

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/viis.

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. 1-888-767-4687
- 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

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



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

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW

2009-10

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

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza, but rates of infection are highest among children. For most people, it lasts only a few days.

It can cause:

- fever
- sore throat
- chills
- muscle aches
- cough
- headache
- fatigue

Some people, such as infants, elderly, and those with certain health conditions, can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. On average, 226,000 people are hospitalized every year because of influenza and 36,000 die — mostly elderly. **Influenza vaccine can prevent influenza.**

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of seasonal influenza vaccine:

1. **Live, attenuated influenza vaccine (LAIV)** contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.

2. **Inactivated influenza vaccine**, sometimes called the "flu shot," is given by injection. *Inactivated influenza vaccine is described in a separate Vaccine Information Statement.*

These "seasonal" influenza vaccines are formulated to prevent annual flu. They do not protect against pandemic H1N1 influenza.

Influenza viruses are always changing. Because of this, influenza vaccines are updated every year, and an annual vaccination is recommended.

Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. When there is a close match the vaccine protects most people from serious influenza-related illness. But even when there is not a close match, the vaccine provides some protection. Influenza vaccine will *not* prevent "influenza-like" illnesses caused by other viruses.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts up to a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can get LAIV?

LAIV is approved for people from 2 through 49 years of age, who are not pregnant and do not have certain health conditions (see #4, below). Influenza vaccination is recommended for people who can spread influenza to others at high risk, such as:

- **Household contacts and out-of-home caregivers** of children up to 5 years of age, and people 65 and older.
- Physicians and nurses, and family members or anyone else in **close contact with people at risk** of serious influenza.

Health care providers may also recommend a yearly influenza vaccination for:

- People who provide **essential community services**.
- People living in **dormitories, correctional facilities**, or under other crowded conditions, to prevent outbreaks.

Influenza vaccine is also recommended for anyone who wants to **reduce the likelihood of becoming ill** with influenza or **spreading influenza to others**.

4 Some people should not get LAIV

LAIV is not licensed for everyone. The following people should get the **inactivated** vaccine (flu shot) instead:

- **Adults 50 years of age and older or children between 6 months and 2 years of age.** (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 with asthma or one or more episodes of wheezing within the past year.
- People who have long-term health problems with:
 - heart disease
 - lung disease
 - asthma
 - kidney or liver disease
 - metabolic disease, such as diabetes
 - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Children or adolescents on long-term aspirin treatment.
- Pregnant women.

Tell your doctor if you ever had Guillain-Barré syndrome (a severe paralytic illness also called GBS). You may be able to get the vaccine, but your doctor should help you make the decision.

The **flu shot** is preferred for people (including health-care workers, and family members) in close contact with anyone who has a *severely* weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit). People in close contact with those whose immune systems are less severely weakened (including those with HIV) may get LAIV.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

Some people should talk with a doctor before getting either influenza vaccine:

- Anyone who has ever had a serious allergic reaction to eggs or another vaccine component, or to a previous dose of influenza vaccine. *Tell your doctor if you have any severe allergies.*
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I get influenza vaccine?

You can get the vaccine as soon as it is available, usually in the fall, and for as long as illness is occurring in your community. Influenza can occur any time from November through May, but it most often peaks in January or February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Most people need one dose of influenza vaccine each year. **Children younger than 9 years of age getting influenza vaccine for the first time** – or who got influenza vaccine for the first time last season but got only one dose – should get 2 doses, at least 4 weeks apart, to be protected.

Influenza vaccine may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

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 from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and no serious problems have been identified. Like all vaccines, LAIV will continue to be monitored for unusual or severe problems.

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 The National Vaccine Injury Compensation Program

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For more information about the National Vaccine Injury Compensation Program, call 1-800-338-2382, or visit their website at www.hrsa.gov/vaccinecompensation.

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/flu

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Vaccine Information Statement
Live, Attenuated Influenza Vaccine (8/11/09) U.S.C. §300aa-26

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