

Symptom Text: Child received FluMist as prescribed in each nostril mom stated about 15 minutes later she started complaining of a headache. They had not left the Health

Department so the mom brought her back in to see the nurse. The child stated her head still hurt but was doing better. Mom was advised to give Tylenol like

Unknown

Unknown

after any other vaccine and if symptoms get worse to see her medical provider.

MEDIMMUNE VACCINES, INC.

Other Meds:NoneLab Data:NoneHistory:NonePrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363504-1

<u>Age</u>	Gender	Vaccine	Date Onset Date	Days	Received	Date St	tatus Date	<u>State</u>	Mfr Report Id	Last Edit Date
4.0	F	27-Oct-2	009 28-Oct-2009	1	28-Oct-20	009 30)-Oct-2009			30-Oct-2009
VAX Detai	il: Type	!	<u>Manufacturer</u>		<u>Lot</u>	Prev Dose	<u>s</u>	<u>Site</u>	Route	Other Vaccine
	FLUN	N(H1N1)	MEDIMMUNE VACCINES	, INC.	500758P	0	Unl	known	Unknown	
	DTAF	o	SANOFI PASTEUR		C3322AA	4	Let	ft arm	Intramuscular	
	IPV		SANOFI PASTEUR		D0413	3	Let	ft arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: hives noted on face and progressed to body and arms

Other Meds: Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363505-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received	Date	Status I	Date S	<u>tate</u>	Mfr Report Id	Last Edit Date
11.0	M	28-Oct-2009	28-Oct-2009	0	28-Oct-2	009	29-Oct-2	2009 (CA		29-Oct-2009
VAX Detai	il: <u>Type</u>	<u>Manu</u>	<u>facturer</u>		<u>Lot</u>	Prev	Doses	<u>Site</u>		Route	Other Vaccine
	FLUN	J(H1N1) MEDII	MMUNE VACCINES	INC.	500765P		0	Unknown		Unknown	

Left arm

Intramuscular

Seriousness: ER VISIT, NOT SERIOUS

FLU

MedDRA PT Immediate post-injection reaction, Paraesthesia, Sensation of foreign body

SANOFI PASTEUR

Symptom Text: Felt he had a lump in his throat right after vaccine given and tingling in his throat. oral benadryl given with resolution of symptoms.

U3216AA

Other Meds: none

Lab Data:

History: asthma - mom not aware that he has history of asthma

Prex Illness: no
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363511-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 5.0 F 25-Oct-2009 29-Oct-2009 23-Oct-2009 2 28-Oct-2009 MD 29-Oct-2009 VAX Detail: Site Other Vaccine

 VAX Detail:
 Type
 Manufacturer
 Lot
 Prev Doses
 Site
 Route

 FLUN(H1N1)
 MEDIMMUNE VACCINES, INC.
 NULL
 0
 Unknown
 Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nasal congestion, Productive cough, Pyrexia

Symptom Text: Fever up to 102.9, nasal congestion, productive cough, occipital headache

Other Meds: None

Lab Data: None needed

History: None Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

<u>Vaers Id:</u> 363513-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	<u>Days</u>	Received D	ate	Status Dat	<u>:e</u>	State	Mfr Report Id	Last Edit Date
6.0	M	27-Oct-2009	Unknown		29-Oct-200	09	29-Oct-200	9	CA		29-Oct-2009
VAX Detai	I: Type	<u>Manı</u>	<u>ıfacturer</u>		<u>Lot</u>	Prev Do	ses	<u>Site</u>		<u>Route</u>	Other Vaccine
	DTAP	SANG	OFI PASTEUR		C3157AA			Left arm		Intramuscular	
	FLU	SANG	OFI PASTEUR		U3203AA			Left arm		Intramuscular	
	FLUN	(H1N1) MED	IMMUNE VACCINES	S, INC.	500796P	0		Unknown		Unknown	
	IPV	SANG	OFI PASTEUR		D0052			Left arm		Subcutaneously	
	VARC	EL MER	CK & CO. INC.		1043Y			Right arm		Subcutaneously	
	FLU(F	I1N1) SANO	OFI PASTEUR		UP004AA	0		Right 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 IIIns:

VAERS Line List Report

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

Vaers Id: 363529-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 16.0 F 27-Oct-2009 27-Oct-2009 0 29-Oct-2009 29-Oct-2009 NE 29-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Malaise, Vomiting

Symptom Text: Pt. mom reports had vomiting throughout night after vaccine. Vomiting ceased by AM but did stay home from school due to ill all night and headache.

Other Meds: DEPO PROVERA 150 mg q 3 mo; LEXAPRO 20 mg

Lab Data:

<u>History:</u> Depression

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363530-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 14.0 F 27-Oct-2009 27-Oct-2009 0 29-Oct-2009 29-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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash

Symptom Text: Red raised rash both arms from elbows to hands 3 hours after H1N1 nasal mist. Resolved by morning. Advised mom if rash returns-give BENADRYL and

contact our office.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363534-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 32.0 29-Oct-2009 OK Μ 28-Oct-2009 29-Oct-2009 1 29-Oct-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Arthralgias, Myalgias developed overnight. Mild-moderate in severity, have been present for greater than 8 hours and continue currently.

Other Meds:

Lab Data:

History: None Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363597-1

Onset Date Received Date State Mfr Report Id Gender **Vaccine Date Days Status Date Last Edit Date** Age F 8.0 28-Oct-2009 28-Oct-2009 0 29-Oct-2009 29-Oct-2009 IΑ 29-Oct-2009 **Type** Site VAX Detail: **Prev Doses** Other Vaccine Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Heart rate increased, Respiratory rate increased, Throat irritation, Vomiting

Symptom Text: 1/2 hr after HINI mist dose, developed chills and scratchy throat. Mother gave her Motrin. About 10pm child is awake with fast breathing, fast heart rate, temp

103.7. Motrin given then vomited harshly for short period of time. Finally sleeping at 3am. Feeling better by morning, and no temp, was sent to school. (I) to

report this to physician.

Other Meds: None Lab Data: None

History: Seasonal Allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363629-1 (S)

Gender **Vaccine Date Onset Date Days Received Date Status Date** State Mfr Report Id **Last Edit Date** Age F 34.0 21-Oct-2009 21-Oct-2009 0 29-Oct-2009 02-Nov-2009 VA 02-Nov-2009 VAX Detail: **Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

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

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Blood pressure fluctuation, Chills, Dizziness, Heart rate increased, Sinus tachycardia, Tachycardia

Symptom Text: Within 5 minutes of vaccine, experienced dizziness, chills, tachycardia/160 beats per minute and fluctuations in blood pressure. Within 6 hours, had elevated

heart beat at rest and one other episode - approx. 6 hrs. after receiving vaccine of sinus tachycardia-170 bpm at rest and blood pressure spike-168/90 - normal around 100/60. Treated with BENADRYL, I.V. for hydration and beta-blocker to regulate heart and b.p. Continued heart rate & bp fluctuations 5 days out.

Continued beta-blockers.

Other Meds: ERRIN and SYNTHROID daily & prenatal vitamin

Lab Data: EKG to assess heart rhythm speed; BP readings; Echocardiogram.

History: Hypothyroidism; prior HELLP Syndrome during pregnancy (April 2008)

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363649-1

Gender **Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date Vaccine Date** Days State <u>Age</u> F 40.0 22-Oct-2009 22-Oct-2009 0 29-Oct-2009 29-Oct-2009 WI 29-Oct-2009 VAX Detail: **Type** Site **Prev Doses** Other Vaccine Manufacturer Lot Route

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Feeling jittery, Headache, Pallor, Pruritus, Vertigo

Symptom Text: Initially felt jittery inside and itchy but no uticaria. VS normal, but pale. Very anxious. With in 1/2hr n/v, occipital HA and vertigo. In ED Tylenol, Meclizine, Zolfran

ODT, and Advil

Other Meds: Not aware of current medications

Lab Data: None

History: no preexisting, allergic to shell fish

Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363659-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 52.0 F CT 28-Oct-2009 Unknown 29-Oct-2009 30-Oct-2009 30-Oct-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: No adverse symptoms noted at this time. Intranasal questionnaire was also utilized and completed by the patient. The patient indicated on that questionnaire

that she was between 2-49.

Other Meds:

Lab Data:

History: No Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363663-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 4.0 Μ 23-Oct-2009 23-Oct-2009 0 29-Oct-2009 30-Oct-2009 TX 30-Oct-2009

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

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Headache

Symptom Text: Headache and "unable to breath" x15-20 min (in car with mom). No color changes, no gasping, no cough, no fever, no emesis. Seen in office 2 hours after

vaccine - exam normal.

Other Meds:NoneLab Data:NoneHistory:NonePrex Illness:None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 363703-1

Onset Date Received Date Status Date State Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days Age 5.0 Μ 26-Oct-2009 26-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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash, Swelling, Swelling face

Symptom Text: Mom noticed "red spot" on back on neck at bedtime. Around 1 pm on 10/27/09 red rash had spread to face, neck, chest. Face was swollen. Took to ER at

Hospital where they administered Benadryl po and "steroid" po. Was given liquid steroid to take daily. On 10/29/09 mom reports child still has rash, swelling,

itching.

Other Meds:

Lab Data:

History: none
Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363708-1 (S)

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 2.0 27-Oct-2009 OK Μ 26-Oct-2009 1 29-Oct-2009 30-Oct-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>

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bronchiolitis, Dyspnoea

Symptom Text: Mom reported "heavy breathing at 8 pm 10/26/09 that continued next day. Took child to ER at Hospital where he was admitted with dx of bronchiolitis.

Other Meds:

Lab Data:

History: none
Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363709-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State Age F 28.0 28-Oct-2009 29-Oct-2009 1 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. UNKNOWN 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Inflammation, Rash, Rash pruritic

Symptom Text: Rash occurred on the stomach, chest and left forearm the morning after receiving the vaccine. It appeared red, inflammed, and itches. Later that afternoon, it

appeared to begin clearing up and has not spread any further.

Other Meds: Patient took benedryl 25 mg the morning the rash appeared. She takes Lexapro 10 mg but skipped her dose when the rash appeared out of fear of worsening

the condition.

Lab Data:NoneHistory:NonePrex Illness:No

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363760-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F GΑ Unknown 23-Oct-2009 Unknown 29-Oct-2009 30-Oct-2009 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: Client was given H1N1 nasal mist and she is 18 weeks pregnant but did not state that she was pregnant before given the vaccination. Client referred to

physician.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363761-1

<u>Age</u>	<u>Gender</u>	Vaccine Da	ate Onset Date	Days	Received	Date State	us Date	State	Mfr Report Id	Last Edit Date
21.0	M	23-Oct-200	9 23-Oct-2009	0	29-Oct-20	009 30-0	ct-2009	TX		02-Nov-2009
VAX Deta	il: Type	<u>N</u>	<u> Manufacturer</u>		<u>Lot</u>	Prev Doses	Sit	<u>e</u>	Route	Other Vaccine
	FLUN	I(H1N1) N	MEDIMMUNE VACCINES,	INC.	500756D	0	Unkno	own	Unknown	
	MNQ	S	SANOFI PASTEUR		U3014	0	Left a	arm	Intramuscular	
	TDAP	, ,	SANOFI PASTEUR		UF500BA	0	Right	arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Depressed level of consciousness, Gait disturbance, Staring

Symptom Text: 1 1/2 hours after administration, disequilibrium, stumbling, staring, slow to answer questions but oriented x 3. Spontaneous resolution.

Other Meds: FOCALIN XR

Lab Data: None
History: None
Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363762-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 5.0 Μ 26-Oct-2009 27-Oct-2009 29-Oct-2009 30-Oct-2009 OK 02-Nov-2009 1 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Pyrexia

Symptom Text: mom reports fever of 103 and cough

Other Meds: Lab Data:

History: none
Prex Illness: no
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 363763-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** F 25-Oct-2009 29-Oct-2009 30-Oct-2009 VA 28.0 22-Oct-2009 3 30-Oct-2009

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

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eyelid disorder, Eyelid oedema, Facial palsy

Symptom Text: Left eyelid droopiness/?swelling; over the next few days, pt developed a right sided Bell's palsy

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363764-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days IL 49.0 Μ 19-Oct-2009 19-Oct-2009 0 29-Oct-2009 30-Oct-2009 30-Oct-2009 Site VAX Detail: Type Manufacturer **Prev Doses** Route Other Vaccine Lot

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Headache, Lethargy, Urticaria

Symptom Text: Developed hives on arms and chest. Experienced headache, diarrhea, and lethargy.

Other Meds: Centrum Silver for men daily vitamin

Lab Data: None

History: Told by Dr.he has chemically sensitive skin.

Prex Illness: None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 363768-1

Gender **Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date Vaccine Date** Days State <u>Age</u> 12.0 F CA 28-Oct-2009 28-Oct-2009 0 29-Oct-2009 30-Oct-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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Itchy rash; After shower it worsened; some hives; itchy rash & hives around mouth, on stomach and back; with benedryl the reaction did not progress and is

being given every 6 hrs.

Other Meds:

<u>Lab Data:</u> I called a 24 hr. nurse advise system and then a doctor called me this morning to talk about the reaction.

History: Allergies to antibiotics: amoxi`cillin; zithromax; keflex; omnicef;

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363771-1

Onset Date Mfr Report Id Gender **Vaccine Date Days Received Date Status Date** State **Last Edit Date** Age F 25.0 28-Oct-2009 28-Oct-2009 0 29-Oct-2009 30-Oct-2009 TX 30-Oct-2009 VAX Detail: **Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500782P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure decreased, Cyanosis, Dizziness, Pallor

Symptom Text: The 25 year old was very apprehensive- stated that her daughter was goig to receive the vaccine for the first time. The 25 yr old received the nasal spray

vaccine first- then held her daughter for the vaccine (nasal)- the child got down from the mother's lap and that's when the mother (25 year old) appeared to be having a reaction and the nurse sat her back in the chair. This was approx 10 minutes after receiving the H1N1 live viral nasal spray vaccine, she became pale, cyanotic around the lips and face, having weakness, dizzinesss. Her BP was 80/50. She was held at the clinic until 7:30 pm and her BP was up to 90/50.

She was recommended to go to the hospital ED but she refused and wanted to go home.

Other Meds: None

Lab Data:

History: No Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363772-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 25.0 F 27-Oct-2009 30-Oct-2009 27-Oct-2009 0 29-Oct-2009 WA 02-Nov-2009

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500759P0UnknownUnknownFLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Fatigue, Headache, Oropharyngeal pain, Wheezing

Symptom Text: Heavy chest, weazing, headache, very tired, slight soar throat I slept 12 hours two nights after.

Other Meds:

Lab Data:

History: ceclor
Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363777-1

Onset Date State Mfr Report Id Gender **Vaccine Date** Days **Received Date Status Date Last Edit Date** Age F 3.0 27-Oct-2009 28-Oct-2009 1 29-Oct-2009 30-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500781P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Emotional distress, Pain in extremity, Pyrexia, Vomiting

Symptom Text: Developed fever to 103, vomiting, abdominal and leg pain. She was in so much distress that she was evaluated in the Emergency Room. I just spoke with

Mom and she said that patient is doing much better.

Other Meds: Bactrim suspension 7.5 ml twice daily--started on 10/27/2009.

<u>Lab Data:</u> Strep and Influenza screens were negative. CXR was negative. Urine culture from 10/27/09 was no growth.

History: None

Prex Illness: Complaining of dysuria, but no fever or abdominal pain.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363781-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 16.0 F KS 29-Oct-2009 29-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500781P Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, No adverse event

Symptom Text: Client recieved Flumist which is contraindicated for a client with Asthma Client did not have reaction at time of vaccination. Called CDC for possible reactions.

Other Meds:

Lab Data:

History: Asthma

Prex Illness:
Prex Vax Illns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 289

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

Vaers Id: 363782-1

Gender **Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date Vaccine Date** Days <u>Age</u> 42.0 F CO 26-Oct-2009 28-Oct-2009 2 29-Oct-2009 30-Oct-2009 02-Nov-2009 VAX Detail: **Type** Site **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 5007765P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear discomfort, Pain, Throat irritation

Symptom Text: I feel like my throat and left ear has a chemical burn. I went to my Dr.'s office at 1 pm they said that I have a irritation to my throat and gave me a pain killer.

Vicodin. The pain is so great that that is not relieving the pain.

Other Meds: Advil Pm

Lab Data: no test as of yet

History: none

Prex Illness: no illness a time of vaccanation

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363785-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 5.0 F 26-Oct-2009 CA 26-Oct-2009 0 29-Oct-2009 30-Oct-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives all over body gave benadryl they went away came back, gave benadryl went away came back, gave again never went away its been 4 days now still

getting hives.

Other Meds:

Lab Data:

History: no Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363791-1

Onset Date Mfr Report Id Gender **Vaccine Date Days Received Date Status Date** State **Last Edit Date** Age F 26.0 28-Oct-2009 28-Oct-2009 0 29-Oct-2009 30-Oct-2009 MI 02-Nov-2009 VAX Detail: **Type Prev Doses** Site Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500797P 0 Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Cough, Hypoventilation, Oropharyngeal pain, Productive cough, Throat tightness

Symptom Text: Within 30 minutes of recieving the H1N1 nasal vaccine I began feeling tightness in my throat. It became difficult to talk in a deep breath and my throat started

to feel sore. Conditions worsened through the night and by morning I had developed a dry cough. At 9:30 am I started having chills and by 12:00 I started running a temperature and my cough became productive. At 12:00 noon my temperature was 102 degrees and Motrin was administered. It is 9pm on October

29th, 2009 and symptoms have not lessened.

Other Meds: Nasacort

Lab Data:

History: none
Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363799-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 35.0 F 26-Oct-2009 26-Oct-2009 29-Oct-2009 30-Oct-2009 IL 30-Oct-2009 0 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500579P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Nausea, Pyrexia

Symptom Text: Fever (102.5), Chills, Nausea

Other Meds:

Lab Data:

History: None Noted

Prex Illness: No

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 293

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

Vaers Id: 363801-1

Gender **Onset Date Received Date** Mfr Report Id <u>Age</u> **Vaccine Date** <u>Days</u> **Status Date** State **Last Edit Date** 18.0 F 28-Oct-2009 29-Oct-2009 30-Oct-2009 MI Unknown 02-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown FLU GLAXOSMITHKLINE NULL Unknown Unknown

BIOLOGICALS

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain

Symptom Text: Body Ache, Headache

Other Meds:

Lab Data:

History: N/A
Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363853-1

Gender Days Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** 6.0 27-Oct-2009 30-Oct-2009 SC Μ 26-Oct-2009 1 02-Nov-2009 02-Nov-2009 Site VAX Detail: Type Other Vaccine

<u>Lot</u> Manufacturer **Prev Doses** Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P Unknown Unknown

ER VISIT, NOT SERIOUS Seriousness:

MedDRA PT Headache, Pyrexia, Vomiting

Symptom Text: Fever, headache, vomiting developed within 24 hrs of H1N1 vaccine administration.

Other Meds:

Lab Data: Throat cx negative

History: None **Prex Illness:** None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363913-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 32.0 F 30-Oct-2009 NE 19-Oct-2009 19-Oct-2009 0 02-Nov-2009 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. UP002AA Right arm Intramuscular

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Headache, Nausea, Palpitations, Vomiting

Symptom Text: headache, weakness, dizziness, nausea, vomiting heart palpatations.

Other Meds:

Lab Data:

History: no Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363922-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 43.0 F 26-Oct-2009 PΑ 25-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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Pain, Weight bearing difficulty

Symptom Text: Significant right hip pain, aggrevated with extending sitting, caused limited weight bearing ability. Resolved in approximately 48 hours

Other Meds:

Lab Data:

History: none

Prex Illness: mild nasal congestion

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363926-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 19.0 21-Oct-2009 30-Oct-2009 02-Nov-2009 ΚY 03-Nov-2009 Unknown

<u>VAX Detail:</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. 500776P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: Pregnant female received LAIV H1N1 at flu clinic. Interpreter present. Not discovered until 10/30 when pt seen in MD office. 11/2/09: Prenatal records received

for dates of care 7/20/09 to 10/30/09. Dx: Pregnant woman received LAIV H1N1 Influenza Vaccine. Assessment: Pregnant woman at 33 weeks gestation

reported to her physician that she had received the LAIV H1N1 Influenza Vaccine at a mass flu clinic.

Other Meds:

Lab Data: 11/2/09: Prenatal records received for dates of care 7/20/09 to 10/30/09. Labs and Diagnostics: + Fetal heart tones.

History: None. 11/2/09: Prenatal records received for dates of care 7/20/09 to 10/30/09. PMH: Condyloma, bacterial vaginosis, chlamydia, late prenatal care.

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363935-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 52.0 F UT 07-Oct-2009 Unknown 30-Oct-2009 02-Nov-2009 02-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: On 10/7/09 patient came to the clinic to receive a H1N1 nasal spray. I administered this vaccine to the patient. The H1N1 spray is only recommended for

patients between the age of 2 years up to 50 years, so this patient was too old to receive this vaccine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363962-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 25-Oct-2009 KS 30.0 Μ 25-Oct-2009 0 30-Oct-2009 02-Nov-2009 02-Nov-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia, Sinus headache

Symptom Text: Low grade fever, up to 101 degrees F., continuing for six days so far. Severe headache and sinus pain.

Other Meds: Transdermal Scopolamine (10/25/09: 3pm - midnight, for air travel) Allegra (daily, for allergies)

Lab Data:

History: Tree/grass pollen and dust mite allergies.

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363964-1

Gender **Onset Date Days Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 8.0 Μ 28-Oct-2009 30-Oct-2009 2 30-Oct-2009 CA 02-Nov-2009 02-Nov-2009 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Tongue disorder, Tongue exfoliation

Symptom Text: Maceration and peeling of tongue

Other Meds:

Lab Data:noneHistory:nonePrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363965-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 32.0 F 29-Oct-2009 29-Oct-2009 30-Oct-2009 0 02-Nov-2009 NM 02-Nov-2009 Site VAX Detail: Type Prev Doses **Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Skin rash lasting about 24 hrs. No other adverse reaction noted.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 363970-1

Gender State <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days 11.0 F ΑZ 22-Oct-2009 22-Oct-2009 0 30-Oct-2009 02-Nov-2009 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chest pain, Constipation, Fatigue, Myalgia, Pain, Pharyngitis

Symptom Text: severe abdominal pain, chest pain, constipation, fatigue, achey, Myalgias, pharygitis

Other Meds:

<u>Lab Data:</u> Lipid profile, CMP, T4, TSH, CBC

History: unknown

Prex Illness:
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364006-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 22.0 F KS 28-Oct-2009 28-Oct-2009 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500736P 0 Right arm Intramuscular

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wheezing

Symptom Text: expiratory and inspiratory wheezing lasting 30 minutes. Observed; no treatment necessary as wheezing resolved on its own with no additional symptoms

developing

Other Meds: none

Lab Data:

History: iv cipro and iv vancomycin

Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364007-1

Onset Date Mfr Report Id Gender **Vaccine Date Days Received Date Status Date** State **Last Edit Date** Age F 22.0 21-Oct-2009 21-Oct-2009 0 30-Oct-2009 02-Nov-2009 IΑ 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500783P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Confusional state, Dizziness, Malaise, Nasal congestion, Rhinorrhoea, Vomiting

Symptom Text: "confusion, dizziness"; "an hour went by and then I threw up"; did not eat before vaccination or after; reports lack of energy; lasted 2 1/2 hours. When asked

how she was feeling, "I stopped taking my allergy medicine for 3 days and don't feel well. My nose and everything is stuffy and runny.

Other Meds: Medication allergies: "can't remember what it is".

<u>Lab Data:</u> Did not see Dr., no testing was done; **History:** Dx. allergies 2 years ago, environmental

Prex Illness: Denies "no"

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364054-1

Gender Days State <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** 7.0 F 25-Oct-2009 27-Oct-2009 CA 2 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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis

Symptom Text: Mom asking if nosebleeds are adverse reaction to H1N1 intranasal received. No profuse blood but some on tissue when nose blown.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364057-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 2.0 Μ 23-Oct-2009 26-Oct-2009 3 30-Oct-2009 02-Nov-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Decreased appetite, Fatigue, Nasal congestion, Pyrexia, Vomiting

Symptom Text: Seen 10/28/09 with symptoms including fever up to 105 degrees, nasal congestion, cough, fatigue and vomiting. Associated symptoms include decreased

appetite.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364061-1

Gender Days **Received Date** State Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Status Date Last Edit Date** 7.0 28-Oct-2009 28-Oct-2009 30-Oct-2009 CA Μ 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown HEPA

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vision blurred

Symptom Text: One hour after receiving H1N1 nasal spray, pt c/o blurry vision to R eye which resolved over 24 hours later.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364070-1 (S)

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> PR 40.0 Μ 27-Oct-2009 28-Oct-2009 1 30-Oct-2009 02-Nov-2009 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500759P 1 Unknown Unknown

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chills, Malaise, Pyrexia

Symptom Text: Patient developed sudden onset of high grade fever(103F), chills, weakness and malaise.

Other Meds:

Lab Data:

History: Patient has a history of Chronic Malabsortion Syndrome and Immunoglobulin deficiency. He is receiving monthly Ig infuesions at home.

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364072-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 22.0 F 29-Oct-2009 29-Oct-2009 TX 0 30-Oct-2009 02-Nov-2009 02-Nov-2009 <u>Site</u> VAX Detail: Type Manufacturer Lot **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500782P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: NONE

Other Meds:UNKNOWNLab Data:none reportedHistory:NOT SPECIFIED

Prex Illness: AS PER CLIENT EIGHT MONTH PREGNANT

Prex Vax IIIns: UNKNOWN~ ()~~0.00~

VAERS Line List Report

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

Vaers Id: 364094-1

Gender **Vaccine Date Onset Date Days Received Date Status Date** State Mfr Report Id **Last Edit Date** Age F SC 38.0 15-Oct-2009 17-Oct-2009 2 30-Oct-2009 02-Nov-2009 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye haemorrhage, Eye swelling, Hyperkeratosis, Lymphadenopathy, Musculoskeletal pain, Musculoskeletal stiffness, Neck pain, Swelling, Vaccination

complication, Vision blurred

Symptom Text: 10-17-09: swelling in both eyes; 10-18-09:bursted blood vessel in right eye; swollen gland left side of neck; 10-19-09: stiffness, pain in left shoulder and neck;

right eye was better, left eye was very blurry. Treated 10-26-09 and diagnosed 10-29-09 with keratosis due to flu vaccine nasal spray by Dr. Fleming @

Unknown

Unknown

Medicus in Anderson, SC. Prescribed Prednisolone Acetate 1% and told to report this and return in 1 week off follow-up.

Other Meds: Vesicare 10 mg 1 qd; Valtrex 1 gram PRN fever blisters

Lab Data: As of now vision is still very blurry- may be slightly inproving.

History: Sulfa drugs

Prex Illness: None

Prex Vax Ilins:

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

Vaers Id: 364108-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 39.0 26-Oct-2009 27-Oct-2009 30-Oct-2009 02-Nov-2009 ΙL 03-Nov-2009 1

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 602763P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: Husband called to report to Claire Dobbins,RN, Director Division of Health Protection, that patient received LAIV IN and that she is in first trimester of pregancy.

Requested records and requested that KCHD consult with patients obstetrician. No symptoms or adverse reactions reported at this time 11/2/09: OB/GYN records received for dates of service 11/2/09. Dx: Pregnant pt. received LAIV H1N1 Flu Vaccine at 5 weeks gestation. Assessment: As above. Plan: 1. US done on date of service, confirmed twin pregnancy. 2. Consultation planned with medical geneticist to discuss teratogenicity. 3. US of fetal anatomy at 20 weeks gestation 4. Potential fetal echocardiogram performed by pediatric cardiologist at 20 weeks IF any information becomes available that the H1N1

influenza vaccination is associated with congenital cardiac abnormalities. 5. The patient was counseled on her ability to terminate her pregnancy for any

reason up to 20 weeks. ICD 9 Code: 655.33.

Other Meds: Unknown

<u>Lab Data:</u> 11/2/09: OB/GYN records received for dates of service 11/2/09. Labs and diagnostics: US confirmed twin pregnancy.

History: pregnant, first trimester. 11/2/09: OB/GYN records received for dates of service 11/2/09. PMH: Gravida 3 Para 1.

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364143-1

Mfr Report Id Gender **Vaccine Date Onset Date** Days **Received Date Status Date** State **Last Edit Date** Age F 6.0 28-Oct-2009 29-Oct-2009 1 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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immunisation reaction, Oedema peripheral, Pruritus, Urticaria

Symptom Text: MOM STATES 10/29/2009 AT BREAKFAST CHILD HAD ITCHING, HIVES AND SWELLING OF HANDS AND FEET. MOM GAVE BENDADRYL, TOOK CHILD

TO EMERGENCY ROOM AND WAS TOLD IT WAS PROBABLY FROM THE H1N1 VACCINE. MOM CALLS 10/30/2009 AFTERNOON AND STATES CHILD HAS SMALL AMT OF SWELLING AND HIVES ON HANDS BUT FEET ARE WORSE WITH SWELLING AND HIVES. MOM WAS INSTRUCTED TO GIVE

BENADRYL AT THE ER.

Other Meds: NONE KNOWN

Lab Data: NO TEST ONLY GIVING BENDADRYL

History: NO Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364155-1

Gender **Vaccine Date Onset Date Days Received Date Status Date** State Mfr Report Id **Last Edit Date** Age F 3.0 21-Oct-2009 24-Oct-2009 3 31-Oct-2009 02-Nov-2009 ОН 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Eye discharge, Lethargy, Pyrexia, Respiratory tract congestion, Rhinorrhoea, Vomiting

Symptom Text: Sudden onset High Fever 103, immediately gave children's Tylenol, alternated Children's Tylenol & Children's Motrin Q4H. By 4am Sunday morning, fever was

103 even with medicine. Other symptoms at this time runny nose, congestion, violent coughing, vomiting (mostly mucus), lathargy, one eye looked a little infected with greenish discharge. High fever lasted until Tuesday around 8:00pm. (4 days) Was giving Tylenol/Motrin Q 3 hours Sunday-Tuesday as

recommended by ER doctor.

Other Meds:

Lab Data: Chest X-ray showed no pnumonia. Upon examination, double ear infection. Swab test was said to be negative for H1N1. Staff skeptical considering

symptoms; considered false results.

History: none Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364156-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 39.0 30-Oct-2009 30-Oct-2009 31-Oct-2009 TX Μ 0 02-Nov-2009 02-Nov-2009 Site VAX Detail: Type Prev Doses **Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500778P 0 Unknown Unknown FLUN

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Muscle spasms, Nausea, Rhinorrhoea

Symptom Text: Headache, Nausea, Runny Nose, Cramps

Other Meds:

Lab Data:

History: None
Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364157-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 4.0 Μ 29-Oct-2009 30-Oct-2009 31-Oct-2009 TX 02-Nov-2009 1 02-Nov-2009 Site VAX Detail: Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 5007SUP 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Rash

Symptom Text: rash on belly and legs diarrhea

Other Meds: Lab Data: History:

Prex Illness:
Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364174-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State Age F 31.0 27-Oct-2009 27-Oct-2009 0 31-Oct-2009 02-Nov-2009 ОН 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Nausea, Pallor, Vision blurred

Symptom Text: Dizzinez, sensation of hot, nausea, blurry vision, pallor, suething. Low blood pressure measured after sympoms started to improve: 105/50, heart rate: 60. I

drunk 600 ml of water and eat salt food. Recovered by 4:15 PM.

Other Meds:

Lab Data: Blood pressure measured after sympoms started to improve: 105/50, heart rate: 60. I drunk 600 ml of water and eat salt food. Recovered by 4:15 PM.

History: no Prex Illness: no

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364187-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 13.0 IL Μ 30-Oct-2009 30-Oct-2009 0 01-Nov-2009 02-Nov-2009 02-Nov-2009 Site VAX Detail: Type Manufacturer **Prev Doses** Route Other Vaccine

 VAX Detail:
 Type
 Manufacturer
 Lot
 Prev Doses
 Site
 Route

 FLUN(H1N1)
 MEDIMMUNE VACCINES, INC.
 500763P
 0
 Unknown
 Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cough, Dizziness, Nasal congestion, Oropharyngeal pain, Pyrexia, Somnolence, Vomiting

Symptom Text: severe fever, dizziness, drowsiness, weakness, vomiting bile, cough, nasal congestion, sore throat,

Other Meds:

Lab Data:

History: none
Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364188-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> 32.0 F OR 27-Oct-2009 29-Oct-2009 2 01-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>

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Musculoskeletal stiffness, Neck pain

Symptom Text: Sudden Stiffness in neck. In ablitity to turn neck abruptly nor look down or up. Neck Pain.

Other Meds:

Lab Data: Havent yet gone to the doctors, I work in a medical facility, I went home early on Friday, and Sunday it still hasent resolove. I will contact my doctor on Monday.

History: none Prex Illness: none

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364200-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days ОН 21.0 Μ 31-Oct-2009 01-Nov-2009 1 01-Nov-2009 02-Nov-2009 02-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Loss of consciousnessSymptom Text: Black out/Light headedness/Dizzness/Headache

Other Meds: Diovan 160mg 1 tablet per day

Lab Data:

History: Hypertensison

Prex Illness: None

Prex Vax IIIns: Headache~Influenza (Seasonal) (no brand name)~1~18.50~Patient

VAERS Line List Report

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

Vaers Id: 364204-1

Gender Days State <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** 18.0 F 30-Oct-2009 IL 28-Oct-2009 2 01-Nov-2009 02-Nov-2009 02-Nov-2009 Site Other Vaccine

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500781P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

Chills, Oropharyngeal pain, Pain, Pyrexia MedDRA PT

Symptom Text: Sore throat, feeling achy, 101 degree fever, chills Taking Tylenol Multisymptom caplets

Other Meds:

Lab Data:

History: None **Prex Illness:** None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364215-1

Gender **Vaccine Date Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** 6.0 Μ 28-Oct-2009 28-Oct-2009 0 01-Nov-2009 02-Nov-2009 MI 02-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria
Symptom Text: HIVES

Other Meds:

Lab Data:

History: ALL: PCN
Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364216-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 4.0 Μ 29-Oct-2009 31-Oct-2009 2 01-Nov-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Oropharyngeal pain, Pyrexia

Symptom Text: Fever lasting more than 2 days. Average temperature 102.7 Sore throat. Abdominal Discomfort

Other Meds:

Lab Data:

History: N/A

Prex Illness: None known

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364218-1

Gender **Vaccine Date Onset Date Days Received Date Status Date** State Mfr Report Id **Last Edit Date** Age F 33.0 28-Oct-2009 30-Oct-2009 2 01-Nov-2009 02-Nov-2009 CA 02-Nov-2009 **VAX Detail: Type Prev Doses** Site Manufacturer Lot Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dysstasia, Gait disturbance, Hyperhidrosis, Hypoaesthesia, Paraesthesia

Symptom Text: On thursday night I started experiencing some tingling in my back. I did not think much of it, but I decided not to go to work. I am a pharmacist so on friday

when I went to work I started sweating and was weak I could barely stang. I went home to rest after cosulting with my physician to rest. I went home to rest and stated experiencing tingling and numbness in my left and right arm. I called the health department that gave me the vaccination and they said noone has complained of that side effect. I received the LAIV H1N1. Icalled my physician again who told me to take Benadryl. On saturday I only had tingling on my right arm so I felt more secure and decided not to go to the ER. Around 4 A.M i woke up with no felling on my right arm and a horrible tingling sensation. My husband encouraged me to rest and rubed my arm. When I woke up I could barely walk and was hobling. My whole right side is tingling and numb. I went to the ER where they performed a CT scan and blood work. Everything looked okay so they sent me home to be evaluated by my doctor on Monday and possible referral

to a neurologist if I am not improving.

Other Meds: none

Lab Data: CT san and blood work. Follow up with PCP and possibly neurology.

History: none
Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364219-1 (S)

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days 44.0 М 28-Oct-2009 29-Oct-2009 1 01-Nov-2009 02-Nov-2009 MI H1N1NasalFlumist 03-Nov-2009 VAX Detail: **Type** Site Manufacturer Lot **Prev Doses** Route Other Vaccine

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Convulsion, Road traffic accident

Symptom Text: Had A Seizure while driving...had not had a seizure during the day for 8 years Hit a light post with my car and damaged vehicle driving at approx. 25 MPH

11/2/09: Hospital records received for dates of stay 10/29/09 to 10/30/09. Dx: Breakthrough Seizure Disorder, History of Seizure, Motor Vehicle Accident. Assessment: Epileptic patient maintained seizure free on Tegretol x 8 years, received H1N1 vaccine and had a seizure while driving his car the following day.

Accident was at low speed and pt. was unhurt. Monitored in the hospital overnight and discharged to home. Keppra started BID.

Other Meds: Carbamezapine

Lab Data: All Blood Work Showed my levels were good. Kept in hospital overnight for observation. Had no other side effects except a headache. 11/2/09: Hospital

records received for dates of stay 10/29/09 to 10/30/09. Labs and Diagnostics: CBC and

History: Epilepsy - Due to Head Trauma Taking Carbamezapine. 11/2/09: Hospital records received for dates of stay 10/29/09 to 10/30/09. PMH: Seizure disorder

Prex Illness: NONE

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 325

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

Vaers Id: 364227-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 4.0 29-Oct-2009 29-Oct-2009 0 02-Nov-2009 03-Nov-2009 MA 03-Nov-2009 VAX Detail: <u>Lot</u> Site Type Manufacturer **Prev Doses** Other Vaccine Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Cough, Febrile convulsion, Pyrexia

Symptom Text: H1N1 LAIV on 10/29. Developed fever and cough later that day. Febrile sz 10/30 0300 (known hx feb. sz).

Other Meds:

Lab Data:NoneHistory:Febrile szPrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364238-1

Gender **Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** State 9.0 Μ 29-Oct-2009 IL H1N1 spray mist 01-Nov-2009 3 02-Nov-2009 03-Nov-2009 03-Nov-2009 Site VAX Detail: Type Prev Doses Manufacturer Lot Route Other Vaccine FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P Unknown Unknown

Seriousness:NO CONDITIONS, NOT SERIOUSMedDRA PTCough, Lacrimation increased, PyrexiaSymptom Text:watery eyes, fever ~ 101, very bad cough

Other Meds: Lab Data:

History: none

Prex Illness: slight cough

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364239-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 20.0 30-Oct-2009 30-Oct-2009 0 30-Oct-2009 03-Nov-2009 NY 03-Nov-2009

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500779P0UnknownUnknownFLU

NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blindness transient, Syncope

Symptom Text: Started to feel weak, fainted-unable to see 5 sec lasted about 20 seconds. Has not eaten at all today. Only drank 16 oz seltzer water. Got up by self-sat/rested

for 15 minutes.

Other Meds: Oral contraceptives

Lab Data:NoneHistory:NonePrex Illness:No

Prex Vax Ilins:

Seriousness:

VAERS Line List Report

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

Vaers Id: 364242-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> F 19.0 26-Oct-2009 29-Oct-2009 3 30-Oct-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500779P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Erythema, Pruritus, Pyrexia, Rash macular, Skin lesion

Symptom Text: Fever (101 PO) 72 hours after vaccine (responded to acetaminophen) and rash: red macular lesions (5-15 mm) with central vesicle over trunk. Some pruritis -

>treated with antihist.

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Page 329

Vaers Id: 364245-1

Onset Date Received Date Status Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days State <u>Age</u> 17.0 Μ 28-Oct-2009 28-Oct-2009 0 02-Nov-2009 03-Nov-2009 PΑ 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Headache, Oropharyngeal pain

Symptom Text: 10/28/09 H1N1 vaccine given to student in school via nasal spray. 10/30 student c/o headache, sore throat and poor appetite since 10/28/09. T 98.5. Lungs

clear. Throat is normal. NAD. SN called mother to inform her of students complaints and nurse assessment. Mother also informed of report to VAERS.

Other Meds:

Lab Data:

History: Eczema; hearing loss right ear

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364254-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 15.0 F 29-Oct-2009 29-Oct-2009 02-Nov-2009 TX 03-Nov-2009 0 03-Nov-2009

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

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pharyngeal oedema, Vomiting

Symptom Text: Nausea, vomiting, feels throat swelling, dizzy.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364255-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 1.3 CA Μ 21-Oct-2009 Unknown 02-Nov-2009 03-Nov-2009 03-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Given nasal H1N1 influenza vaccine by mistake. No treatment needed, follow up call revealed no ill effects.

Other Meds: None
Lab Data: None
History: None
Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364267-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 21.0 F SD 21-Oct-2007 24-Oct-2007 3 02-Nov-2009 03-Nov-2009 03-Nov-2009

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

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Dizziness, Headache, Vomiting

Symptom Text: Headache, Vomitting 20-30 minutes from 8:00 AM until 1:00PM, dizziness, body chills until administered IV fluids and Zofran.

Other Meds:

Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

Page 333

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

Vaers Id: 364270-1

Gender **Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** State 5.0 F 30-Oct-2009 01-Nov-2009 2 02-Nov-2009 03-Nov-2009 MA 03-Nov-2009 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

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

ER VISIT, NOT SERIOUS Seriousness: MedDRA PT Cough, Myalgia, Pyrexia **Symptom Text:** Fever 104 Cough Myalgia

Other Meds: none

Lab Data:

History: none **Prex Illness:** no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364272-1

Gender **Onset Date Received Date** Mfr Report Id **Last Edit Date Vaccine Date** Days **Status Date** State <u>Age</u> 42.0 F 15-Oct-2009 17-Oct-2009 2 02-Nov-2009 03-Nov-2009 IΑ 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500759T 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dizziness, Headache, Nausea, Oropharyngeal pain, Pain, Pyrexia

Symptom Text: aches and pains started on 10/17/2009. On 10/18/2009 am high fever 102.7, cough, sore throat, head ache, nausea, dizziness through 10/24/2009. Continued

to have severe cough, sore throat, head ache until 10/28/2009. Continued to have cough until 11/2/2009.

Other Meds: NONE

Lab Data: tested positive for influenza A.

History:

Prex Illness: HEALTHY.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364274-1

Gender **Vaccine Date Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** State 5.0 Μ 24-Sep-2009 29-Sep-2009 5 02-Nov-2009 03-Nov-2009 SD 03-Nov-2009 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 507713P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PTFacial palsySymptom Text:Bells Palsy

Other Meds: Lab Data:

History: none Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364278-1

Gender Days <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** F CA 40.0 14-Oct-2009 17-Oct-2009 3 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Headache, Oropharyngeal pain, Pain, Rhinorrhoea

Symptom Text: Runny nose, body ache, severe headache, sore throat, coughing lasting for 3 days, treated with Tylenol and rest

Other Meds:

Lab Data: N/A
History: No
Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364288-1

Onset Date Received Date State Mfr Report Id Gender **Vaccine Date Days Status Date Last Edit Date** Age F 46.0 31-Oct-2009 01-Nov-2009 1 02-Nov-2009 03-Nov-2009 WA 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500796P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Joint stiffness, Myalgia, Oral herpes, Oropharyngeal pain, Productive cough

Symptom Text: I woke in the am with extreme fatigue and generalized muscle aches and a cold sore. This progressed through the day to the evening with severe muscle

aches and joint pain and stiffness in all joints except my hands and feet. I also am experiencing a sore throat and a slightly productive cough that continues

today. I took Tylenol and Benedryl at bedtime.

Other Meds: Sertraline, Levothyroxine, Hyzaar, propranolol

Lab Data:

History: HTN, DMII, Hypothyroidism, migraine, depression

Prex Illness: no

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364292-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 2.0 F GΑ 02-Nov-2009 02-Nov-2009 0 02-Nov-2009 03-Nov-2009 03-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500745P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis

Symptom Text: Child was given H1N1 nasal mist. Child had nosebleed immediately following administration. Left nostril bleed lightly for approx 20 min. Bleeding stopped with

tissue and gentle pressure.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364293-1

State <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days 36.0 F ΑZ 20-Oct-2009 Unknown 02-Nov-2009 03-Nov-2009 03-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy, Unevaluable event

Symptom Text: Client was possibly pregnant and was given the H1N1 Flumist instead of the inactivated vaccine. Client was called and spoke with Dr.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364298-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days F 49.0 31-Oct-2009 31-Oct-2009 0 02-Nov-2009 03-Nov-2009 IL 03-Nov-2009 VAX Detail: **Type** Site Manufacturer Lot **Prev Doses** Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500781P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Dizziness, Fatigue, Headache, Myalgia, Nasal congestion, Oropharyngeal pain, Pyrexia, Wheezing

Symptom Text: Initial reactions: Increased nasal congestion, dizziness, strong wheezing cough. By 11/01/09: fever (up to 101.7), headache (mild), muscle aches, tiredness,

continued strong cough. Spent the day 11/01/09 resting. Fever diminished within 24 hours. Mild cough and sore throat persist 11/02/09.

Other Meds: daily aspirin regime - 81mg daily Emeren-C - 1 pkg daily Walgreens Calcium Citrate Plus - 1 tablet daily Walgreens Glucosamine Chondroitin Complex Triple

Strength - 2 tablets daily

Lab Data: none - did not seek medical attention from a physician since fever was gone in 24 hours.

History: Allergies to many trees, molds, dust, animal dander, grasses Food allergies to potatoes, tomatoes, green peppers (night shades)

Prex Illness: Postnasal drip from seasonal allergies

Prex Vax IIIns:

Page 340

FLU

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 341

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

Vaers Id: 364302-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** F 23-Oct-2009 24-Oct-2009 WI 8.0 1 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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Fever of 103 degrees beginning at 9:00 PM 10/24/09, to 105.3 degrees on 10/25 AM. Chest x-ray 10/25 "OK".

Other Meds:

Lab Data: Chest x-ray "OK" per mom

History:

Prex Illness: Cough x 1 mo.

Prex Vax IIIns:

VAERS Line List Report

Page 342

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

Vaers Id: 364329-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 23.0 22-Oct-2009 23-Oct-2009 1 02-Nov-2009 03-Nov-2009 WI 03-Nov-2009

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

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Gait disturbance, Nausea, Vertigo

Symptom Text: Patient was given H1N1 LAIV nasal spray on 10/22/09. On 10/23/09 patient experienced dizzy spells, nausea, and inability to walk unassisted. Patient saw MD

and was treated for vertigo. MD told patient that vaccine settled in her ear.

Other Meds:

Lab Data:UnknownHistory:ScoliosisPrex Illness:None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364332-1

Gender Days State <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** 14.0 F 15-Oct-2009 ΑZ 17-Oct-2009 2 02-Nov-2009 03-Nov-2009 03-Nov-2009

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500760P0UnknownUnknownHPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Headache, Pyrexia

Symptom Text: Slightly elevated temperature from Oct 17th-Oct 19th accompanied by headache. Then developed cough. Still has slight cough.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 344

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

Vaers Id: 364339-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 25.0 F 12-Oct-2009 12-Oct-2009 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500756P Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea

Symptom Text: 10/21/09 Reported symptoms since 10/12/09 day given H1N1 FLumist. C/O headache, nausea and dizziness. No temp. Informed to f/u with primary MD as

eeded

Other Meds: None
Lab Data: None
History: None
Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364343-1

Gender **Onset Date Received Date** Mfr Report Id **Last Edit Date Vaccine Date Days Status Date** State Age F 24.0 20-Oct-2009 20-Oct-2009 0 02-Nov-2009 03-Nov-2009 ΜI 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: 10/20/09 Client received vaccine and states that 3 hours later she started to develop hives. Did not seek treatment or take medication until 10/21/09 when she

saw MD and started BENADRYL PO. Next day hives progressed to entire body so she went to ER and was given 5 day prednisone regimen (10/22/09).

Other Meds: Birth control pills (YAZ)

Lab Data:

History: Penicillin; amoxicillin; erythromycin; clindamycin; vancomycin

Prex Illness: Denies

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364347-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 11.0 Μ 20-Oct-2009 20-Oct-2009 02-Nov-2009 OR 03-Nov-2009 0 03-Nov-2009 VAX Detail: Site Type Prev Doses **Other Vaccine** Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash on face, shoulder 2 hrs after mist.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364354-1

Gender **Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** State 48.0 F 22-Oct-2009 23-Oct-2009 02-Nov-2009 NY 03-Nov-2009 1 03-Nov-2009

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

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Pyrexia

Symptom Text: Fever, shortness of breath.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364359-1

<u>Age</u>	<u>Gender</u>	Vaccine Date	Onset Date	Days	Received D	ate	Status Date	<u>State</u>	Mfr Report Id	Last Edit Date
11.0	M	13-Oct-2009	15-Oct-2009	2	02-Nov-20	09	03-Nov-2009	CA		03-Nov-2009
VAX Detail: Ty		<u>Manufacturer</u>			<u>Lot</u>	Prev Do	ses	<u>Site</u>	Route	Other Vaccine
	FLUN	N(H1N1) ME	EDIMMUNE VACCINES	S, INC.	500761P	0	Ur	nknown	Unknown	
	FLU	SA	NOFI PASTEUR		NULL	3	Ur	nknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

Bronchospasm, Cough, Headache, Lobar pneumonia, Oropharyngeal pain, Pyrexia MedDRA PT

Symptom Text: Onset fever, headache, sore throat, cough and slight bronchospasm which persisted on and off 10/16-10/21. Developed secondary left lower lobe bacterial

pneumonia on 10/21/09. Treated in ER. TAMIFLU given 10/16-10/21-full 5 d course.

None Other Meds:

CXR; blood tests; rapid flu (neg) Lab Data:

History: None **Prex Illness:** None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 349

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

Vaers Id: 364362-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 3.0 Μ 20-Oct-2009 26-Oct-2009 02-Nov-2009 LA 03-Nov-2009 6 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500769P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Influenza, Pyrexia

Symptom Text: Pt with 104.3 degree fever, flu symptoms.

Other Meds:

Lab Data:CBCHistory:NonePrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364366-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 5.0 F 20-Oct-2009 28-Oct-2009 02-Nov-2009 LA 03-Nov-2009 8 03-Nov-2009 VAX Detail: Site

 /AX Detail:
 Type
 Manufacturer
 Lot
 Prev Doses
 Site
 Route
 Other Vaccine

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Influenza, Nasopharyngitis, Pyrexia

Symptom Text: Pt with 103 degree fever, cold/flu symptoms.

Other Meds:

Lab Data:CBCHistory:NonePrex Illness:None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364413-1

Gender Days Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** F 28-Oct-2009 02-Nov-2009 NV26.0 28-Oct-2009 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500765P 1 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Oropharyngeal pain, Pyrexia, Vomiting

Symptom Text: Pt. has fever 100.5, chills, sore throat, vomiting. 10/31/09 started.

Other Meds: None

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 352

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

Vaers Id: 364415-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State Age F 24.0 27-Oct-2009 28-Oct-2009 1 02-Nov-2009 03-Nov-2009 ΜI 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500764P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia facial, Hypoaesthesia oral, Lip swelling, Paraesthesia, Paraesthesia oral

Symptom Text: On 10/27/089 at 4:00 PM patient received intranasal live H1N1 Flumist. When she woke up the next AM (10/28/09) she noticed that her upper lip was swollen

and tingling. In addition she felt tingling and numbness on bilateral midface around the nose and mouth area. ALLEGRA was prescribed 180 mg, 5 tablets to

take, one tablet once a day.

Other Meds: Birth control pills

<u>Lab Data:</u> None History: NKDA

Prex Illness: Denies illness

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364437-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 7.0 MO Μ 22-Oct-2009 22-Oct-2009 0 02-Nov-2009 03-Nov-2009 MO-2009-25 03-Nov-2009 VAX Detail: Site Type Manufacturer **Prev Doses** Route Other Vaccine Lot

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: at 3:40 PM mom noticed rash on the face, checked further no other rash areas. Rash under eyes, nose and temple. Treatment with benadryl and cold wash

cloths relieves symptoms.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364443-1

Onset Date State Mfr Report Id Gender **Vaccine Date Days Received Date Status Date Last Edit Date** Age 44.0 M 27-Oct-2009 28-Oct-2009 1 02-Nov-2009 03-Nov-2009 MN 03-Nov-2009 VAX Detail: Site Other Vaccine

 YAX Detail:
 Type
 Manufacturer
 Lot
 Prev Doses
 Site
 Route

 FLUN(H1N1)
 MEDIMMUNE VACCINES, INC.
 500764P
 0
 Unknown
 Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Decreased appetite, Diarrhoea, Fatigue, Influenza, Myalgia, Nausea, Pyrexia

Symptom Text: I am an internal medicine physician. I experienced a classic syndrome for acute influenza. I had sudden severe cough and fever to 102.5F. Fever spikes

occurred repeatedly over next 60 hours. Diarrhea, nausea, anorexia, prostration, severe myalgias. Started Relenza 24 hours after symptom onset, and I think it

did help. Was able to return to work today 11-2-09 with some residual cough and diarrhea.

Other Meds: lisinopril 10 mg qday

Lab Data: History:

Prex Illness: Slight cold (rhinorrhea, slight cough)

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364451-1

Gender **Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** 2.0 28-Oct-2009 02-Nov-2009 CA 03-Nov-2009 Μ 01-Nov-2009 4 03-Nov-2009 Site VAX Detail: Type Prev Doses **Other Vaccine** Manufacturer Lot Route

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Respiratory rate increased, Wheezing

Symptom Text: WHEEZING. BREATHING HEAVY & FAST.

Other Meds:

Lab Data:

History: No. Prex Illness: No.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364466-1

Onset Date Received Date Mfr Report Id Gender **Vaccine Date** Days **Status Date** State **Last Edit Date** Age F 25.0 27-Oct-2009 27-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500754P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: After vaccination, patient reported that she was pregnant.

Other Meds: None reported.

Lab Data: None. Patient instructed to call Physician and take our immunization record (showing that Novel H1N1 was administered) with her, and ask her physician for

further instruction or evaluation. Patient was asked to follow-up with the Brazos C

History: None. After vaccination with Novel H1N1 FluMist, patient reported that she was pregnant.

Prex Illness: None.

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364476-1

<u>Age</u> Gender **Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date Vaccine Date** Days 22.0 F SD 27-Oct-2009 29-Oct-2009 2 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>

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: Patient came to see Dr. Kay today after doing a home pregnancy test. Pregnancy is confirmed by serum. Patient states she received a H1N1 Flumist last week

at the Nursing Home where she works.

Other Meds:

Lab Data: Serum test for pregnancy was positive at the clinic.

History: none Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364481-1

Gender <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 31.0 Μ 28-Oct-2009 01-Nov-2009 4 02-Nov-2009 03-Nov-2009 MD 03-Nov-2009

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.500761P1UnknownUnknownFLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis, Erythema, Pruritus, Rash

Symptom Text: allergic reaction to the patients face. inflammation around the eyes,rash, itching, redness, acute onset.

Other Meds:

Lab Data:noneHistory:nonePrex Illness:none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364488-1 <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 4.0 23-Oct-2009 24-Oct-2009 1 02-Nov-2009 03-Nov-2009 TX 03-Nov-2009 VAX Detail: Site Type Manufacturer Lot **Prev Doses** Other Vaccine Route IPV SANOFI PASTEUR Left arm B04763 3 Unknown MMR MERCK & CO. INC. 0679Y Right arm Unknown FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500756P 0 Unknown Unknown **DTAP GLAXOSMITHKLINE** AC14B080AA 4 Right arm Unknown **BIOLOGICALS** VARCEL MERCK & CO. INC. 1073Y 1 Left arm Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Swelling on Rt. arm. Tx. ice packs, TYLENOL or MOTRIN.

Other Meds:

Lab Data:

History: None
Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364489-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 35.0 F 19-Oct-2009 21-Oct-2009 2 02-Nov-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza

Symptom Text: Myself and husband came down with flu after 6 yr old twins got H1N1 Flumist (48 hr after). He tested positive for Influenza A and H1N1 is being sent off.

Other Meds: CYMBALTA; xanax; AMBIEN

Lab Data: None for me-husband's Dr put me on TAMIFLU

History: Fibromyalgia; arthritis

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364490-1

Days Mfr Report Id <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** 38.0 19-Oct-2009 IN Μ 21-Oct-2009 2 02-Nov-2009 03-Nov-2009 03-Nov-2009

Unknown

Unknown

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Influenza

Symptom Text: Pt came down w/Influenza A 48 hours after his twins got their H1N1 Flumist.

Other Meds: Pain meds

Lab Data: Rapid test Influenza +, H1N1 tested

History: Bulging discs

Prex Illness: None

Prex Vax IIIns:

Page 361

FLU

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 362

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

Vaers Id: 364491-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Age Days 7.0 F OK 30-Oct-2009 30-Oct-2009 0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Rash

Symptom Text: 10/30/09 rash and 103 degree temp PM, approximately 7:00 PM. Call to ER. Instructed to give child BENADRYL and TYLENOL by ED physicians. Mother

reported rash lasted approximately 3 hrs. 11-2-09 office visit at PCP office. Dx with flu. Prescribed TAMIFLU.

Other Meds: None

Lab Data: Dx by PCP with flu 11-2-09

History: None Prex Illness: None

Prex Vax Illns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 363

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

Vaers Id: 364496-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 3.0 Μ 29-Oct-2009 31-Oct-2009 2 02-Nov-2009 03-Nov-2009 ΗΙ 03-Nov-2009 VAX Detail: Site Type Manufacturer Lot **Prev Doses** Other Vaccine Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500715P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Wheezing

Symptom Text: Developed febrile illnes with wheeze required multiple visits, nebulized albuterol.

Other Meds:

Lab Data: Negative nasal flu. Chest xray: Mild peribronchial thickening without evidence of a focal pneumonia

History: none

Prex Illness: none - exposure to playmate prior

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364498-1

Gender State <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Days 39.0 F IL 26-Oct-2009 Unknown 02-Nov-2009 03-Nov-2009 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: PT IS PREGNANT AND RCVD NASAL DOSE OF VACCINE

Other Meds:

Lab Data:

History: PREGNANCY - 27 WKS EGA.

Prex Illness: NO

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364499-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State <u>Age</u> 41.0 Μ 28-Oct-2009 30-Oct-2009 2 02-Nov-2009 03-Nov-2009 PΑ 03-Nov-2009 **Type** Site VAX Detail: **Prev Doses** Other Vaccine Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500756P 1 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate increased, Pruritus, Urticaria

Symptom Text: BROKE OUT IN HIVES ON HAIRLINE, EARS, FACE & ARMS. COMPLAINED OF ITCHING. NO SOB. FELT HIS HEART WAS GOING FAST. TREATED

WITH ALLEGRA AND BENEDRYL WITH RELIEF. NO KNOWN ALLERGIES TO VACCINE COMPONENTS.

Other Meds: NONE Lab Data: NONE

History: NONE KNOWN OR REPORTED.

Prex Illness: NO, NONE REPORTED.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364500-1

Gender Days Mfr Report Id <u>Age</u> **Vaccine Date Onset Date Received Date Status Date** State **Last Edit Date** 2.0 27-Oct-2009 30-Oct-2009 02-Nov-2009 OR Μ 3 03-Nov-2009 03-Nov-2009

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

FLU SANOFI PASTEUR U3261AA Left arm Intramuscular FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Mother reported hives on feet and then on arms.

Other Meds:

Lab Data:noneHistory:nonePrex Illness:none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364534-1

Onset Date Received Date Status Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days State Age F 5.0 29-Oct-2009 30-Oct-2009 1 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500763P 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Cough, Oropharyngeal pain, Rhinorrhoea, Vomiting

Symptom Text: Sore throat, Temp, vomitting, cough, runny nose, chills began early morning of 10/30/2009. Parent did not report time of onset. Parent indicated that she

suspected the LAIV vaccine. However, child possibly exposed prior to vaccination. Local schools reporting high incidence of H1N1 Flu illness. No medical care

being sought at time of report.

Other Meds:

Lab Data:

History: no Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364537-1

Gender **Onset Date** Days **Received Date** Mfr Report Id **Last Edit Date** <u>Age</u> **Vaccine Date Status Date** State 5.0 31-Oct-2009 02-Nov-2009 2 02-Nov-2009 WA 03-Nov-2009 Μ 03-Nov-2009 VAX Detail: Site Type **Prev Doses Other Vaccine** Manufacturer Lot Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Rhinorrhoea

Symptom Text: temp 102.6, runny nose

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364548-1

Onset Date Received Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Status Date** State Age 8.0 Μ 28-Oct-2009 28-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500796P 0 Unknown Unknown FLUN

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Pyrexia, Urticaria

Symptom Text: Temp 99 in the afternoon and then 102.5 by evening. Thursday, temp still 100.2 and kept home from school. Friday, went to school. By Friday evening, hives

on back, chest, upper arms. No fever at that time. Sunday evening, fever of 100 degrees. Home from school again today. Mom reports good appetite and

fever down with medication. Advised to stay home until fever free 24 hours without fever reducing medication. No one else ill in household.

Other Meds: Unknown

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364549-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days CO 39.0 Μ 13-Oct-2009 16-Oct-2009 3 02-Nov-2009 03-Nov-2009 03-Nov-2009

VAX Detail: Site Type Manufacturer **Prev Doses** Other Vaccine Lot Route

> FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500751P Unknown Unknown

NO CONDITIONS, NOT SERIOUS Seriousness:

MedDRA PT Blister, Oral herpes

Symptom Text: Client states that he had vestible like lesions at base of nostril (cold sore like)that oozed and then crusted over. He stated that he had never gotten cold sores

ever before.

Other Meds:

None Lab Data: Unknown History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364550-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 13.0 24-Oct-2009 27-Oct-2009 02-Nov-2009 03-Nov-2009 WA 03-Nov-2009 Μ 3

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives

Other Meds:

Lab Data: Hives for 2 days, Gave him benadryl, cleared up

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364555-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 48.0 F 16-Oct-2009 24-Oct-2009 WA 8 02-Nov-2009 03-Nov-2009 03-Nov-2009 Site

VAX Detail:TypeManufacturerLotPrev DosesSiteRouteOther VaccineFLUN(H1N1)MEDIMMUNE VACCINES, INC.NULLUnknownUnknownFLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Shingles, mild, R ant chest

Other Meds:Thyroid supplement, Lithium (both chronic, for years)Lab Data:Responded to antiviral treatment with Acyclovir

<u>History:</u> Polycystic kidney disease, asymptomatic

Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364562-1

Gender **Onset Date** Days **Received Date** Mfr Report Id <u>Age</u> **Vaccine Date Status Date** State **Last Edit Date** 27.0 F 17-Oct-2009 19-Oct-2009 SC 2 02-Nov-2009 03-Nov-2009 03-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

 $\underline{\textbf{MedDRA PT}} \qquad \text{Fatigue, Malaise, Nasal congestion, Rhinorrhoea}$

Symptom Text: Runny/congested nose, extreme fatigue, malaise

Other Meds:

Lab Data:

History: Penicillin

Prex Illness: No.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364567-1

Days State Mfr Report Id Gender **Vaccine Date Onset Date Received Date Status Date Last Edit Date** Age F 39.0 23-Oct-2009 23-Oct-2009 0 02-Nov-2009 03-Nov-2009 NJ 03-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 5570989 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Cough, Dizziness, Flushing, Palpitations

Symptom Text: Right after I had the H1N1 live internasal vaccine I had a racing heart beat, felt faint, flush, cold sweats, coughing for two days.

Other Meds: I take: Depakote 625 mg at night, seroquel 25 mg. at night, luvoxyl .05mcg. at night

Lab Data: I went for a follow up examination because I was coughing a few days later. Today/seven days after the initial visit to the ENT specialist I was just told I have a

'sinus infection' I am now taking Zithromax (3 day supply).. I was told thi

History: Allergic to all dairy, graves disease/hypoactive thyroid

Prex Illness: No

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364568-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 38.0 Μ 23-Oct-2009 23-Oct-2009 0 02-Nov-2009 03-Nov-2009 NJ 03-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 5571040 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Sensory disturbance

Symptom Text: Felt my right leg the blood 'pulsating' through the femoral artery region for several seconds. This occurred approx 5 to 6 times throughout the day only when I

sat or drove my car (note I was working after I had this vaccination). This stopped at approx. 3pm.

Other Meds:

<u>Lab Data:</u> none History: none

Prex Illness: stuffy nose/cold

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32 VAERS Line List Report

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

Page 376

Vaers Id: 364579-1

Onset Date Received Date Status Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days State Age 36.0 Μ 02-Nov-2009 02-Nov-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500782P 0 Unknown Unknown FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Cough, Skin warm

Symptom Text: head feeling very hot, no fever. occassional cough, and pain in right lung/chest.

Other Meds: geodon, welchol, atenolol, prevacid, niravam

Lab Data:

History: i told them i had quit smoking 1.5 months ago. it had actually been 2 months sinc i quit smoking. it was obvious that i was concerned about my lungs. despite

this, they choose to give me the nasal vaccine.

Prex Illness: no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364581-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 2.0 Μ 01-Nov-2009 01-Nov-2009 0 02-Nov-2009 03-Nov-2009 ND 03-Nov-2009 VAX Detail: <u>Lot</u> Site Type Manufacturer **Prev Doses** Other Vaccine Route

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Discomfort, Pyrexia

Symptom Text: discomfort, shivering, fever 103.3 by ear. Treated with 1 tsp ibuprofen, followed 3 hours later by 1 tsp acetomeniphin

Other Meds: No other vaccines given on same date or in preceding 4 weeks. No other known adverse reactions to prior vaccinations.

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364584-1

<u>Age</u>	Gender	Vaccine Date	Onset Date	Days	Received	<u>Date</u>	Status	<u>Date</u>	<u>State</u>	Mfr Report Id	Last Edit Date
50.0	М	29-Oct-2009	29-Oct-2009	0	03-Nov-2	009	03-Nov-	2009	AZ		03-Nov-2009
VAX Detai	il: <u>Type</u>	<u>Man</u>	<u>ufacturer</u>		<u>Lot</u>	Prev	Doses	<u>Site</u>		Route	Other Vaccine
	FLUN	N(H1N1) MED	MEDIMMUNE VACCINES, INC.		500765P	0		Right arm		Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Fatigue, Feeling abnormal, Hypoaesthesia, Muscle spasms, Nausea, No reaction on previous exposure to drug, Oedema peripheral, Paraesthesia,

Photosensitivity reaction, Pruritus, Skin burning sensation, Vertigo

Symptom Text: I had no trouble at all with the regular flu shot 3 weeks ago. With the H1N1 vaccination I noticed photosensitivity in 30 to 40 minutes. By the following morning

had developed skin itching and burning, numbness, electrical shocking sensations, vertigo, unusual muscle cramping, mildly swollen hands and feat, mild

chills, mild nausea, foggy consciousness, and severe fatigue. A very different experience than the seasonal vaccination 3 weeks prior.

Other Meds:

<u>Lab Data:</u> Still watchful waiting. No objective testing as of report date.

<u>History:</u> Seasonal allergies with chronic high eosinophile count. Hyperlipidema.

Prex Illness: Contracted HSV2 in April 2009. Not symptomatic and otherwise healthy at time of vaccination.

Prex Vax Illns:

VAERS Line List Report

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

Vaers Id: 364586-1

Days <u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** 21.0 ОН Μ 29-Oct-2009 31-Oct-2009 2 03-Nov-2009 03-Nov-2009 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown

NO CONDITIONS, NOT SERIOUS Seriousness:

Body temperature increased, Headache, Oropharyngeal pain, Pain MedDRA PT

Symptom Text: Sore Throat, Minor Fever, Headache, General/Minor Ache Acetaminophen

Other Meds:

Lab Data:

History:

Prex Illness: No.

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364591-1

Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days <u>Age</u> 14.0 F IL 15-Oct-2009 19-Oct-2009 4 03-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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest X-ray, Cough, Headache, Influenza like illness, Pain, Pyrexia

Symptom Text: FLu like sysmptoms, fever, aches, cough, headache. Treatment was OTC fever reducers, did have chest x-ray. Doctor suspected H1N1 - did not test. But

suspected flu mist was cause.

Other Meds:

Lab Data:

History: allergy to apples

Prex Illness: none

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364611-1

Gender **Vaccine Date Onset Date** Days **Received Date** State Mfr Report Id **Last Edit Date** <u>Age</u> **Status Date** 13.0 Μ 02-Nov-2009 02-Nov-2009 0 03-Nov-2009 03-Nov-2009 FL 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. NULL Unknown Unknown Unknown

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Very tired

Other Meds:

Lab Data:

History: None Prex Illness: None

Prex Vax IIIns:

Report run on: 04 NOV 2009 10:32

VAERS Line List Report
Page 382

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

Vaers Id: 364623-1

Onset Date Mfr Report Id **Last Edit Date** Gender **Vaccine Date** Days **Received Date Status Date** State Age F 18.0 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>

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500776P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Cough, Dyspnoea, Immediate post-injection reaction, Oropharyngeal pain, Skin warm, Tremor

Symptom Text: AFTER RECEIVING MIST, PATIENT COMPLAINED OF CHEST PAIN, SHORTNESS OF BREATH, WAS SHAKEY, COMPLAINED OF HER THROAT BEING

"SORE", AND HER EAR BEING HOT. SHE BEGAN COUGHING IMMEDIATELY AFTER THE MIST WAS ADMINISTERED.

Other Meds:

Lab Data:

History: NONE NOTED
Prex Illness: NONE NOTED

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364636-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days 27.0 F 29-Oct-2009 30-Oct-2009 1 03-Nov-2009 03-Nov-2009 VA 03-Nov-2009

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

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort

Symptom Text: Chest tightening. Patient denies wheezing, cough. Patient waited until she got home and took Albuteral inhalers.

Other Meds: Albuterol Inhaler Prn Wheezing

Lab Data: None

History: Asthma stated well controlled

Prex Illness: None

Prex Vax Ilins:

VAERS Line List Report

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

Vaers Id: 364637-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days F 48.0 23-Oct-2009 24-Oct-2009 1 03-Nov-2009 03-Nov-2009 WI 03-Nov-2009

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

FLUN(H1N1) MEDIMMUNE VACCINES, INC. 500762P 0 Unknown Unknown

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchitis, Headache, Oropharyngeal pain, Pain, Pyrexia, Rhinorrhoea

Symptom Text: Fever (100 degrees), body aches, headahce, sore throat, and runny nose. On 10/28/09 was seen by provider and diagnosed with bronchitis. Started on

azithromycin

Other Meds:

Lab Data:noneHistory:noPrex Illness:no

Prex Vax IIIns:

VAERS Line List Report

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

Vaers Id: 364643-1

<u>Age</u> Gender **Vaccine Date Onset Date Received Date Status Date** State Mfr Report Id **Last Edit Date** Days KS 30.0 Μ 28-Oct-2009 29-Oct-2009 1 03-Nov-2009 03-Nov-2009 03-Nov-2009

VAX Detail: Type Manufacturer Lot Prev Doses Site Route Other Vaccine

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Left foot was tingling. Tingling progressed over the next few days up the left leg. Today (11/2/09)she states her left foot feels like it is asleep.

Other Meds: None

Lab Data: Unknown, she is to visit PCP today.

History: None Prex Illness: None

Prex Vax IIIns:

Total Non Serious 367 95%

Total Serious Non Fatal 15 4%

Total Death: 3 1%

Total All Reports: 385