



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH IMMUNIZATION PROGRAM

PLEASE COPY THIS FOR ALL HEALTH CARE PROVIDERS
IN YOUR PRACTICE

TO: All Users of State Supplied Vaccine

FROM: Mick Bolduc
Vaccines For Children (VFC) Coordinator

DATE: April 20, 2010

SUBJECT: Update on Rotavirus Vaccine

The primary purpose of this communication is to provide you with an update on Rotavirus vaccine.

Rotavirus Vaccine

The Food and Drug Administration will be convening a meeting of its Vaccines and Related Biological Products Advisory Committee on May 7th to discuss available data concerning Glaxo Smith Kline's Rotarix brand rotavirus vaccine as well as make recommendations for future use of the product. Since any decision concerning Rotarix will not be made until that meeting, the Immunization Program will continue to make Merck's RotaTeq brand rotavirus vaccine available throughout the month of May. **All rotavirus orders in May will be filled with RotaTeq.**

Providers should order RotaTeq in the space labeled "Rotavirus (Rotarix)" on the current Vaccine Order Form. When reporting your doses administered data, you can report your RotaTeq doses in the "Rotavirus" space provided on the doses administered page. As a reminder RotaTeq is administered in a 3 doses series so children who have already received one dose of Rotarix should receive 2 additional doses of RotaTeq.

New Vaccine Information Statements

Enclosed are the latest Vaccine Information Statements for Pneumococcal Conjugate Vaccine (updated 4/16/10) and Human Papillomavirus Vaccine (updated 3/30/10). As a reminder all Vaccine Information Statements can be downloaded at www.cdc.gov/vaccines/pubs/vis/default.htm

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

HPV (HUMAN PAPILLOMAVIRUS) VACCINE

Cervarix®

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis>.

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 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 website 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 website 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 website at <http://www.cdc.gov/hpv> and <http://www.cdc.gov/vaccines>



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Human Papillomavirus (HPV) *Cervarix* 3/30/2010

PNEUMOCOCCAL CONJUGATE VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

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 dropped by nearly 80% among children under 5.

PCV13 may 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.

PCV13 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, 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, and 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 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 PCV 13** (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 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 website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

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

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 website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

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- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
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 - Visit CDC's website at www.cdc.gov/vaccines.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
PCV13 **4/16/2010**

42 U.S.C. §300aa-26

HPV (HUMAN PAPILLOMAVIRUS) VACCINE

Gardasil®

WHAT YOU NEED TO KNOW

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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 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 website at <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967.

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Vaccine Information Statement (Interim)
Human Papillomavirus (HPV) *Gardasil* 3/30/2010