

2009 H1N1 INFLUENZA VACCINE

LIVE, ATTENUATED
(the nasal spray vaccine)

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 (sometimes 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 virus is a new virus strain. 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 protection from seasonal flu.*

Live, attenuated intranasal vaccine (or LAIV) is sprayed into the nose. **This sheet describes the live, attenuated intranasal vaccine.**

An **inactivated** vaccine is also available, which is given as a shot. It is described in a separate sheet.

The 2009 H1N1 LAIV does not contain thimerosal or other preservatives. It is licensed for people from 2 through 49 years of age.

The vaccine virus is attenuated (weakened) so it will not cause illness.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

LAIV is approved for people from 2 through 49 years of age who are not pregnant and do not have certain health conditions (see number 5 below). Groups recommended to receive 2009 H1N1 LAIV first are healthy people who:

- are from 2 through 24 years of age,
- are from 25 through 49 years of age and
 - live with or care for infants younger than 6 months of age, or
 - are health care or emergency medical personnel.

As more vaccine becomes available, other healthy 25 through 49 year olds should also be vaccinated.

Note: While certain groups should not get LAIV – for example pregnant women, people with long-term health problems, and children from 6 months to 2 years of age – it is important that they be vaccinated. They should get the flu shot.

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 LAIV 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.*

2009 H1N1 LAIV should not be given to the following groups.

- children younger than 2 and adults 50 years and older
- pregnant women,
- anyone with a weakened immune system,
- anyone with a long-term health problem such as
 - heart disease - kidney or liver disease
 - lung disease - metabolic disease such as diabetes
 - asthma - anemia and other blood disorders
- children younger than 5 years with asthma or one or more episodes of wheezing during the past year,
- anyone with certain muscle or nerve disorders (such as cerebral palsy) that can lead to breathing or swallowing problems,
- anyone in close contact with a person with a *severely* weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit),
- children or adolescents on long-term aspirin treatment.

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.

Tell your doctor if you 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.

2009 H1N1 LAIV may be given at the same time as most other vaccines. Tell your doctor if you got any other vaccines within the past month or plan to get any within the next month. H1N1 LAIV and seasonal LAIV should not be given together.

6 What are the risks from 2009 H1N1 LAIV?

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 risks from 2009 H1N1 LAIV are expected to be similar to those from seasonal LAIV:

Mild problems:

Some children and adolescents 2-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough • fever
- headache and muscle aches • wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion • sore throat
- cough, chills, tiredness/weakness • headache

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 vaccination.
- In 1976, an earlier type of inactivated swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). LAIV has not been 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





Texas Department of State Health Services

Addendum to 2009 H1N1 Live, Attenuated 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: 2009 H1N1 LAIV 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) M F	
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)			
Address: Street		City	County	State TX	Zip	
Age Group Category: (Check only one please)						
<input type="checkbox"/> 19-24 years		<input type="checkbox"/> 25-49 years		<input type="checkbox"/> 6-23 months		<input type="checkbox"/> 24-59 months
				<input type="checkbox"/> 5-18 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)		
Clinic/Office Address:						
Date Vaccine Administered:						
Vaccine Manufacturer:						
Vaccine Lot Number:						
Site of Administration: <input type="checkbox"/> Nasal _____						
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.

Printed name of person to be vaccinated: _____

under 18 18 or over

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

1. Is the person to be vaccinated younger than 2 years of age or older than 49 years of age?

YES

NO

If YES, person is not eligible for Intranasal Influenza vaccine. Please consider injectable influenza vaccine.

2. 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".

3. Is the person to be vaccinated moderately or severely ill today?

YES

NO (Proceed to question #4)

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).

4. Has the person to be vaccinated ever 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).

5. Has 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.

6. 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.

7. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?

YES

NO

If YES, the person is not eligible for vaccination with the intranasal influenza vaccine, please consider using injectable influenza vaccine.

8. If the person to be vaccinated is less than 5 years of age, in the past 12 months has a healthcare provider ever told you that he or she had wheezing or asthma?

YES

NO

If YES, the person is not eligible for vaccination with the intranasal influenza vaccine, please consider using injectable influenza vaccine.

9. Does the person to be vaccinated have a weakened immune system due to illness or long-term treatment?

YES

NO

If YES, the person is not eligible for vaccination with the intranasal influenza vaccine, please consider using injectable influenza vaccine.

10. If the person to be vaccinated is a child or teen, is he or she receiving aspirin therapy or aspirin-containing therapy?

YES

NO

If YES, the person is not eligible for vaccination with the intranasal influenza vaccine, please consider using injectable influenza vaccine.

11. Is the person to be vaccinated pregnant or planning to become pregnant within the next month?

YES

NO

If YES, the person is not eligible for vaccination with the intranasal influenza vaccine, please consider using injectable influenza vaccine.

12. Has the person to be vaccinated taken anti-viral (such as Tamiflu or Relenza) agent within the last 48 hours?

YES

NO

If YES, the person is not eligible for vaccination with the intranasal influenza vaccine at this time, please consider using injectable influenza vaccine, or they will have to return 48 hours after completing the anti-viral.

13. Does the person to be vaccinated live with or expect to have close contact with a person whose immune system is severely compromised and who must in a protective isolation (such as in a hospital room with reverse air flow)?

YES

NO

If YES, the person is not eligible for vaccination with the intranasal influenza vaccine, please consider using injectable influenza vaccine.

14. Have you received any other vaccination in the past 4 weeks?

YES

NO

If YES, which ones?

If the individual states that have received a live virus vaccine (such as MMR, varicella, and Flu Mist) within the last 4 weeks, then they are not a candidate for intranasal vaccine at this time; please consider using injectable vaccine.

Note: Two live vaccines (such as MMR, varicella, and Flu Mist) must be separated by 4 weeks if not given at the same time (exception - nasal vaccines cannot be given at the same time), but live and inactivated vaccines can be given at any time.

Signature of person providing information _____

Date month ____ day ____ year 2010

Telephone number _____