VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza vaccine can prevent influenza (flu).

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

Each year thousands of people in the United States die from flu, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2 Live, attenuated influenza vaccine

CDC recommends everyone 6 months of age and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

Live, attenuated influenza vaccine (called LAIV) is a nasal spray vaccine that may be given to non-pregnant people **2 through 49 years of age**.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to

protect against three or four viruses that are likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine does not cause flu.

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

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Is younger than 2 years or older than 49 years of age.
- Is pregnant.
- Has had an allergic reaction after a previous dose of influenza vaccine, or has any severe, lifethreatening allergies.
- Is a child or adolescent 2 through 17 years of age who is receiving aspirin or aspirin-containing products.
- Has a weakened immune system.
- Is a **child 2 through 4 years old who has asthma or a history of wheezing** in the past 12 months.
- Has taken influenza antiviral medication in the previous 48 hours.
- Cares for severely immunocompromised persons who require a protected environment.
- Is 5 years or older and has asthma.
- Has other underlying medical conditions that can put people at higher risk of serious flu complications (such as lung disease, heart disease, kidney disease, kidney or liver disorders, neurologic or neuromuscular or metabolic disorders).
- Has had Guillain-Barré Syndrome within 6 weeks after a previous dose of influenza vaccine.



In some cases, your health care provider may decide to postpone influenza vaccination to a future visit.

For some patients, a different type of influenza vaccine (inactivated or recombinant influenza vaccine) might be more appropriate than live, attenuated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

4 Risks of a vaccine reaction

- Runny nose or nasal congestion, wheezing and headache can happen after LAIV.
- Vomiting, muscle aches, fever, sore throat and cough are other possible side effects.

If these problems occur, they usually begin soon after vaccination and are mild and short-lived.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

What if there is a serious problem?

5

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- 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 www.cdc.gov/flu

Vaccine Information Statement (Interim)

Live Attenuated Influenza Vaccine



8/15/2019 | 42 U.S.C. § 300aa-26

Screening Checklist for Contraindications

PATIENT NAME	-
DATE OF BIRTH//	
month day year	

to Live Attenuated Intranasal Influenza Vaccination

For use with people age 2 through 49 years: The following questions will help us determine if there is any reason we should not give you or your child live attenuated intranasal influenza vaccine (LAIV, FluMist) today. If you answer "yes" to any question, it does not necessarily mean you (or your child) should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	know
1. Is the person to be vaccinated sick today?			
2. Does the person to be vaccinated have an allergy to a component of the influenza vaccine?			
3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?			
4. Is the person to be vaccinated younger than age 2 years or older than age 49 years?			
5. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease (including asthma), kidney disease, neurologic disease, liver disease, metabolic disease (e.g., diabetes), or have a cochlear implant or spinal fluid leak, or no spleen?			
6. If the person to be vaccinated is a child age 2 through 4 years, in the past 12 months, has a healthcare provider told you the child had wheezing or asthma?			
7. Does the person to be vaccinated have cancer, leukemia, HIV/AIDS, or any other immune system problem; or, in the past 3 months, have they taken medications that affect the immune system (e.g., prednisone or other steroids, drugs for the treatment of rheumatoid arthritis, Crohn's disease, psoriasis, or anticancer drugs) or have they had radiation treatments?			
8. Is the person to be vaccinated receiving influenza antiviral medications?			
9. Is the person to be vaccinated a child or teen age 6 months through 17 years and receiving aspiring or salicylate-containing medicine?	n- 🔲		
10. Is the person to be vaccinated pregnant or could she become pregnant within the next month?			
11. Has the person to be vaccinated ever had Guillain-Barré syndrome?			
12. 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 be in protective isolation (e.g., an isolation room of a bone marrow transplant unit)?			
13. Has the person to be vaccinated received any other vaccinations in the past 4 weeks?			
FORM COMPLETED BY	_ DATE		
FORM REVIEWED BY	DATE_		



Information for Healthcare Professionals about the Screening Checklist for Contraindications to Live Attenuated Intranasal Influenza Vaccination

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the sources listed at the bottom of this page.

1. Is the person to be vaccinated sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. People with an acute febrile illness usually should not be vaccinated until their symptoms have improved. Minor illnesses with or without fever do not contraindicate use of influenza vaccine. Do not withhold vaccination if a person is taking antibiotics. However, if nasal congestion might reduce delivery of the vaccine, delay LAIV or use another type of appropriate influenza vaccine.

2. Does the person to be vaccinated have an allergy to a component of the influenza vaccine?

A history of an anaphylactic reaction such as wheezing, difficulty breathing, circulatory collapse or shock, or who required epinephrine or another emergency medical intervention after a previous dose of intranasal live attenuated influenza vaccine (LAIV; tradename FluMist) usually means no further doses of LAIV should be given. ACIP recommends that people with a history of egg allergy who have experienced only hives after exposure to egg may receive any recommended and age-appropriate influenza vaccine that is otherwise appropriate for their health status without specific precautions (except a 15 minute observation period for syncope). People who report having had an anaphylactic reaction to egg may also receive any age-appropriate influenza vaccine. The vaccine should be administered in a medical setting (e.g., a health department or physician office). Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions. For a complete list of vaccine components (i.e., excipients and culture media) used in the production of the vaccine, check the package insert (at www.immunize.org/fda) or go to www.cdc.gov/ vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf.

3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?

Patients reporting a serious reaction to a previous dose of LAIV should be asked to describe their symptoms. Immediate – presumably allergic – reactions are usually a contraindication to further vaccination with LAIV.

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

LAIV is not licensed or recommended for use in people younger than age 2 years or older than age 49 years.

5. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease (including asthma), kidney disease, neurologic disease, liver disease, metabolic disease (e.g., diabetes), or have a cochlear implant, spinal fluid leak or no spleen?

The safety of LAIV in people with any of these health conditions has not been established. These conditions, including asthma in people age 5 years and older, should be considered precautions for the use of LAIV.

6. If the person to be vaccinated is a child age 2 through 4 years, in the past 12 months, has a healthcare provider told you that the child had wheezing or asthma?

LAIV is not recommended for a child this age if their parent or guardian answers yes to this question or if the child has a history of asthma or recurrent wheezing. Instead, the child should be given the inactivated injectable influenza vaccine (IIV).

7. Does the person to be vaccinated have cancer, leukemia, HIV/AIDS, or any other immune system problem; or, in the past 3 months, have they taken medications that affect the immune system (e.g., prednisone or other steroids, drugs for the treatment of rheumatoid arthritis, Crohn's disease, psoriasis, or anticancer drugs) or have they had radiation treatments?

People with weakened immune systems should not be given LAIV. Instead, they should be given the inactivated injectable influenza vaccine (IIV).

8. Is the person to be vaccinated receiving influenza antiviral medications?

Receipt of certain influenza antivirals (e.g., amantadine, rimantadine, zanamivir, oseltamivir, baloxavir, peramivir) could reduce LAIV vaccine effectiveness; therefore, providers should defer vaccination with LAIV in people who took these antivirals within the previous 48 hours and to advise avoiding use of these antivirals for 14 days after vaccination, if feasible. Influenza antivirals may be used in people vaccinated with IIV.

9. Is the person to be vaccinated a child or teen age 6 months through 17 years who is receiving aspirin therapy or aspirin-containing therapy?

Because of the theoretical risk of Reye's syndrome, children age 6 months through 17 years on aspirin therapy should not be given LAIV. Instead they should be vaccinated with the inactivated injectable influenza vaccine (IIV).

10. Is the person to be vaccinated pregnant or could she become pregnant within the next month?

Pregnant women or women planning to become pregnant within a month should not be given LAIV. All pregnant women should, however, be vaccinated with the inactivated injectable influenza vaccine. Pregnancy testing is not necessary before administering LAIV.

11. Has the person to be vaccinated ever had Guillain-Barré syndrome?

It is prudent to avoid vaccinating people who are not at high risk for severe influenza complications and who are known to have developed Guillain-Barré syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination. As an alternative, clinicians might consider using influenza antiviral chemoprophylaxis for these people. Although data are limited, the established benefits of influenza vaccination for the majority of people who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

12. 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 be in protective isolation (e.g., an isolation room of a bone marrow transplant unit)?

Inactivated injectable influenza vaccine is preferred for people who anticipate close contact with a severely immunosuppressed person during periods in which the immunosuppressed person requires care in protective isolation (e.g., in a specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes). Either the inactivated injectable influenza vaccine or LAIV may be used in people who have close contact with people having lesser degrees of immunosuppression.

13. Has the person to be vaccinated received any other vaccinations in the past

People who were previously given an injectable live virus vaccine (e.g., MMR, MMRV, varicella, zoster [Zostavax], yellow fever) should wait at least 28 days before receiving LAIV (30 days for yellow fever). LAIV can be given on the same days as other live vaccines. There is no reason to defer giving LAIV if people were vaccinated with an inactivated vaccine or if they have recently received blood or other antibody-containing blood products (e.g., IG).

SOURCES

- 1. CDC. Epidemiology & Prevention of Vaccine-Preventable Diseases, Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. at www.cdc.gov/vaccines/pubs/pinkbook/index.html
- 2. CDC. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- CDC. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, . . . Access links to current ACIP recommendations at www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html