

2009 H1N1 INFLUENZA VACCINE

INACTIVATED
(the "flu shot")

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (also called Swine Flu) is caused by a new strain of influenza virus. It has spread to many countries.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, and sometimes through touching objects contaminated with the virus.

Signs of 2009 H1N1 can include:

- Fatigue
- Fever
- Sore Throat
- Muscle Aches
- Chills
- Coughing
- Sneezing

Some people also have diarrhea and vomiting.

Most people feel better within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had flu infections in the past usually have some immunity to seasonal flu viruses (their bodies have built up some ability to fight off the viruses).

The 2009 H1N1 flu is a new flu virus. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu (their bodies are not prepared to fight off the virus).

3 2009 H1N1 influenza vaccine

Vaccines are available to protect against 2009 H1N1 influenza.

- These vaccines are made just like seasonal flu vaccines.
- They are expected to be as safe and effective as seasonal flu vaccines.
- They will not prevent "influenza-like" illnesses caused by other viruses.
- They will not prevent seasonal flu. *You should also get seasonal influenza vaccine, if you want to be protected against seasonal flu.*

Inactivated vaccine (vaccine that has killed virus in it) is injected into the muscle, like the annual flu shot. **This sheet describes the inactivated vaccine.**

A **live, intranasal** vaccine (the nasal spray vaccine) is also available. It is described in a separate sheet.

Some inactivated 2009 H1N1 vaccine contains a preservative called thimerosal to keep it free from germs. Some people have suggested that thimerosal might be related to autism. In 2004 a group of experts at the Institute of Medicine reviewed many studies looking into this theory, and found no association between thimerosal and autism. Additional studies since then reached the same conclusion.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

Groups recommended to receive 2009 H1N1 vaccine first are:

- Pregnant women
- People who live with or care for infants younger than 6 months of age
- Health care and emergency medical personnel
- Anyone from 6 months through 24 years of age
- Anyone from 25 through 64 years of age with certain chronic medical conditions or a weakened immune system

As more vaccine becomes available, these groups should also be vaccinated:

- Healthy 25 through 64 year olds
- Adults 65 years and older

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

WHEN

Get vaccinated as soon as the vaccine is available.

Children through 9 years of age should get **two doses** of vaccine, about a month apart. Older children and adults need only one dose.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 flu vaccine if you have a **severe (life-threatening) allergy to eggs**, or to **any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies.*

Also tell them if you have ever had:

- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain Barré Syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Pregnant or breastfeeding women can get inactivated 2009 H1N1 flu vaccine.

Inactivated 2009 H1N1 vaccine may be given at the same time as other vaccines, including seasonal influenza vaccine.

6 What are the risks from 2009 H1N1 influenza vaccine?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The virus in inactivated 2009 H1N1 vaccine has been killed, so you cannot get influenza from the vaccine.

The risks from inactivated 2009 H1N1 vaccine are similar to those from seasonal inactivated flu vaccine:

Mild problems:

- soreness, redness, tenderness, or swelling where the shot was given
- fainting (mainly adolescents)
- headache, muscle aches
- fever
- nausea

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:

- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, an earlier type of swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 Vaccine injury compensation

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call **1-888-275-4772** or visit the program's website at: www.hrsa.gov/countermeasurescomp/default.htm.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/h1n1flu or www.cdc.gov/flu
- Visit the web at www.flu.gov



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement
2009 H1N1 Inactivated Influenza Vaccine 10/2/09



Texas Department of State Health Services

Addendum to 2009 H1N1 Inactivated Influenza Vaccine Information Statement

1. I agree that the person named below will get the vaccine checked below.
2. I received or was offered a copy of the Vaccine Information Statement (VIS) for the vaccine listed above.
3. I know the risks of the disease this vaccine prevents.
4. I know the benefits and risks of the vaccine.
5. I have had a chance to ask questions about the disease the vaccine prevents, the vaccine, and how the vaccine is given.
6. I know that the person named below will have the vaccine put in his/her body to prevent the disease this vaccine prevents.
7. I am an adult who can legally consent for the person named below to get the vaccine. I freely and voluntarily give my signed permission for this vaccine.

***STATEMENT:** I authorize the release of any medical or other information necessary to process the claim. I also request payment of government benefits to the party who accepts assignment.

Vaccine to be given: Inactivated 2009 H1N1 Influenza Vaccine

Provider Identification No.: _____ Medicare Health Insurance Claim No.: _____

Information about person to receive vaccine (Please print)					For Clinic/Office Use	
Name: Last	First	Middle Initial	Birthdate (mm/dd/yy)	Sex (circle one)	Clinic/Office Address:	
				M F	Date Vaccine Administered:	
Mother's First Name (if client is less than 18 years of age)			Mother's Maiden Name (if client is less than 18 years of age)			Vaccine Manufacturer:
Address: Street	City	County	State	Zip	Vaccine Lot Number:	
			TX		Site of Administration: <input type="checkbox"/> Imm / where? _____	
Age Group Category: (Check only one please)						
<input type="checkbox"/> 6-23 months		<input type="checkbox"/> 24-59 months		<input type="checkbox"/> 5-18 years		
<input type="checkbox"/> 19-24 years		<input type="checkbox"/> 25-49 years		<input type="checkbox"/> 50-64 years		
<input type="checkbox"/> 65+ years						
Signature of person to receive vaccine or person authorized to make the request (parent or guardian)				Date: _____ (mm/dd/yy)		
Witness				Date: _____ (mm/dd/yy)		
Signature of Vaccine Administrator:						
Title of Vaccine Administrator:						
Dose Number: (Please check one)						
<input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> Unknown						

Consent for Retention of Disaster-Related Information and Release of Information to Authorized Entities

I understand that, by granting the consent below, I am authorizing retention of my (or my child's) disaster-related information by DSHS beyond the 5 year retention period. I further understand that DSHS will include this information in the state's central immunization registry ("ImmTrac"). Once in ImmTrac, my (or my child's) disaster-related information may by law be accessed by:

- a state agency, for the purpose of aiding and coordinating communicable disease prevention and control efforts, and/or
- a physician or other health care provider legally authorized to administer immunizations, antivirals, and other medications, for treating the client as a patient;

I understand that I may withdraw this consent to retain information in the ImmTrac Registry beyond the 5 year retention period and my consent to release information from the Registry, at any time by written communication to the Texas Department of State Health Services, ImmTrac Group - MC 1946, P.O. Box 149347, Austin, Texas 78714-9347.

By my signature below, I GRANT consent to retain my disaster-related information (or my child's information if under age 18) in the Texas immunization registry beyond the 5 year retention period.

Client (or parent, legal guardian or managing conservator): _____

Printed Name

Date (mm/dd/yy) _____ Signature _____

PRIVACY NOTIFICATION - With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)

Privacy Notice: I acknowledge that I have received a copy of my immunization provider's HIPAA Privacy Notice.

Notice: Alterations or changes to this publication is prohibited without the express written consent of the Texas Department of State Health Services, Immunization Branch.

Instructions: File this consent statement in the patient's chart.



Department of State Health Services, Immunization Branch
Screening Questionnaire for Injectable 2009 H1N1 Influenza Vaccine

1. Have you read the vaccine information statement(s) for the vaccine(s) you plan to receive today?
 YES _____ NO _____

If YES, "Do you have any questions?"
 If NO, "Please take a few moments to read it/them now".

2. Is the person to be vaccinated moderately or severely ill today?
 YES _____ NO (Proceed to question #3) _____

If YES, please describe the illness. (Mild illness, such as colds or seasonal allergies, even if accompanied by a low-grade fever, is not a contraindication to vaccination. Vaccination should always be delayed if illness is moderate to severe).

3. Is the person to be vaccinated had a serious reaction after receiving a vaccination?
 YES _____ NO _____

If YES, please describe the vaccine involved and the reaction. (Anaphylactic reaction to any vaccine contraindicates further doses of that vaccine).

4. Is the person to be vaccinated ever been paralyzed with Guillain-Barré syndrome (an illness with sudden muscle weakness and some loss of senses in the fingers and toes)?
 YES _____ NO _____

If YES, defer immunization and consult with your doctor. Flu vaccine may slightly increase your risk for recurrence.

5. Does the person to be vaccinated have a serious allergy to eggs?
 YES _____ NO _____

If YES, please clarify with the recipient that the allergy is "serious." In general, persons who can eat eggs or egg product without reaction can be vaccinated. A history of anaphylactic or anaphylactic-like allergy to eggs or egg product is a contraindication to flu vaccination.

Printed name _____

Signature _____

Date _____