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

Vaccine Information Statement
2009 H1N1 LAIV 10/2/09