

INACTIVATED 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
- fatigue
- cough
- headache
- muscle aches

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 Inactivated influenza vaccine

There are two types of seasonal influenza vaccine:

1. **Inactivated** (killed) vaccine, or the “flu shot” is given by injection into the muscle. 2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This 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.

Some inactivated influenza vaccine contains a preservative called thimerosal. Some people have suggested that thimerosal may be related to developmental problems in children. In 2004 the Institute of Medicine reviewed many studies looking into this theory and concluded that there is no evidence of such a relationship. Thimerosal-free influenza vaccine is available.

3 Who should get inactivated influenza vaccine?

*Anyone who wants to **reduce the likelihood of becoming ill with influenza or spreading influenza to others.***

*All children **6 months and older** and all **older adults:***

- All children from 6 months through 18 years of age.
- Anyone 50 years of age or older.

*Anyone who is **at risk of complications from influenza, or more likely to require medical care:***

- Women who will be **pregnant** during influenza season.
- Anyone with **long-term health problems** with:
 - heart disease
 - kidney disease
 - liver disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- Anyone with a **weakened immune system** due to:
 - HIV/AIDS or other diseases affecting the immune system
 - long-term treatment with drugs such as steroids
 - cancer treatment with x-rays or drugs
- Anyone with certain **muscle or nerve disorders** (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone 6 months through 18 years of age on **long-term aspirin treatment** (they could develop Reye Syndrome if they got influenza).
- **Residents of nursing homes** and other **chronic-care facilities.**

Anyone who lives with or cares for people at high risk for influenza-related complications:

- **Health care providers.**
- **Household contacts and caregivers of children** from birth up to 5 years of age.
- **Household contacts and caregivers** of
 - people 50 years and older, or
 - anyone with medical conditions that put them at higher risk for severe complications from 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.
- People at high risk of influenza complications who **travel** to the Southern hemisphere between April and September, or to the tropics or in organized tourist groups at any time.

4 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, including pneumococcal vaccine.

5 Some people should talk with a doctor before getting influenza vaccine

Some people should not get inactivated influenza vaccine or should wait before getting it.

- Tell your doctor if you have any **severe** (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.
 - Influenza vaccine virus is grown in eggs. People with a severe egg allergy should not get the vaccine.
 - A severe allergy to any vaccine component is also a reason to not get the vaccine.
 - If you have had a severe reaction after a previous dose of influenza vaccine, tell your doctor.
- 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.
- 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.

6 What are the risks from inactivated influenza vaccine?

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.

Serious problems from influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

- soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever • aches

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

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.
- In 1976, a type of influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

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



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



Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (8/11/09) 42 U.S.C. §300aa-26

LIVE, INTRANASAL INFLUENZA VACCINE

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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 vaccination. 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 50 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
 - kidney or liver disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - 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?

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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 vaccination.
- 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.

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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?

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Vaccine Information Statement
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