

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Immunization Program

PLEASE COPY THIS FOR ALL HEALTH CARE PROVIDERS IN YOUR PRACTICE

TO: All Users of State Supplied Vaccines

FROM: Vincent Sacco, MS
Immunization Program Manager

Lynn Sosa, MD
Deputy State Epidemiologist

DATE: July 23, 2012

SUBJECT: Update on Seasonal Flu Vaccine Availability and DTaP/IPV/Hib vaccine supply

The primary purpose of this communication is to notify you of the availability of seasonal flu vaccine and to provide you with an update on the supply of DTaP/Hib/IPV combination vaccine (brand name Pentacel®).

Pediatric Influenza Vaccine

The Advisory Committee on Immunization Practices (ACIP) recommends that all children aged 6 months through 18 years be vaccinated yearly against influenza. The 2012–13 trivalent vaccine will contain A/California/7/2009 (H1N1)-like, A/Victoria/361/2011 (H3N2)-like, and B/Wisconsin/1/2010-like antigens. The full 2012 Prevention & Control of Influenza Recommendations will be published sometime in August and be available at: www.cdc.gov/mmwr/.

The Immunization Program will provide several different formulations of vaccine available to immunize all children aged 6 through 59 months regardless of insurance status as well as all VFC-eligible and SCHIP children aged 5 through 18 years. As a reminder, VFC eligibility is defined as follows:

- Medicaid enrolled
- No health insurance
- American Indian or Alaskan Native

SCHIP children are those children enrolled in HUSKY B.

In addition, children aged 5 through 18 years who are underinsured (have health insurance that does not cover the cost of immunizations) can be referred to a Federally Qualified Health Center (FQHC) to be immunized with VFC-supplied vaccine.

Beginning August 1st, you can begin to order flu vaccine for your patient population. Please limit your vaccine request to your actual need for the current month. The majority of our influenza vaccine supply is expected to be available in September and October.

Vaccination schedule for children aged 6 months through 8 years

Children aged 6 months through 8 years who have received two or more doses of flu vaccine since July 2010 should receive one dose of the 2012–13 influenza vaccine. Children aged 6 months through 8 years

who have received less than two doses of flu vaccine since July 2010 should receive two doses of the 2012–13 influenza vaccine separated by at least 4 weeks. Please see the enclosed algorithm to help determine the proper number of doses needed.

Below is a list of the flu formulations we will be supplying this season:

Vaccine	Package	Dose	Age	Thimerosal	NDC #	CPT Code
Fluzone (Sanofi)	Single dose syringe	0.25 mL	6-35 months	NO	49281-0112-25	90655
Fluzone (Sanofi)	Single dose syringe	0.5 mL	3 years and older	NO	49281-0012-50	90656
Fluzone (Sanofi)	Single dose vial	0.5 mL	3 years and older	NO	49281-0012-10	90656
Fluarix (GSK)	Single dose syringe	0.5 mL	3 years and older	NO	58160-0879-52	90656
FluVirin (Novartis)	Single dose syringe	0.5 mL	4 years and older	NO	66521-0115-02	90656
FluMist (MedImmune)	Single dose sprayer	0.2 mL	2-49 years	NO	66019-0110-10	90660

We will do our best to fill your monthly order as completely as possible, but you may not initially receive all the doses you requested, especially for orders placed in August and September before the full influenza vaccine supply is available. We will send out multiple monthly shipments as additional influenza vaccine becomes available. Please be sure to check your order immediately upon receipt to verify which formulation you have received.

Proper Flu Dosage By Patient Age

Age Group	Dosage	No. of Doses	Route
6–35 months	0.25 mL	1 or 2	IM or intranasal**
3–8 years	0.50 mL	1 or 2	IM or intranasal**
9 years and older	0.50 mL	1	IM or intranasal**

** Intranasal administration of live attenuated influenza vaccine is only approved for children 2 years of age and older and is a 0.2 mL dose

Enclosed are the 2012-13 Vaccine Information Statements (VIS) for both Live, Intranasal Influenza Vaccine and for Inactivated Influenza Vaccine. The VIS can also be accessed at:

www.cdc.gov/vaccines/pubs/vis/default.htm#flu or www.immunize.org/vis/

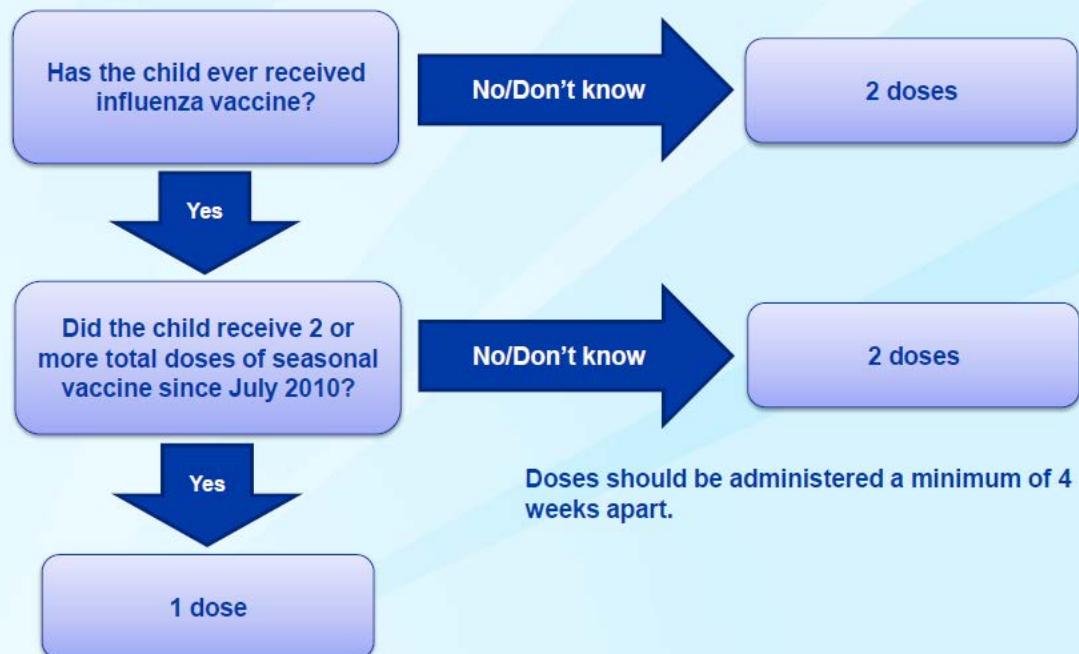
DTaP/Hib/IPV update

Sanofi Pasteur has informed CDC that the delay in the supply of Pentacel® will continue through March 2013. The continued delay will result in the Immunization Program receiving about 2/3 the amount of Pentacel® that we normally distribute each month. Providers can continue to order additional doses of DTaP, IPV, and Hib vaccines as well as DTaP/IPV/Hep B combination vaccine (Pediarix®) accordingly to ensure they have enough vaccine to fully immunize children based on the recommended schedule.

As always, if you have any questions please call the State Immunization Program at (860) 509-7929.

Proposed 2012-2013 Algorithm for Children 6 Mos. Through 8 yrs.

Option 1



Influenza Vaccine

Inactivated

What You Need to Know

2012 - 2013

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 <http://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.

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 Inactivated influenza vaccine

There are two types of influenza vaccine:

1. **Inactivated** (killed) vaccine, the “flu shot,” is given by injection with a needle.

2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A “high-dose” inactivated influenza vaccine is available for people 65 years of age and older. Ask your doctor for more information.

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 shot. Protection lasts about a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your doctor for more information.

3

Who should get inactivated influenza vaccine and when?

WHO

All people **6 months of age and older** should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

WHEN

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 at 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, including pneumococcal vaccine.

4

Some people should not get inactivated influenza vaccine or should wait.

- 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.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

- 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.
- 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 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 inactivated 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 • headache • itching • fatigue

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

Moderate problems:

Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time appear to be at increased risk for seizures caused by fever. Ask your doctor for more information.

Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

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 inactivated 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.

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

One brand of inactivated flu vaccine, called Afluria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Your doctor can give you more information.

6 What if there is a severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious 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** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

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

People 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.

8 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
 (Inactivated)



7/2/2012

42 U.S.C. § 300aa-26

VACCINE INFORMATION STATEMENT

Influenza Vaccine

Live, Intranasal

What You Need to Know

2012 - 2013

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 <http://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.

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
 - 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.
- 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
- fever
- wheezing

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- cough, chills, tiredness/weakness
- sore throat
- 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)



7/2/2012

42 U.S.C. § 300aa-26