VACCINE INFORMATION STATEMENT

Influenza Vaccine
Live, Intranasal
What You Need to Know

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.

Anyone can get influenza, but rates of infection are highest
among children. For most people, symptoms last only a few
days. They include:
• fever/chills • sore throat • muscle aches • fatigue
• cough • headache • runny or stuffy nose

Other illnesses can have the same symptoms and are often
mistaken for influenza.

Young children, people 65 and older, pregnant women, and
people with certain health conditions — such as heart, lung
or kidney disease, or a weakened immune system — 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. Each year thousands of
people die from influenza and even more require
hospitalization.

By getting flu vaccine you can protect yourself from
influenza and may also avoid spreading influenza to others.

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

There are two types of influenza vaccine:

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

2. Inactivated (killed) influenza vaccine, the "flu shot," is
given by injection with a needle. This vaccine is described
in a separate Vaccine Information Statement.

Influenza viruses are always changing, so annual vaccination
is recommended. Each year scientists try to match the viruses
in the vaccine to those most likely to cause flu that year. Flu
vaccine will not prevent disease from other viruses, including
flu viruses not contained in the vaccine.

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

LAIV does not contain thimerosal or other preservatives.

3 Who can receive LAIV?

LAIV is recommended for healthy people 2 through 49
years of age, who are not pregnant and do not have certain
health conditions (see #4, below).

4 Some people should not
receive LAIV

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

• Adults 50 years of age and older or children from 6
through 23 months of age. (Children younger than 6
months should not get either influenza vaccine.)

• Children younger than 5 years with asthma or one or
more episodes of wheezing within the past year.

• Pregnant women.

• 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.

• Anyone in close contact with someone whose immune
system is so weak they require care in a protected
environment (such as a bone marrow transplant unit).

Close contacts of other people with a weakened immune
system (such as those with HIV) may receive LAIV.

Healthcare personnel in neonatal intensive care units or
oncology clinics may receive LAIV.

• Children or adolescents on long-term aspirin treatment.

Tell your doctor if you have any severe (life-threatening)
allergies, including a severe allergy to eggs. A severe allergy
to any vaccine component may be a reason not to get the
vaccine. Allergic reactions to influenza vaccine are rare.

Tell your doctor if you ever had a severe reaction after a
dose of influenza vaccine.

Tell your doctor if you ever had Guillain-Barré Syndrome
(a severe paralytic illness, also called GBS). Your doctor
will help you decide whether the vaccine is recommended
for you.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
Tell your doctor if you have gotten any other vaccines in the past 4 weeks.

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

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 about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I receive influenza vaccine?

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community. Influenza can occur any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor.

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 very 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:
• runny nose, nasal congestion or cough
• headache and muscle aches
• abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:
• runny nose or nasal congestion
• cough, chills, tiredness/weakness
• sore throat
• wheezing
• 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 the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html
and
www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

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 doctor 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

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382, or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

9 How can I learn more?

• Ask your doctor. 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

Vaccine Information Statement (Interim)
Influenza Vaccine (Live, Attenuated)
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