

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH IMMUNIZATION PROGRAM

PLEASE COPY THIS FOR ALL HEALTH CARE PROVIDERS IN YOUR PRACTICE

TO: All Users of State Supplied Vaccines

FROM: Vincent Sacco, MS MS Lynn Sosa, MD Rym Josa

Immunization Program Manager Deputy State Epidemiologist

DATE: August 12, 2010

SUBJECT: Seasonal Flu Vaccine now Available

The primary purpose of this communication is to notify you of the availability of seasonal flu vaccine for your **VFC-eligible population** and to make you aware of the flu formulations we will be providing this influenza season.

Pediatric Influenza Vaccine

The Advisory Committee on Immunization Practices (ACIP) recommends that all children 6 months to 18 years of age be vaccinated yearly against influenza. The 2010–11 trivalent vaccine will contain A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The full 2010 Prevention & Control of Influenza Recommendations can be found at: www.cdc.gov/mmwr/preview/mmwrhtml/rr59e0729a1.htm?s cid=rr59e0729a1 e

As influenza vaccine becomes available, the Immunization Program will have several different formulations of vaccine to immunize all VFC-eligible children 6 months-18 years of age. As a reminder, VFC eligibility is defined as follows:

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

In addition, those individuals 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 on September 1st, you can order flu vaccine for your VFC-eligible population. Please be sure to have your order submitted to the Immunization Program no later than the first business day of the month. Please limit your vaccine request to what you actually need for that month. The majority of our influenza vaccine supply is expected to be available by the end of October.

Vaccination of children 6 months – 8 years of age

Children 6 months—8 years of age whose vaccination status is unknown, or who have never received seasonal influenza vaccine before, or who only received 1 dose of seasonal vaccine for the first time in 2009—10, as well as children who did not receive at least one dose of 2009 H1N1 monovalent vaccine, should receive 2 doses of 2010—11 seasonal influenza vaccine (minimum interval between doses of 4 weeks). Please see the chart below for the proper flu dosing by patient age.

Below is a	a list of	the flu	ı formulations y	we will be sup	plying this	s influenza season:
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Vaccine	Package	Dose	Age	Thimerosal	NDC#	CPT Code
Fluzone	Multi-dose	Age	6 months	YES	49281-0386-15	90657/90658
(Sanofi)	Vial	Dependent	and older			
Fluzone	Single dose	0.25 mL	6-35 months	NO	49281-0010-25	90655
(Sanofi)	Syringe					
Fluzone	Single dose	0.5 mL	3 years and	NO	49281-0010-50	90656
(Sanofi)	syringe		older			
Fluzone	Single dose	0.5 mL	3 years and	NO	49281-0010-10	90656
(Sanofi)	vial		older			
*Afluria	Single dose	0.5 mL	*9 years and	NO	33332-0010-01	90656
(CSL)	syringe		older			
Fluarix	Single dose	0.5 mL	3 years and	NO	58160-0877-46	90656
(GSK)	syringe		older			
FluMist	Single dose	0.2 mL	2-49 years	NO	66019-0108-10	90660
(MedImmune	sprayer					

*ACIP voted on August 5, 2010 that CSL's seasonal influenza vaccine should only be administered to individuals 9 years of age and older due to reports of elevated rates of fever and febrile seizures predominantly in children 6 months-4 years of age. Children 5-8 years of age who are at an increased risk of influenza complications can be administered the CSL 0.5 mL vaccine if no other seasonal flu vaccine is readily available. (www.cdc.gov/media/pressrel/2010/s100806.htm)

We will do our best to fill your monthly order as completely as possible, but you may not receive all the doses you requested, especially for orders placed in September and October before the full influenza vaccine supply is available. Thus, continue to order seasonal flu vaccine on a monthly basis. Please understand that if you do not receive the full requested number of flu doses, you should order flu vaccine during the next order cycle according to your current needs; we do not keep your flu requests on "backorder". We will try to fill as many orders as possible with thimerosal free formulations but you may receive thimerosal-containing multi-dose vials as well. Please be sure to check your order immediately upon receipt to verify which formulation you have received.

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 2010-11 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.

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

INACTIVATED VACCINE INFLUENZA VACCINE WHAT YOU NEED TO KNOW 2010-11

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis Hojas de Informacián Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite 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
- sore throat
- chills
- fatigue

- cough
- headache
- muscle aches

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

Infants, the elderly, 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 medcal conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from seasonal influenza and even more require hospitalization.

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

Inactivated influenza vaccine

There are two types of 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*.

A "high-dose" inactivated influenza vaccine is available for people 65 years of age and older. Ask your healthcare provider 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.

The 2010-2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses – influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

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 healthcare provider 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.

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

WHEN

Getting the vaccine as soon as it is available will 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 November 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 healthcare provider.

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



Some people should not get inactivated influenza vaccine or should wait

• Tell your healthcare provider 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 influenza vaccine.
- A severe allergy to any vaccine component is also a reason not to get the vaccine.
- If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.
- Tell your healthcare provider if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your provider 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 healthcare provider about whether to reschedule the
 vaccination. People with a mild illness can usually get the
 vaccine.

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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

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 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.

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. Ask your healthcare provider for more information.

The safety of vaccines is always being monitored. For more information, visit:

www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and

 $www.cdc.gov/vaccines a fety/Activities/Activities_Index.html$

6

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 healthcare 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.



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**.

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How can I learn more?

- Ask your healthcare 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 (8/10/10) 42 U.S.C. §300aa-26

LIVE, INTRANASAL VA CCINE INFLUENZA VA CCINE WHAT YOU NEED TO KNOW 2010-11

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

fever

- sore throat
- chills
- fatigue

- cough
- headache
- · muscle aches

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

Infants, the elderly, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease or a weakened immune system – can get much sicker. Influenza 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 seasonal influenza and even more require hospitalization.

By getting vaccinated 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, or the "flu shot," is given by injection into the muscle. *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.

The 2010 – 2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses– influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

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).

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

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 healthcare provider 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 influenza vaccine.
 - A severe allergy to any vaccine component is also a reason not to get the vaccine.
 - If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.

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

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

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When should I receive influenza vaccine?

Getting the vaccine as soon as it is available will 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 November through May. In recent seasons, most infections have occured 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 healthcare provider.

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 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 the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:

 $www.cdc.gov/vaccines a fety/Vaccine_Monitoring/Index.html \\ and$

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Vaccine Information Statement (Interim) Live, Attenuated Influenza Vaccine (8/10/10) U.S.C. §300aa-26