

all, and almost all of them will be protected from severe rotavirus diarrhea.

Babies who get the vaccine are also much less likely to be hospitalized or to see a doctor because of rotavirus diarrhea.

A virus (or parts of the virus) called porcine circovirus is in both rotavirus vaccines. This virus is not known to infect people and there is no known safety risk. For more information, see <http://www.fda.gov>, and search for "porcine circovirus."

### 3. Who should get rotavirus vaccine and when?

There are two brands of rotavirus vaccine. A baby should get either 2 or 3 doses, depending on which brand is used.

The doses are recommended at these ages:

First Dose: 2 months of age

Second Dose: 4 months of age

Third Dose: 6 months of age (if needed)

The first dose may be given as early as 6 weeks of age, and should be given by age 14 weeks 6 days. The last dose should be given by 8 months of age.

Rotavirus vaccine may be given at the same time as other childhood vaccines.

### 4. Some Babies Should Not Get Rotavirus Vaccine or Should Wait

- A baby who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe (life threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.

- Babies with "severe combined immunodeficiency" (SCID) should not get rotavirus vaccine.

- Babies who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes babies who have moderate or severe diarrhea or vomiting. Ask your doctor or nurse. Babies with mild illnesses should usually get the vaccine.

- Check with your doctor if your baby's immune system is weakened because of:

- HIV/AIDS, or any other disease that affects the immune system

- Treatment with drugs such as long-term steroids

- Cancer, or cancer treatment with x-rays or drugs

In the late 1990s a different type of rotavirus vaccine was used. This vaccine was found to be associated with

an uncommon type of bowel obstruction called "intussusception," and it was taken off the market.

The new rotavirus vaccines have not been associated with intussusception.

However, babies who have had intussusception, from any cause, are at higher risk for getting it again. If your baby has ever had intussusception, discuss this with your doctor.

### 5. What are the risks from rotavirus vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of any vaccine causing serious harm, or death, is extremely small.

Most babies who get rotavirus vaccine do not have any problems with it.

- Babies might become irritable, or have mild, temporary diarrhea or vomiting after a dose of rotavirus vaccine.

- Rotavirus vaccine does not appear to cause any serious side effects.

### 6. What if there is a moderate or 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 <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 <http://www.hrsa.gov/vaccinecompensation>.

### 8. How can I learn more?

- Your provider 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 <http://www.cdc.gov/vaccines>.

Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, Rotavirus 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.*

[FR Doc. 2010-19782 Filed 8-10-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Proposed Vaccine Information Materials for Pneumococcal Conjugate Vaccine and Human Papillomavirus 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 pneumococcal conjugate vaccine and human papillomavirus vaccines.

**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 HHS 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. A list of State health department contacts for obtaining copies of these materials is included in a December 17, 1999 **Federal Register** notice (64 FR 70914).

#### **Proposed Pneumococcal Conjugate Vaccine (13-Valent) Information Materials**

##### *Proposed Human Papillomavirus Vaccine Information Materials*

With the February 1, 2007 addition of human papillomavirus vaccine to the National Vaccine Injury Compensation Program, updating of ACIP's HPV recommendations in December 2009, and the licensure of 13-valent pneumococcal conjugate vaccine in April 2010, CDC, as required under 42 U.S.C. 300aa-26, is proposing vaccine information materials covering those vaccines, which are included in this notice. Interim materials have been available for use pending completion of the formal development process.

#### **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 "Human Papillomavirus (HPV) Vaccine: What You Need to Know (Gardasil®)," "Human Papillomavirus (HPV) Vaccine: What You Need to Know (Cervarix®)," and "Pneumococcal Conjugate 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.

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#### **Proposed Pneumococcal Conjugate Vaccine Information Statement**

##### *Pneumococcal Conjugate Vaccine: What You Need to Know*

#### 1. Pneumococcal Disease

Infection with *Streptococcus pneumoniae* bacteria can make children very sick.

It causes blood infections, pneumonia, and meningitis, mostly in young children. (Meningitis is an infection of the covering of the brain.) Although pneumococcal meningitis is relatively rare (less than 1 case per 100,000 people each year) it is fatal in about 1 of 10 cases in children.

Pneumococcal meningitis can also lead to other health problems, including deafness and brain damage.

Before routine use of pneumococcal conjugate vaccine, pneumococcal infections caused:

- Over 700 cases of meningitis,
- 13,000 blood infections,
- About 5 million ear infections, and
- About 200 deaths

annually in the United States in children under five.

Children younger than 2 years of age are at higher risk for serious disease than older children.

Pneumococcal bacteria are spread from person to person through close contact.

Pneumococcal infections may be hard to treat because some strains of the bacteria have become resistant to the drugs that are used to treat them. This makes prevention of pneumococcal infections through vaccination even more important.

#### 2. Pneumococcal Conjugate Vaccine (PCV13)

There are more than 90 types of pneumococcal bacteria. The new pneumococcal conjugate vaccine (PCV13) protects against 13 of them. These bacteria types are responsible for most severe pneumococcal infections among children. PCV13 replaces a previous conjugate vaccine (PCV7), which protected against 7 pneumococcal types and has been in use since 2000. During that time severe pneumococcal disease has dropped by nearly 80% among children under 5.

PCV13 can also prevent some cases of pneumonia and some ear infections. But pneumonia and ear infections have many causes, and PCV13 only works against the types of pneumococcal bacteria targeted by the vaccine.

PCV is given to infants and toddlers, to protect them when they are at greatest risk for serious diseases caused by pneumococcal bacteria.

In addition to receiving PCV13, older children with certain chronic illnesses may get a different vaccine called PPSV23. There is a separate Vaccine Information Statement for that vaccine.

### 3. Who should get PCV13 vaccine and when?

#### Infants and Children Under 2 Years of Age

PCV13 is recommended as a series of 4 doses, one dose at each of these ages:

- 2 months.
- 4 months.
- 6 months.
- 12 through 15 months.

Children who miss their shots at these ages should still get the vaccine. The number of doses and the intervals between doses will depend on the child's age. Ask your health care provider for details.

Children who have begun their immunization series with PCV7 should complete the series with PCV13.

#### Older Children and Adolescents

- Healthy children between their 2nd and 5th birthdays who have not completed the PCV7 or PCV13 series before age 2 years should get 1 dose.

- Children between the 2nd and 6th birthdays with medical conditions such as:

- Sickle cell disease,
- A damaged spleen or no spleen,
- Cochlear implants,
- Diabetes,
- HIV/AIDS or other diseases that affect the immune system (such as diabetes, cancer, or liver disease), or
- Chronic heart or lung disease or who take medications that affect the immune system, such as immunosuppressive drugs or steroids, should get 1 dose of PCV13 (if they received 3 doses of PCV7 or PCV13 before age 2 years), or 2 doses of PCV13 (if they have received 2 or fewer doses of PCV7 or PCV13).

A dose of PCV13 may be administered to children and adolescents 6 through 18 years of age who have certain medical conditions, even if they have previously received PCV7 or PPSV23.

Children who have completed the 4-dose series with PCV7: Healthy children who have not yet turned 5, and children with medical conditions who have not yet turned 6, should get one additional dose of PCV13.

Ask your health care provider if you have any questions about any of these recommendations.

PCV13 may be given at the same time as other vaccines.

### 4. Some Children Should Not Get PCV13 or Should Wait

Children should not get PCV13 if they had a serious (life-threatening) allergic reaction to a previous dose of this vaccine, to PCV7, or to any vaccine containing diphtheria toxoid (for example DTaP).

Children who are known to have a severe allergy to any component of PCV7 or PCV13 should not get PCV13. Tell your health care provider if your child has any severe allergies.

Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting the vaccine.

### 5. What are the risks from PCV13?

Any medicine, including a vaccine, could possibly cause a serious problem, such as a severe allergic reaction. However, the risk of any vaccine causing serious harm, or death, is extremely small.

In studies, most reactions after PCV13 were mild. They were similar to reactions reported after PCV7, which has been in use since 2000. Reported reactions varied by dose and age, but on average:

- About half of children were drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a higher fever (over 102.2°F).
- Up to about 8 out of 10 became fussy or irritable.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the 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 may file a claim with VICP by calling 1-800-338-2382 or visiting their Web site at <http://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 <http://www.cdc.gov/vaccines>.

Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, PCV13, (00/00/0000) (Proposed), 42 U.S.C. 300aa-26.

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### Proposed Human Papillomavirus Vaccine Information Statement (Gardasil)

*HPV (Human Papillomavirus Virus) Vaccine (Gardasil®): What You Need to Know*

#### 1. What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause cervical cancer in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 10,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women and other types of cancer in both men and women. It can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

## 2. HPV Vaccine—Why get vaccinated?

HPV vaccine is important because it can prevent most cases of cervical cancer in females, if it is given before a person is exposed to the virus.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

The vaccine you are getting is one of two vaccines that can be given to prevent HPV. It may be given to both males and females. In addition to preventing cervical cancer, it can also prevent vaginal and vulvar cancer in females, and genital warts in both males and females.

The other vaccine is given to females only, and only for prevention of cervical cancer.

## 3. Who should get this HPV vaccine and when?

### Females: Routine Vaccination

- HPV vaccine is recommended for girls 11 or 12 years of age. It may be given to girls starting at age 9.

### Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine before their first sexual contact—because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

### Females: Catch-Up Vaccination

- The vaccine is also recommended for girls and women 13 through 26 years of age who did not get all 3 doses when they were younger.

### Males

Males 9 through 26 years of age may get HPV vaccine to prevent genital warts. As with females, it is best to be vaccinated before the first sexual contact.

HPV vaccine is given as a 3-dose series

1st Dose: Now

2nd Dose: 1 to 2 months after Dose 1

3rd Dose: 6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

## 4. Some People Should Not Get HPV Vaccine or Should Wait

- Anyone who has ever had a life-threatening allergic reaction to any

component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.

- HPV vaccine is not recommended for pregnant women. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

- Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's HPV in pregnancy registry at 800-986-8999. This will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a moderate or severe illness should wait until they are better.

## 5. What are the risks from this vaccine?

This HPV vaccine has been used in the U.S. and around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

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

Several mild to moderate problems are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:

- Pain (about 8 people in 10).

- Redness or swelling (about 1 person in 4).

- Fever:

- Mild (100 °F) (about 1 person in 10).

- Moderate (102 °F) (about 1 person in 65).

- Other problems:

- Headache (about 1 person in 3).

- Fainting:

- Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after vaccination can help prevent fainting and injuries caused by falls. Tell your provider if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

## 6. What if there is a severe reaction?

What should I look for?

Serious allergic reactions including rash; swelling of the hands and feet, face, or lips; and breathing difficulty.

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 may file a claim with VICP by calling 1-800-338-2382 or visiting their Web site at <http://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 <http://www.cdc.gov/std/hpv> and <http://www.cdc.gov/vaccines>.

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

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## Proposed Human Papillomavirus Vaccine Information Statement (Cervarix)

*HPV (Human Papillomavirus Virus) Vaccine (Cervarix®): What You Need to Know*

### 1. What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause cervical cancer in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 10,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women and other types of cancer in both men and women. It can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

## 2. HPV Vaccine—Why get vaccinated?

HPV vaccine is important because it can prevent most cases of cervical cancer in females, if it is given before a person is exposed to the virus.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

The vaccine you are getting is one of two vaccines that can be given to prevent HPV. It is given to females only.

The other vaccine may be given to both males and females, and can also prevent some vaginal and vulvar cancers, and genital warts.

## 3. Who should get this HPV vaccine (Cervarix) and when?

### Routine Vaccination

- HPV vaccine is recommended for girls 11 or 12 years of age. It may be given to girls starting at age 9.

### Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine before their first sexual contact—because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

### Catch-Up Vaccination

- The vaccine is also recommended for girls and women 13 through 26 years of age who did not get all 3 doses when they were younger.

HPV vaccine is given as a 3-dose series:

1st Dose: Now

2nd Dose: 1 to 2 months after Dose 1

3rd Dose: 6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

## 4. Some People Should Not Get HPV Vaccine or Should Wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to latex.

- HPV vaccine is not recommended for pregnant women. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's HPV in pregnancy registry at 888-452-9622. This will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a moderate or severe illness should wait until they are better.

## 5. What are the risks from this vaccine?

This HPV vaccine has been in use around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

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

Several mild to moderate problems are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions where the shot was given:
  - Pain (about 9 people in 10).
  - Redness or swelling (about 1 person in 2).
  - Other mild reactions:
    - Fever of 99.5 °F or higher (about 1 person in 8).
    - Headache or fatigue (about 1 person in 2).
    - Nausea, vomiting, diarrhea, or abdominal pain (about 1 person in 4).
    - Muscle or joint pain (up to 1 person in 2).
    - Fainting:
      - Brief fainting spells and related symptoms (such as jerking

movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls. Tell your provider if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

## 6. What if there is a severe reaction?

What should I look for?

Serious allergic reactions including rash; swelling of the hands and feet, face, or lips; and breathing difficulty.

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 may file a claim with VICP by calling 1-800-338-2382 or visiting their Web site at <http://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 <http://www.cdc.gov/std/hpv> and <http://www.cdc.gov/vaccines>.

Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, Human Papillomavirus Vaccine (Cervarix) (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.*

[FR Doc. 2010-19784 Filed 8-10-10; 8:45 am]

BILLING CODE 4163-18-P

## 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