



California Department of Health Services

SANDRA SHEWRY
Director

State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

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TO: Private Sector Vaccines for Children (VFC) Providers

FROM: Howard Backer, M.D., M.P.H., Chief
Immunization Branch

SUBJECT: Influenza Vaccine Availability for VFC Children; and
VFC Vaccine Order Form, DHS IMM 376F.

This memo is divided into sections to enable you to quickly access the information you need:

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SUMMARY

On July 28, 2006, the federal Advisory Committee on Immunization Practices (ACIP) published its annual **Influenza Recommendations (MMWR, July 28, 2006 / 55(RR10);1-42)**, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm?s_cid=rr5510a1_e. The VFC Influenza Resolution for this current flu season can also be found online at: http://www.cdc.gov/nip/vfc/acip_resolutions/0206influenza.pdf.

This year's recommendations for pediatric influenza vaccination included an increase in age limit for the vaccination of healthy children. According to the new expanded eligibility, all VFC-eligible children aged 6-59 months should receive an annual influenza vaccination. ACIP also emphasized the importance of administering two doses of influenza vaccine to previously unvaccinated children aged six months to nine years.

Beginning September 14, 2006, the California VFC Program will accept influenza vaccine orders for the 2006-2007 influenza season. Orders will be accepted throughout the season as supply permits.

A new "Influenza Vaccine Order Form" is enclosed and **must** be used when placing influenza vaccine orders. Since this new form includes additional products that were not available during the previous influenza season, orders submitted prior to this notification must be re-submitted utilizing the new Influenza Vaccine Order Form.

We expect to receive initial supplies of flu vaccine from the manufacturers by early October. The VFC Program will begin delivery of your approved order as soon as the vaccine is in our inventory.

2006-2007 INFLUENZA VACCINE COMPOSITION

The vaccine's composition for this year's flu vaccine is identical to the recommended composition issued by the World Health Organization on February 15, 2006.

Influenza vaccine for use in the 2006–2007 United States influenza season includes the following influenza virus strains:

- A/New Caledonia/20/99 (H1N1)-like virus;
- A/Wisconsin/67/2005 (H3N2)-like virus (A/Wisconsin/67/2005 and A/Hiroshima/52/2005 strains);
- B/Malaysia/2506/2004-like virus (B/Malaysia/2506/2004 and B/Ohio/1/2005 strains)

AVAILABLE INFLUENZA VACCINES

VFC Program will make available a variety of approved influenza vaccine products for immunization of VFC-eligible children 6 months to 18 years of age during the 2006-2007 influenza season. Please refer to the attached "Approved Influenza Vaccine Products" chart describing available products, presentation, formulation, and recommended ages for use.

Due to a limited supply of preservative-free influenza formulation, preservative-free vaccines should be reserved for administration to children younger than three years of age. The California Mercury Free Act of 2004 took effect July 1, 2006, and states that pregnant women or children younger than three years old may only receive vaccine doses that contain trace levels or no mercury. [Health and Safety (H&S) Code Section 124172, Chapter 837, Statutes of 2004 (AB 2943, Pavley)].

ELIGIBILITY FOR VFC-SUPPLIED INFLUENZA VACCINE

VFC-supplied Influenza vaccine may be used for all VFC-eligible children in the following ACIP recommended groups:

Eligible Groups for Inactivated Influenza Vaccine

- Children aged six months through 59 months.
- Children and adolescents aged five through 18 years with any of the following:
 - Chronic disorders of the pulmonary or cardiovascular systems, including asthma.
 - Have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]).
 - Have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration.
 - Are receiving long-term aspirin therapy and may therefore be at risk for developing Reye syndrome after influenza.
 - Are residents of nursing homes and other chronic-care facilities that house persons at any age who have chronic medical conditions.
- Adolescent females aged <19 years who will be pregnant during influenza season.
- Children and adolescents aged five through 18 years who are household contacts of persons in the following high-risk groups:
 - any children less than five years old;
 - children or adolescents in any of the other groups listed above;
 - any person 50 years or older;
 - adults with chronic disorders of the pulmonary or cardiovascular systems;
 - adults who have required regular medical follow-up or hospitalization during the preceding year for chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]).

Eligible Groups for Live Attenuated Influenza Vaccine (LAIV)

- All healthy children and adolescents aged five years through 18 years, particularly:
- Children and adolescents aged five through 18 years who are household contacts of persons in the following high-risk groups, provided that the contacts are not severely immunocompromised (e.g., patients with hematopoietic stem cell transplants) and requiring care in a protective environment:
 - any children less than 5 years old;
 - children or adolescents in any of the other groups listed above;
 - any person 50 years or older;
 - adults with chronic disorders of the pulmonary or cardiovascular systems;
 - adults who have required regular medical follow-up or hospitalization during the preceding year for chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]).

DOSAGE AND ADMINISTRATION

Inactivated Influenza Vaccine

Children under nine years of age, receiving inactivated influenza vaccine for the first time, require two doses, one month apart.

- For children 6-35 months of age, one dose is equivalent to 0.25mL.
- For children >35 months of age, one dose is equivalent to 0.5mL

Children under nine years who received only one dose of influenza vaccine during a prior season are recommended to receive only one dose this season.

Inactivated influenza vaccine should be administered intramuscularly in the anterolateral aspect of the thigh for infants and young children. Adults and older children should be vaccinated in the deltoid muscle.

LAIV

Children aged five – nine years previously unvaccinated with LAIV should receive two doses of LAIV separated by six – ten weeks. Children under nine years who have received one or more doses of any influenza vaccine in the past are recommended to receive only one dose this season.

LAIV is only administered intranasally and it must be thawed before administration. LAIV is supplied in a prefilled single-use sprayer containing 0.5 mL of vaccine. One half of the sprayer's contents (.25 mL) should be sprayed into each nostril. Do not repeat a dose if the patient sneezes after administration of the dose.

STORAGE OF INFLUENZA VACCINES

Trivalent Inactivated Vaccine (TIV) should be refrigerated at a temperature range of 35° to 46°F (2° to 8°C), with a preferred temperature of 40°F. Do not freeze or expose this vaccine to freezing temperatures.

Live, Attenuated Influenza Vaccine (LAIV) must be maintained in a continuously frozen state at 5°F (-15°C) or colder. No freeze/thaw cycles are permitted with this vaccine. It may be stored in either a manual defrost freezer or in a frost-free freezer compartment. More detailed information concerning storing and administering this vaccine can be found in the Recommendations for the Handling and Storage of Selected Biologicals (CDC, 2005), available at: http://www.cdc.gov/nip/publications/vac_mgt_book.pdf.

ORDERING INSTRUCTIONS

The enclosed copy of the new **VFC Influenza Vaccine Order Form**, DHS 8501 F (9/06), **must** be used when placing influenza vaccine orders. The order form includes a variety of different products available for the 2006-2007 influenza season. Please retain a copy of submitted order for your records to assist you in placing future orders. You may fax your completed influenza vaccine order to 1-877-329-9832 (877-FAXX-VFC). In order to avoid unnecessary delays in the processing of your influenza vaccine order, please make sure to follow these steps:

- a. Submit your influenza order utilizing the new VFC Influenza Vaccine Order Form, DHS 8501 F (9/06). **Please do not utilize any other VFC order form to place your vaccine order.** This year's product availability differs from previous seasons and the new form includes additional products that were not listed in previous year's order forms.
- b. If you have placed an influenza vaccine order prior to September 6, please re-submit your order utilizing the new form. These orders will be placed in a "Back Order" listing in the order received. The VFC Program will begin shipments of vaccine as soon as inventories of influenza vaccine are received.
- b. When placing your order, request sufficient influenza vaccine to vaccinate healthy VFC-eligible children 6 to 59 months of age in your practice, as well as high-risk children 5 to 18 years of age. Please note that Influenza vaccine orders will be approved according to your practice's profile estimates and estimate of the proportion of children you will vaccinate.
- c. **You may reorder influenza vaccine as needed throughout the 2006-2007 Flu season.** The VFC Program will continue to ship vaccines as long as our inventory and national supplies last. Unlike all other pediatric vaccines, influenza vaccine supplemental orders may be submitted at any time. You do not have to wait two months in between orders.

If necessary, the VFC Program may adjust the number of doses sent due to demand or limitations on supply.

BILLING NOTES

Medi-Cal: To bill Medi-Cal for vaccines and administration of influenza vaccines, use only CPT-4 codes 90657, 90658, 90659, and 90660 (LAIV). In addition, the **-SK (high risk) modifier** must be used for all influenza vaccines, including LAIV; document your patients high priority category in the patient's medical record (not on the claim form). If VFC vaccine is used, the provider will only be reimbursed for the administration fee. Medi-Cal Program providers who are unable to obtain influenza vaccine from the VFC Program for their Medi-Cal beneficiaries should purchase it privately and bill Medi-Cal using the appropriate CPT-4 codes.

CHDP:

The CHDP program will reimburse for influenza vaccine and its administration.

- If influenza vaccine is provided by the VFC Program use code "53".
- If influenza vaccine is purchased because the vaccine is not available through VFC use code "54".
- The provider must indicate "high risk factor" in the "Comments/Problems" box for code numbers 53 and 54 when used for influenza vaccine administered.
- If Live Attenuated Influenza Vaccine (LAIV), intranasally administered is provided by the VFC Program use code "71".

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- Code 71 is payable for ages five years through eighteen years, eleven months, administration fee only.
- The provider must indicate "For Household Members of Persons with High Risk Factor" in the "Comments/Problems" box for code number 71 when used for influenza vaccine administered.

RETURN OF UNUSED VIALS OF INFLUENZA VACCINE

All VFC Providers must return all expired or spoiled influenza vaccine (including vials, syringes, and nasal sprayer packages) to General Injectables & Vaccines, Inc. (GIV). Return these vaccines to: **General Injectables & Vaccines, Inc. (GIV), Route 21-52, Bastian, VA 24314.**

VIS STATEMENTS

Copies of the current interim Vaccine Information Statement (VIS) for the Inactivated Influenza Vaccine and the Live, Attenuated Influenza Vaccine (LAIV), dated 06/30/06, are included in this mailing and are also at <http://www.cdc.gov/nip/publications/VIS/default.htm>. Federal regulation requires that you provide the VIS to a parent or guardian before the child receives influenza vaccine.

HELPFUL RESOURCES

To help you remind parents about new pediatric flu shots recommendations, we are enclosing two copies of the "**Guess Who Needs a Flu Shot**" (IMM-782) self-adhering cling-on flyer. This piece is suitable for posting in a medical office waiting room or patient exam room and requires no tape or thumb tacks. In addition, a sample "**Guess Who Needs a Flu Shot**" (IMM-781) reminder postcard is enclosed. To order additional copies of these materials, VFC providers should contact their local health department. Listings are at <http://www.dhs.ca.gov/ps/dcdc/izgroup/pdf/lhdlist.pdf>

QUESTIONS?

If you have any questions, please call your VFC Field Representative or the VFC Program at: 877-243-8832 (877-2GET-VFC).

Enclosures - Inactivated Influenza Vaccine Information Statement (6/30/06)
Live Intranasal Influenza Vaccine Information Statement (6/30/06)
VFC Vaccine Order Form, DHS 8501 F (8/06)
"Guess Who Needs a Flu Shot" postcard (IMM-781)
"Guess Who Needs a Flu Shot" cling-on flyers (IMM-782)

cc: DHS Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators
Local Health Department CHDP Program Directors
Vanessa Baird, Chief, Medi-Cal Managed Care Division, CDHS
Marian Dalsey, M.D., Chief, Children Medical Services Branch, CDHS
Michael Farber, M.D., Chief Medical Officer, Medi-Cal Managed Care, CDHS
Susann Steinberg, M.D., Chief, Maternal, Child and Adolescent Health/Office of

Family Planning Branches, CDHS

Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB

Marcia Ehinger, M.D., Medi-Cal Benefits Branch, CDHS

Kathy Chance, M.D., Children Medical Services Branch, CDHS

VACCINES FOR CHILDREN (VFC) PROGRAM INFLUENZA VACCINES ORDER FORM

FAX (877) 329-9832

DATE	VFC PIN NUMBER
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NAME OF PHYSICIAN'S OFFICE, PRACTICE, CLINIC, ETC.	CONTACT PERSON
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DELIVERY ADDRESS (Number and Street—No P.O. Boxes)	<input type="checkbox"/> CHECK HERE IF THIS IS A NEW ADDRESS.	CITY	ZIP CODE
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TELEPHONE	FAX	EMAIL	COUNTY
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DELIVERY: Please specify all days and times you may receive vaccine.

DAY AND TIME <input type="checkbox"/> Tue. _____	DAY AND TIME <input type="checkbox"/> Wed. _____	STORAGE CAPACITY (check all that apply) <input type="checkbox"/> Dorm Style Under the Counter Refrigerator <input type="checkbox"/> Refrigerator/Freezer Combination <input type="checkbox"/> Stand alone freezer <input type="checkbox"/> Commercial/Laboratory Grade Unit
DAY AND TIME <input type="checkbox"/> Thu. _____	DAY AND TIME <input type="checkbox"/> Fri. _____	

1. Product Selection VFC INFLUENZA VACCINES (USE REGULAR PEDIATRIC ORDER FORM FOR ALL OTHER AVAILABLE VFC VACCINES)	2. Product Presentation Vaccines are Shipped in the following presentations	3. Usage and Inventory Information			4. New Vaccine Order (Minimum 10 doses) Order in multiple of 10 doses
		INFORMATION IN THIS SECTION IS REQUIRED FOR ALL VFC VACCINES, EVEN WHEN ONLY ORDERING ONE PRODUCT. INCOMPLETE ORDERS WILL NOT BE PROCESSED.			
		VACCINE INVENTORY (DOSES ON HAND)			
		Number of VFC Doses Used Since Last Order. Enter "0" if None	Number of Doses (VFC Only) On-Hand	Lot Number	Expiration Date

AVAILABLE THROUGHOUT FLU SEASON AS SUPPLY PERMITS

Fluzone® 0.25 mL Pediatric Dose Preservative- Free (Age 6–35 months)	10 pack- single dose pre-filled syringes						doses
Fluzone® 0.5 mL No Preservative (Age 36 mos-18 yrs)	10 pack- Single dose vials						doses
	10 pack - single dose pre-filled syringes						
Fluzone® 0.5 mL With Preservative (Age 36 mos–18 yrs)	10 dose vials						doses
Fluvirin® 0.5 mL With Preservative (Ages 4–18 yrs)	10 dose vials						doses
FluMist® (Live Attenuated Intranasal Vaccine, LAIV) (Healthy Children Ages 5–18 yrs) MUST BE STORED FROZEN	10 pack- Single dose sprayers						Minimum Order 20 Doses (increments of 10) doses

STATE USE ONLY

ASSIGNED		ASSIGNED	
APPROVED		ENTERED	



See reverse side for instructions on completing this order form.



Instructions for the Completion of the VFC Influenza Vaccines Order Form

In order to ensure that your influenza vaccine order is processed as quickly as possible, the VFC Influenza Vaccine Order form **must** be completely filled out. Fill in all blank sections of the form. Orders submitted in outdated forms may delay the processing of your vaccine order.

Instructions:

1. Enter the California VFC Program PIN number assigned to your site.

The PIN number is the six-digit Provider Identification Number assigned to your clinic upon enrolling in the VFC Program. (This is not your medical license or CHDP/Medi-Cal provider numbers). Your PIN can be found in the upper, right portion of one of your VFC shipping invoices under the title, "FOR RETURNS REFER TO." You may also contact the VFC Office to obtain your PIN #.

2. Use the same facility name that is on record with the VFC Program.

The facility name can be found on the packing slips that accompany the vaccine shipments. Do not change this VFC facility name without first notifying the VFC Program in writing, even if the clinic name has changed or is incorrect.

3. Specify the current address where the VFC Program should deliver vaccines to your site.

Check the appropriate box on the order form if this is a new address. (Remember to include a letter regarding the change of address with your vaccine order.)

4. Specify the current and correct days and times during which you can receive delivery of VFC vaccine.

The VFC Program's wholesale distributor delivers vaccine Tuesday through Friday only. When specifying delivery times, take into account times of the day during which you cannot receive deliveries of VFC vaccine (e.g., lunch).

5. Check the appropriate box that best describe your refrigerator unit (s).

6. Select your desired products.

7. Record usage of all VFC influenza vaccines you have administered since your last vaccine order.

For your **initial** order during the 2006 -2007 Flu season, enter -0- in the "Usage" section. Please do not record usage of vaccines administered during the previous flu season. Subsequent influenza vaccine orders must include the number of doses administered since your previous order. This information is easily obtained from a usage log or any other usage report (e.g., Registry-generated usage report).

8. List current Influenza vaccine inventory of all Influenza VFC vaccines when completing the order form.

For your **initial** order during the 2006 -2007 Flu season, enter -0- in the "Inventory" section. Subsequent influenza vaccine orders must include a listing of vaccines remaining in your inventory since your previous order, and their corresponding lot numbers, and expiration dates.

9. All VFC expired or spoiled flu products must be returned to the VFC Program contracted vaccine distributor, General Injectables & Vaccines, Inc. (GIV) to Route 21 & 52 Bastian, VA 24314, in order to obtain the Federal Excise Tax credit.

When Completed: FAX to: (877) 329-9832 (toll-free)

OR

Mail to: Vaccines for Children Program
State of California Department of Health Services,
Immunization Branch
850 Marina Bay Parkway, Building P
Richmond, CA 94804

Always keep a copy for your records!

For Questions Call: (877) 243-8832

OR

Contact your local VFC Representative

INACTIVATED INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2006-07

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the **influenza virus**, which spreads from person to person through coughing or sneezing.

Other illnesses have the same symptoms and are often mistaken for influenza. But only the influenza virus can cause influenza.

Anyone can get influenza. For most people, it lasts only a few days. It can cause:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Some people get much sicker. Influenza can lead to pneumonia and can be dangerous for people with heart or breathing conditions. It can cause high fever and seizures in children. Influenza kills about 36,000 people each year in the United States, mostly among the elderly.

Influenza vaccine can prevent influenza.

2 Inactivated Influenza vaccine

There are two types of influenza vaccine:

An **inactivated** (killed) vaccine, or “flu shot,” has been used in the United States for many years. It is given by injection.

A **live**, weakened vaccine was licensed in 2003. It is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are always changing. Therefore, influenza vaccines are updated every year, and an annual vaccination is recommended.

For most people influenza vaccine prevents serious influenza-related illness. It will *not* prevent “influenza-like” illnesses caused by other viruses.

It takes about 2 weeks for protection to develop after the vaccination, and protection can last up to a year.

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

Some inactivated influenza vaccine contains thimerosal, a preservative that contains mercury. Some people believe thimerosal may be related to developmental problems in children. In 2004 the Institute of Medicine published a report concluding that, based on scientific studies, there is no evidence of such a relationship. If you are concerned about thimerosal, ask your doctor about thimerosal-free influenza vaccine.

3 Who should get inactivated influenza vaccine?

Inactivated influenza vaccine can be given to people 6 months of age and older. It is recommended for **people who are at risk of complications from influenza**, and for **people who can spread influenza to those at high risk** (including all household members):

People at high risk for complications from influenza:

- People **65 years of age and older**.
- Residents of **long-term care facilities** housing persons with chronic medical conditions.
- People who have **long-term health problems** with:
 - heart disease
 - kidney disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- People with certain **muscle or nerve disorders** (such as seizure disorders or severe cerebral palsy) that can lead to breathing or swallowing problems.
- People 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
- People 6 months to 18 years of age on **long-term aspirin treatment** (these people could develop Reye Syndrome if they got influenza).
- Women who will be **pregnant** during influenza season.
- **All children** 6-59 months of age.

People who can spread influenza to those at high risk:

- **Household contacts and out-of-home caretakers** of children from 0-59 months of age.
- Physicians, nurses, family members, or anyone else in **close contact with people at risk** of serious influenza.

Influenza vaccine is also recommended for adults 50-64 years of age and anyone else who wants to **reduce their chance of getting influenza**.

A yearly influenza vaccination should be *considered* for:

- People who provide **essential community services**.
- People living in **dormitories** 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?

The best time to get influenza vaccine is in **October** or **November**.

Influenza season usually peaks in February, but it can peak any time from November through May. So getting the vaccine in December, or even later, can be beneficial in most years.

Some people should get their flu shot in **October** or earlier:

- people **50 years of age and older**,
- younger people at **high risk** from influenza and its complications (including **children 6 through 59 months of age**),
- **household contacts** of people at high risk,
- **health care workers**, and
- **children younger than 9 years of age** getting influenza vaccine for the first time.

Most people need one flu shot each year. **Children younger than 9 years of age getting influenza vaccine for the first time** should get 2 doses, given at least one month apart.

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
- 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 within a few minutes to a few hours after the shot.
- In 1976, a certain 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 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.

8

The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details 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 immunization 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)**
 - Visit CDC's website at www.cdc.gov/flu



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2006-07

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which spreads from infected persons to the nose or throat of others.

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 get much sicker. Influenza can lead to pneumonia and can be dangerous for people with heart or breathing conditions. It can cause high fever and seizures in children. Influenza kills about 36,000 people each year in the United States.

Influenza vaccine can prevent influenza.

2 Live, attenuated influenza vaccine (nasal spray)

There are two types of influenza vaccine:

Live, attenuated influenza vaccine (LAIV) was licensed in 2003. LAIV contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils rather than injected into the muscle. It is recommended for healthy children and adults from 5 through 49 years of age, who are not pregnant.

Inactivated influenza vaccine, sometimes called the “flu shot,” has been used for many years and is given by injection. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are constantly changing. Therefore, influenza vaccines are updated every year, and annual vaccination is recommended.

For most people influenza vaccine prevents serious influenza-related illness. It will *not* prevent “influenza-like” illnesses caused by other viruses.

It takes about 2 weeks for protection to develop after vaccination, and protection can last up to a year.

3 Who can get LAIV?

Live, intranasal influenza vaccine is approved for **healthy children and adults from 5 through 49 years of age**, including those who can spread influenza to people at high risk, such as:

- **Household contacts and out-of-home caretakers** of children from 0-59 months of age.
- Physicians and nurses, and family members or any one else in **close contact with people at risk** of serious influenza.

Influenza vaccine is also recommended for anyone else who wants to **reduce their chance of getting influenza.**

LAIV may be considered for:

- People who provide **essential community services.**
- People living in **dormitories** or under other crowded conditions, to prevent outbreaks.

4 Who should *not* get LAIV?

LAIV is not licensed for everyone. The following people should check with their health-care provider about getting the **inactivated** vaccine (flu shot).

- **Adults 50 years of age or older** or **children younger than 5.**
- People who have **long-term health problems** with:
 - heart disease
 - kidney disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- People with a **weakened immune system.**
- Children or adolescents on **long-term aspirin treatment.**
- **Pregnant women.**
- Anyone with a history of **Guillain-Barré syndrome** (a severe paralytic illness, also called GBS).

Inactivated influenza vaccine (the flu shot) is the preferred vaccine for people (including health-care workers, and family members) coming in **close contact with anyone who has a severely weakened immune system** (that is, anyone who requires care in a protected environment).

Some people should talk with a doctor before getting *either* influenza vaccine:

- Anyone who has ever had a serious allergic reaction to **eggs** or to a **previous dose** of influenza vaccine.
- 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?

The best time to get influenza vaccine is in **October** or **November**, but LAIV may be given as soon as it is available. Influenza season usually peaks in February, but it can peak any time from November through May. So getting the vaccine in December, or even later, can 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** should get 2 doses. For LAIV, these doses should be given 6-10 weeks apart.

LAIV 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. However, 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 5-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- headache and muscle aches
- fever
- 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

These symptoms did not last long and went away on their own. Although they can occur after vaccination, they may not have been caused by the vaccine.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is within a few minutes to a few hours after the vaccination.

- If rare reactions occur with any new product, they may not be identified until thousands, or millions, of people have used it. Over four million 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.

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 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 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

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details 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 immunization 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)**
 - Visit CDC's website at www.cdc.gov/flu



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES**

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Vaccines for Children (VFC) Program

Approved Influenza Vaccine Products Available During the 2006-2007 Influenza Season

Vaccine	Manufacturer	Product Name	Thimerosal Free*	Formulation	Age Indication	VFC Age Eligibility	Number of Doses	
Inactivated, Trivalent Vaccine (TIV)	sanofi Pasteur	Fluzone® Pediatric Dose Preservative- Free	Yes	10 pack - single dose, 0.25 mL, pre-filled syringe	6–35 months	6–35 months	1 or 2 doses ¹ (recommended dosage 0.25 mL)	
		Fluzone® No Preservative	Yes	10 pack- single dose, 0.5 mL, pre-filled syringe	> 36 months	3– 18 years	1 or 2 doses ¹ (recommended dosage 0.50 mL)	
				10 pack - single dose, 0.5 mL, vials	> 36 months			
		Fluzone®	No	10 dose vial	>6 months			
	Novartis Vaccine (formerly Chiron Corporation)	Fluvirin™	No	10 dose vial	> 4 years			4 – 18 years
MedImmune Vaccines, Inc	FluMist™ (Live Attenuated Intranasal Vaccine, LAIV)	Yes	10 pack- Single dose² intranasal sprayer	Healthy children 5-18 years	5–18 years			1 or 2 doses ¹ (recommended dosage 0.50 mL)

¹Two doses administered > 1 month apart are recommended for children 6 mos-9 years receiving influenza vaccine for the first time. If the child received 1 dose last season, then only 1 dose should be administered this season.

² One dose equals 0.5mL divided equally between each nostril.

³Two doses administered at least 6 weeks apart are recommended for children 5 to 9 years of age receiving influenza vaccine for the first time. If the child received 1 dose last season, then only 1 dose should be administered this season.

* Effective July 1, 2006, pregnant women or children younger than three years old may only receive vaccine doses that contain trace levels (< 0.5 micrograms per 0.5 milliliter dose) or no mercury [Health and Safety (H&S) Code Section 124172, Chapter 837, Statutes of 2004 (AB 2943, Pavley)].