

Dated: August 3, 2010.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Vaccine Information Materials for Influenza Vaccine

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with Comment Period.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa-26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on proposed new vaccine information materials for trivalent influenza vaccines. In addition, to ensure that influenza vaccine information materials are available at the beginning of the upcoming influenza vaccination season, the proposed materials included in this notice are also considered interim vaccine information materials covering influenza vaccines for use pending issuance of final influenza materials following completion of the formal NCVIA development process.

DATES: Written comments are invited and must be received on or before October 12, 2010.

ADDRESSES: Written comments should be addressed to Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

FOR FURTHER INFORMATION CONTACT: Skip Wolfe, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E-52, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-8809.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine

information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: hepatitis B, *haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and trivalent influenza vaccines. Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC Web site at: <http://www.cdc.gov/vaccines/pubs/VIS/>. In addition, single camera-ready copies may be available from State health departments.

Proposed Influenza Vaccine Information Materials

The Advisory Committee on Immunization Practices (ACIP)

recommendations for use of trivalent influenza have changed only slightly since the previous Vaccine Information Statements were published. For the 2010-2011 influenza season, 2009 H1N1 influenza vaccine is being incorporated into the seasonal vaccine formulation.

Development of Vaccine Information Materials

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

In addition, we invite written comment on the proposed vaccine information materials that follow, entitled "Inactivated Influenza Vaccine: What You Need to Know" and "Live Intranasal Influenza Vaccine: What You Need to Know." Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their mandatory use. We also propose to revise the June 9, 2010 Instructions for the Use of Vaccine Information Statements to update references to these vaccine information materials.

Influenza Vaccine Information Materials—Additional Considerations

CDC has traditionally issued a new Vaccine Information Statement annually for influenza vaccines since the formulation of antigens contained in the vaccine is specific for each year. However, known benefits and risks for each year's influenza vaccine are generally the same. In such cases, the only revision to the influenza VIS is the notation of the flu season for which the VIS has been issued (e.g., 2009-10). Therefore, we propose that when the VIS for a particular influenza season is identical to the previous year's edition, except for the date notation and any reference to the influenza strain content of that year's vaccine (if the safety profile is expected to be comparable to that of previous years' influenza vaccines), CDC will no longer publish a **Federal Register** notice seeking comment on such edition. Instead, each new year's edition of the influenza VIS will be published on the CDC Web site at: <http://www.cdc.gov/vaccines/publications/VIS/>. In addition, the Instructions for the Use of Vaccine Information Statements will be updated at that time to note new edition dates for influenza Vaccine Information Statements. New edition influenza Vaccine Information Statements for the upcoming flu season will generally be

available on the CDC Web site by [insert month] of each year.

Whenever substantive revisions are going to be made to an influenza VIS, the full development process, including consultation and publication of a **Federal Register** notice with opportunity for comment, will be utilized.

We invite comment on this proposed method of issuing revised influenza Vaccine Information Statements in the future.

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As noted above, the vaccine information materials which follow will serve as interim influenza Vaccine Information Statements for use when administering any 2010–11 influenza vaccine until final materials are effective and available for distribution.

* * * * *

Proposed (and Interim) Influenza Vaccine Information Statements:

Inactivated Influenza Vaccine: What You Need to Know 2010–2011

Vaccine Information Statements are available in Spanish and many other languages. See 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.

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, such as infants, elderly, and those with certain health conditions, 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 seasonal influenza and even more require hospitalization. Influenza vaccine can prevent influenza.

2. 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 provider.

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

Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. When there is a close match the vaccine protects most people from serious influenza-related illness. But even when there is not a close match, the vaccine provides some protection. The 2010–2011 vaccine provides protection against H1N1 (pandemic) influenza, which is expected to be one of the viruses causing influenza this season. Influenza vaccine will not prevent “influenza-like” illnesses caused by other viruses.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts up to a year. Some inactivated influenza vaccine contains a preservative called thimerosal. Some people have suggested that thimerosal may be related to autism in children. In 2004 the Institute of Medicine reviewed many studies looking into this theory and concluded that there is no evidence of such a relationship. Thimerosal-free influenza vaccine is available.

3. Who should get inactivated influenza vaccine and when?

Who

- All people 6 months of age and older.

People who got the 2009 H1N1 vaccine still need to get vaccinated with the 2010–2011 influenza vaccine.

When

You can get the vaccine as soon as it is available, usually in the fall, and for as long as illness is occurring in your community. Influenza can occur any time, but most influenza occurs from November through May. In most seasons, most infections occur 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 2 doses to be protected. Ask your provider.

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. 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 ever had a severe reaction after a 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.

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 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. People 65 and older who get the high-dose vaccine may be more likely to experience some of these problems.

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 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.

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 provider 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 <http://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.

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 Web site at www.hrsa.gov/vaccinecompensation.

8. How can I learn more?

- Ask your 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 Web site at www.cdc.gov/flu.

Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, Inactivated Influenza Vaccine, (00/00/0000) (Proposed), 42 U.S.C. 300aa-26.

Live, Intranasal Influenza Vaccine: What You Need To Know 2010–2011

Vaccine Information Statements are available in Spanish and many other languages.

See <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.

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, such as infants, elderly, and those with certain health conditions, 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 seasonal influenza and even more require hospitalization. Influenza vaccine can prevent influenza.

2. Live, Intranasal 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 influenza vaccine, or the "flu shot," is given by injection. *Inactivated influenza vaccine is described in a separate Vaccine Information Statement.*

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

Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. When there is a close match the vaccine protects most people from serious influenza-related illness. But even when there is not a close match, the vaccine provides some protection. The 2010–2011 vaccine provides protection against H1N1 (pandemic) influenza, which is expected to be one of the viruses causing influenza this season. Influenza vaccine will not prevent "influenza-like" illnesses caused by other viruses.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts up to a year. LAIV does not contain thimerosal or other preservatives.

3. Who can receive LAIV?

LAIV is recommended for healthy people from 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 vaccine still need to get vaccinated with the 2010–2011 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 between 6 months and 2 years of age. (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 with asthma or one or more episodes of wheezing within the past year.

- 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.

- Pregnant women.

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.

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.

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

- Anyone who has ever had a serious allergic reaction to eggs or another vaccine component, or to a previous dose of influenza vaccine. *Tell your doctor if you have any severe allergies.*

- 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?

You can get the vaccine as soon as it is available, usually in the fall, and for as long as illness is occurring in your community. Influenza can occur any time, but most influenza occurs from November through May. In most seasons, most infections occur 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 2 doses to be protected. Ask your 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 mild reactions, including:

- 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 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 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 provider 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.

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9. How can I learn more?

- Ask your 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

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Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, Live, Attenuated Influenza Vaccine, (00/00/0000) (Proposed) 42 U.S.C. 300aa–26.

Dated: August 3, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Vaccine Information Materials for Measles, Mumps, Rubella, and Varicella Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa–26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on proposed new vaccine information materials for measles, mumps rubella (MMR); varicella, and measles, mumps, rubella; and varicella (MMRV).

DATES: Written comments are invited and must be received on or before October 12, 2010.

ADDRESSES: Written comments should be addressed to Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E–05, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

FOR FURTHER INFORMATION CONTACT: Skip Wolfe, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E–52, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–8809.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub L. 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment