

# Questions and Answers about Human Papillomavirus (HPV) Vaccine

## A. Information for Providers

### What is HPV?

Human Papillomavirus, (HPV) is one of the most common sexually transmitted infections in the United States (U.S.) Some strains of HPV are responsible for warts of the hands and feet, and other strains are responsible for warts of the penis, scrotum, vulva, vagina, anus, rectum, urethra, cervix and mouth. HPV is spread through skin-to-skin and mucous membrane contact during sexual activity. HPV can be spread in the absence of vaginal and rectal intercourse. Rarely, an infected woman may transmit the virus to her newborn during delivery. There is no evidence that Cesarean section prevents perinatal transmission of HPV.

Research has shown that 99.7% of cervical cancers are caused by HPV infection. There are 120 different types of HPV of which 35 are linked to infection of the genital tract. Genital HPV types are divided into low-risk and high-risk types based on their potential to cause cervical and other lower genital tract cancers.

### What are the subtypes of the virus that are of concern?

HPV types 6 and 11 cause 90% of genital warts. HPV types 16 and 18 cause 70% of cervical cancers. The subtypes that cause warts do not also cause cancer.

### What is the burden of HPV infections?

It is estimated that 20 million people in the U.S. are currently infected with HPV and over 6 million new HPV infections are diagnosed each year. Based on national estimates, 80% of sexually active men and women will acquire HPV infection at some point in their lives.

The majority of genital HPV infections are transient, asymptomatic, and clinically unrecognizable. Furthermore, most HPV infections will clear without medical intervention within two years of infection. Recurrence or re-infection with the same or a different subtype of HPV can occur; consequently sex partners of infected patients should be evaluated for HPV infection.

### What are the health effects of HPV infection?

While usually asymptomatic, depending on the strain, genital or rectal warts may appear soon after infection. Although HPV is usually cleared by an individual's immune system a few months following infection, the virus can persist for long periods of time due to host, viral and environmental factors, and years later be triggered to cause symptoms such as warts or precancerous changes. Due to the potentially long periods of dormancy, genital HPV is not evidence that a person is having sex outside of his/her current relationship.

### How is HPV transmitted?

HPV is an extremely contagious sexually transmitted virus and can be transmitted through sexual activity that does not necessarily involve intercourse, but only skin-to-skin and mucous membrane contact. There are a few studies that indicate that HPV can even be spread by inanimate objects such as underwear or gloves. HPV is difficult to identify and avoid in people who are sexually active because it is often not possible to see the lesions.

### Is there a vaccine that prevents HPV infection?

Two different drug companies have produced vaccines against certain types of HPV. Merck's vaccine, Gardasil, protects against infection with four subtypes of HPV: 16, 18, 6 and 11. The vaccine is 100% effective in preventing infection from the strains of HPV that cause 7 out of 10 cases of cervical cancer and 9 out of 10 cases of genital warts. GlaxoSmithKline's (GSK) bivalent vaccine, Cervarix, protects against types 16 and 18, thereby, protecting patients from 70% of cervical cancers. Only Merck's vaccine has been approved for use in the U.S. GSK has not submitted an application for use in the U.S.

### What are the benefits of a vaccine against HPV?

The FDA approved vaccine will prevent 7 out of 10 cases of cervical cancer and 9 out of 10 cases of genital warts. In addition, the vaccine also will significantly reduce the number of false positive Pap tests, and thus reduce the number of costly and potentially unnecessary diagnostic procedures performed on women. In total, the vaccine will have a tremendous benefit on the health care of women.

### What is the vaccine's duration of protection?

While it is important to vaccinate before sexual debut, information on the duration of protection offered by the vaccine is incomplete. Studies show that serum antibody levels remain high after HPV vaccination for at least four years. Currently, there is no test available for serologic correlates of protection after vaccination. Ongoing studies are investigating whether vaccinated individuals will need a booster in future years.

### What will the dosage be?

Merck has suggested three doses of the vaccine: an initial dose followed by doses at 1 or 2 months and 6 months. Merck's vaccine will consist of HPV L1 virus like protein: 20 µg against type 6 and 20 µg against type 18, and 40 µg against types 11 and 16. Additionally, Merck has added 225 µg of aluminum adjuvant. GSK's vaccine will consist of 20 µg of each HPV 16 and HPV 18 L1 virus like proteins, 500 µg of aluminum hydroxide and 50 µg of 3-deacylated monophosphoryl lipid A.

### How much does the vaccine cost?

While the cost of the approved vaccine will vary, it is estimated that the vaccine will cost approximately \$120 per injection for a total of \$360 for the complete series.

### Will insurance companies provide reimbursement for the vaccine?

Since the Advisory Committee on Immunization Practices (ACIP) recommends the vaccine routinely for females aged 11-12 and also approved its use for females 13-26 and stated that the vaccine could be administered to females as early as age 9, it is likely that the vaccine will be covered by health insurers and the Vaccines for Children Program.

### What if someone is uninsured or underinsured?

Uninsured individuals aged 19 and under who are economically eligible for the VFC program may be able to receive the vaccine at no cost. In addition, Merck has created a new patient assistance program for vaccines. Through this new program, Merck will provide free vaccines to adults who are uninsured and unable to afford vaccines. Merck vaccines, including Gardasil, will become available through this program in the third quarter of 2006. You may also contact your local health department to see if they are offering the vaccine at low or no cost for the uninsured.

### Where can someone get the vaccine?

Talk with your healthcare provider to see if they have the HPV vaccine. If you are uninsured, or unable to afford the costs of the vaccine, contact your local health department or a community health center in your area to see if they are offering the vaccine at low or no cost.

### For what age groups are the vaccine recommended?

The FDA approved the use of the vaccine for females aged 9-26 years. ACIP recommends the vaccine routinely for females aged 11-12 and also approved its use for females 13-26 and stated that the vaccine could be administered to females as early as age 9. While CDC is not bound to adhere to ACIP's recommendations, it usually does.

### Why are 11 and 12 year olds the priority age for the vaccine?

It is important to vaccinate people before they have sexual encounters and risk becoming infected with HPV. Fifteen to 25 year-olds have the highest prevalence of HPV infection. Vaccination must, therefore, occur earlier in adolescence. Limited data on the duration of immune protection precludes initiating HPV vaccination in early childhood at this time.

There is also evidence that the vaccine has a 2 to 3 times greater immunogenicity when given to females ages 9-11 compared to females aged 15-25.

### Why is the vaccine recommended for females?

The evidence from clinical trials at this point has been limited to females. There are trials underway for males, and it is possible that vaccination may some day be approved for males.

### How safe is the vaccine? What are the side effects?

The vaccine is very safe. The clinical trials that have included thousands of women from all over the world have not shown any serious adverse side effects. Participants in the studies complained of minor skin irritation and pain at the site of injection and sometimes experienced headaches for a few days after injection.

### Is parental consent required for vaccine administration to a minor?

Under the existing New York State Public Health Law, the HPV vaccine is not defined as a "treatment" and, therefore, parental consent is required prior to administration of the vaccine.

## B. Answering Parents' Questions about HPV

This section provides suggested answers to common questions from parents, using non-technical language.

### How can HPV infection be prevented?

There are two ways to prevent all forms of HPV:

1. Abstinence - do not have any sexual activity with another person. HPV can be spread during sexual activity other than vaginal, rectal or oral intercourse.
2. Monogamy - people who have never had sexual activity with anyone else commit to only having sexual activity with each other over their lifetimes.

Most people who don't practice abstinence or monogamy will become infected with HPV. About three-quarters of everyone in the U.S. between the ages of 15 and 49 have been infected with HPV in their lifetime. Condoms can prevent some diseases, but HPV can be passed on, even if a condom is used.

### Does the vaccine send a message that it's okay to have sex and therefore encourage or lead to increased sexual activity?

There is no evidence that receiving the HPV vaccine encourages earlier initiation of sex or increased sexual activity. In fact, research shows that sexual activity is unlikely to result from receiving the HPV vaccine. Making sexual activity safer does not cause teens to become sexually active at an earlier age. Besides, there are still plenty of risks associated with sexual activity remaining, including pregnancy, HIV, herpes, and other sexually transmitted infections (STI's.) These risks should provide plenty of motivation for teenagers to delay sex.

Two of the most important influences on teenagers' decision to become sexually active are *peer pressure* and the use of *alcohol* or other drugs. Parents are the primary educators for teens on sexuality. Parents can weaken the power of peer pressure and drug use by talking with their sons and daughters about sexual health and relationships, and the risks of drug use. Research shows that informed teenagers and teenagers with involved parents are more likely to delay the initiation of sexual activity.

You can have your daughter vaccinated and still tell her, without hypocrisy, that she shouldn't have sex as a teenager. Having your daughter vaccinated is sending her the message that when she does become sexually active, she should do so as safely as possible. By way of example, we may teach our three-year-old to look both ways before crossing the street, even though it will be many years before we will let her cross the street on her own.

### Why should my daughter be vaccinated at age 11 or 12? She's not sexually active. Can't we wait?

Many parents have difficulty looking ahead to the time when their children will become sexually active. Ready or not, now is the time to start thinking about the future sexual health of your child. Research has shown that the vaccine is two to three times more effective when given to females aged 9 to 11 compared to females aged 15 to 25. It's a unique window of opportunity.

Also, for the vaccine to work, your daughter has to be vaccinated *before* she comes into contact with the virus. Once she is infected with the virus, it's too late for the vaccine to help. If she is infected with the virus, she could get cervical cancer later in life and cervical cancer kills thousands of women every year. So it's best to be safe. We don't plan to get the flu or tetanus, but we get vaccinated so that we know we are protected from these illnesses in the future.

If your daughter isn't sexually active, she's protected from HPV infection. However, most teens do become sexually active. The sexual life of your daughter probably isn't something you will know everything about, but if she is vaccinated you can be sure that:

- If she becomes sexually active, she'll be protected from the kinds of HPV that cause 7 out of 10 cases of cervical cancer.
- If she is sexually assaulted, she'll likewise be protected. (Among female high school students nationwide, about 12% report having been sexually assaulted.)

### Should my son take this vaccine?

At this point, the vaccine is only approved for females. There is a good chance that it will eventually be approved for males as well. When this happens, it will be important for young men to get the vaccine because it will help prevent genital warts and certain cancers in men, and it will help prevent the spread of the cancer-causing types of HPV to women.

## C. Public Education Information

### HPV is not HIV or herpes.

It is important that patients realize that although these are all viruses that can be sexually transmitted, they do not cause the same health problems or symptoms; nor are they treated by the same methods or medication.

### Do women need to continue to get Pap tests?

Yes. Merck's vaccine only protects against the two types of HPV that cause 7 out of 10 cases of cervical cancer. Additionally, it is currently unknown how long the vaccine will protect against HPV, so it is important to see your healthcare professional for continued Pap screening.

### What are the recommended cervical cancer screening intervals?

The U.S. Preventive Services Task Force currently recommends cervical cancer screening at least every three years beginning three years after the onset of sexual activity or at age 21, whichever comes first. Pap tests are commonly used to screen for cervical cancer.

The American Cancer Society recommends:

- All women should begin cervical cancer screening about three years after they begin having vaginal intercourse, but no later than when they are 21 years old. Screening should be done every year with the regular Pap test or every two years using the newer liquid-based Pap test.
- Beginning at age 30, women who have had three normal Pap test results in a row may get screened every two to three years with either the regular or newer liquid-based Pap test. Women who have certain risk factors such as diethylstilbestrol (DES) exposure before birth, HIV infection, or a weakened immune system due to organ transplant, chemotherapy, or chronic steroid use should continue to be screened annually.
- Another reasonable option for women over 30 is to get screened every three years with both a Pap test (either the regular or newer liquid-based) and a test for the cancer causing strains of HPV.
- Women 70 years of age or older who have had three or more normal Pap tests in a row and no abnormal Pap test

results in the last 10 years may choose to stop having cervical cancer screening. Women with a history of cervical cancer, DES exposure before birth, HIV infection or a weakened immune system should continue to have screening as long as they are in good health.

- Women who have had a total hysterectomy (removal of the uterus and cervix) do not need to receive cervical cancer screening, unless the surgery was done as a treatment for cervical cancer or precancer. Then, because of their increased risk, they should continue to receive a Pap test of their remaining vaginal tissue.
- Women who have had a partial hysterectomy that left an intact cervix should continue to follow the guidelines above for women without a hysterectomy.

Are there any other resources where I can look to find out more information on HPV, the HPV vaccine and cervical cancer?

- [American Social Health Association \(ASHA\)](#)  
P.O. Box 13827  
Research Triangle Park, NC 27709  
(919) 361-8400  
(919) 361-8425 (fax)
- [American Cancer Society](#)  
1599 Clifton Rd NE  
Atlanta, GA 30329  
800-ACS-2345  
(404) 329-7530
- [National Center for HIV, STD & TB Prevention](#)  
Centers for Disease Control and Prevention  
Atlanta, GA 30333  
[nchstp@cdc.gov](mailto:nchstp@cdc.gov)  
Toll-free voice information: 888-232-3228  
CDC STI Hotline: 800-227-8922
- [The Centers for Disease Control and Prevention](#)  
[Genital HPV Infection - CDC Fact Sheet](#)
- [National Cancer Institute](#)  
1-800-4-CANCER
- [National HPV and Cervical Cancer Public Education Campaign](#)  
1-866-280-6605
- [Association of Reproductive Health Professionals \(ARHP\)](#)  
2401 Pennsylvania Avenue – NW, Suite 350  
Washington, DC 20037-1730
- [Women's Cancer Network](#)  
1-312-578-1439
- [Cancer Research and Prevention Foundation](#)
- [American College of Obstetrics and Gynecology - ACOG](#)
- [New York State Department of Health](#)
- [Planned Parenthood](#)
- [National Women's Health Resource Center](#)

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