

## Fact Sheet

### What is HPV?

Human papillomavirus (HPV) is the name of a group of viruses that includes more than 100 different types. More than 30 of these viruses are sexually transmitted, and they can infect the genital area of men and women including the skin of the penis, vulva, or anus, and the lining of the vagina, cervix, or rectum.

Some of these viruses are called “high-risk” types; they may cause abnormal Pap tests and can also lead to cancer of the cervix, vulva, vagina, anus, or penis. Others are called “low-risk” types; they may cause mild Pap test abnormalities or genital warts.

### How common is HPV in the United States?

HPV is the most common sexually-transmitted infection in the United States. Approximately 20 million people are currently infected with HPV. At least 50% of sexually active men and women acquire genital HPV infection at some point in their lives. By age 50, at least 80% of women will have acquired genital HPV infection. About 6.2 million Americans get a new genital HPV infection each year.

### How does HPV spread?

HPV is spread through sexual contact. Most infected persons have no symptoms and are unaware they are infected and can unintentionally transmit the virus to a sex partner. Rarely, a pregnant woman passes HPV to her baby during vaginal delivery.

### What are the symptoms of HPV?

Most people who become infected with HPV have no symptoms. Some people get visible genital warts, or have pre-cancerous changes in the cervix, vulva, anus, or penis.

Genital warts usually appear as soft, moist, pink, or flesh-colored swellings, usually in the genital area. They can be raised or flat, single or multiple, small or large, and sometimes cauliflower shaped. They can appear on the vulva, in or around the vagina or anus, on the cervix, and on the penis, scrotum, groin, or thigh. After sexual contact with an infected person, warts may appear within weeks or months, or not at all.

### How serious is HPV?

Most HPV infections don't cause any symptoms and eventually go away, as the body's own defense system clears the virus. Women with temporary HPV infections may develop mild Pap test abnormalities that go away with time.

About 10% of women infected with HPV develop persistent HPV infection. Women with persistent high-risk HPV infections are at greatest risk for developing cervical cancer precursor lesions (abnormal cells on the lining of the cervix) and cervical cancer. (See next question.)

### What are possible complications from HPV?

Cervical cancer in women is the most serious possible complication from HPV infection. Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. Every year in the United States, about 10,000 women get cervical cancer and 3,700 die from it. Worldwide, cervical cancer is the second most common cancer in women; it is estimated to cause over 470,000 new cases and 233,000 deaths each year.

Persistent infection with high-risk types of HPV is also associated with cancers of the vulva, vagina, penis, and anus. However, these cancers are much less common than cervical cancer. The American Cancer Society estimates that about 1,530 men were diagnosed with penile cancer and 1,910 men were diagnosed with anal cancer in the U.S. in 2006. The risk for anal cancer is 17 times higher among gay and bisexual men than among heterosexual men.

The risk is also higher among men with compromised immune systems, including those with HIV. Genital HPV infection with low-risk types of HPV is associated with genital warts in men and women.

About 1% of sexually active adults in the U.S. have visible genital warts at any point in time. Occasionally, low-risk HPV infections can be transmitted during birth, resulting in respiratory tract warts in infants and children.

### **How is HPV infection diagnosed?**

Genital warts in men and women are diagnosed by visual inspection.

Most women are diagnosed with HPV infection on the basis of abnormal Pap tests. Also, a specific test is available to detect HPV DNA in women. The test may be used in women with mild Pap test abnormalities or in women more than age 30 years at the time of Pap testing. The results of HPV DNA testing can help healthcare providers decide if further tests or treatment are necessary. No HPV tests are available for men.

### **Can genital HPV infection be cured?**

There is no “cure” for HPV infection, although the infection usually goes away on its own. Approximately 90% of women with HPV infection become HPV-negative within two years. However, it is possible that the virus remains in a “sleeping” state and could be reactivated years later.

There are treatments for the health problems that HPV can cause, such as genital warts, cervical cell changes, and cancers of the cervix, vulva, vagina, and anus.

Visible genital warts can be removed by medications the patient applies, or by treatments performed by a healthcare provider. No one treatment is best. Warts might return, especially in the first 3 months after treatment. It is not known whether treatment of genital warts will reduce the chance of passing the virus on to a sex partner. If left untreated, genital warts may go away, remain unchanged, or increase in size or number.

### **How can people reduce their risk for acquiring genital HPV infection?**

The surest way to eliminate risk for genital HPV infection is to refrain from any genital contact with another individual.

For people who are sexually active, a long-term, mutually monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections. However, it is difficult to determine whether a partner who has been sexually active in the past is currently infected.

For those who are sexually active and who are not in long-term mutually monogamous relationships, reducing the number of sexual partners and choosing a partner less likely

to be infected may reduce the risk of genital HPV infection. Partners less likely to be infected include those who have had no or few prior sex partners.

It is not known how much protection condoms provide against HPV, since areas that are not covered by a condom can be exposed to the virus. However, condoms may reduce the risk of genital warts and cervical cancer.

In 2006, a vaccine became available to protect females from four HPV types.

**When did HPV vaccine become available?**

On June 8, 2006, the Food and Drug Administration (FDA) licensed the first vaccine developed to prevent cervical cancer and other diseases in females caused by certain types of genital human papillomavirus (HPV). The vaccine, Gardasil (by Merck), protects against four HPV types which are responsible for 70% of cervical cancers and 90% of genital warts.

**What kind of vaccine is it?**

HPV vaccine is an inactivated (not live) vaccine.

**How is this vaccine given?**

This vaccine is given as a shot in the muscle.

**Who should get this vaccine?**

The HPV vaccine is recommended for girls age 11-12 years, but can be administered to girls as young as age 9 years. The vaccine also is recommended for females age 13-26 years who have not yet received or completed the vaccine series.

The vaccine should be given as a series of three injections over a six-month period. The second and third doses should be given two and six months after the first dose. The vaccine can be administered at the same visit as other needed vaccines.

It is best if the vaccine is given before onset of sexual activity. However, females who are sexually active also may benefit from vaccination. Females who have not been infected with any vaccine HPV type would receive the full benefit of vaccination and those who already have been infected with one or more HPV type would still get protection from the vaccine types they have not acquired. Few young women are infected with all four HPV types in the vaccine.

HPV vaccine can be given to females who have an abnormal Pap test or genital warts. However, the vaccine will not have any helpful effect on existing Pap test abnormalities, HPV infection, or genital warts.

**Why is the HPV vaccine recommended for such young girls?**

This is because the vaccine is most effective in girls/ women who have not yet acquired any of the four HPV types covered by the vaccine. Girls/women who have not been infected with any of those four HPV types will get the full benefits of the vaccine.

**Why is the HPV vaccine only recommended for girls/women age 9–26 years?**

The vaccine has been widely tested in females age 9-to-26 years. Research on the vaccine's safety and efficacy has only recently begun with older women. The FDA will

consider licensing the vaccine for these women when there is research to show that it is safe and effective for them.

**What about vaccinating males?**

Studies are now being done to find out if the vaccine works to prevent HPV infection and disease in males. When more information is available, this vaccine may be licensed and recommended for them as well. HPV vaccine could protect men directly by preventing penis and anus cancer and also women indirectly, by preventing HPV infection being passed along to them during sexual contact.

**Should individuals be screened before getting vaccinated?**

No. Girls/women do not need to get an HPV test or Pap test to find out if they should get the vaccine. An HPV test or a Pap test can tell that a woman may have HPV, but these tests cannot tell the specific HPV type(s) that a woman has. Even individuals with one HPV type could get protection from the other vaccine HPV types they have not yet acquired.

**How effective is this vaccine?**

Four studies, one in the United States and three multinational, were conducted to show how well Gardasil worked in women between ages 16-26 years. A total of 21,000 women were given either the vaccine or a placebo. The results showed that in women who had not already been infected, the vaccine was nearly 100% effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed.

Two studies measured the immune response to the vaccine among younger females age 9-15 years. Their immune response was as good as that found in 16-26 year olds, indicating that the vaccine should have similar effectiveness when used in this younger age group.

**How long does vaccine protection last? Will a booster shot be needed?**

The length of immunity is usually not known when a vaccine is first introduced. So far, studies have shown women to still be protected after five years. More research is being done to find out how long protection will last, and if a booster dose will eventually be needed.

**Who recommends this vaccine?**

The Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) all recommend this vaccine. The vaccine is also recommended by the American Cancer Society.

**How safe is this vaccine?**

The HPV vaccine has been tested in over 11,000 females (age 9-26 years) in many countries around the world, including the United States. These studies found that the HPV vaccine was safe and caused no serious side effects. A post-licensure safety monitoring plan is in place.

**What side effects have been reported with this vaccine?**

Mild problems may occur with HPV vaccine, including pain at the injection site (8 people in 10), redness or swelling at injection site (1 person in 4), mild fever (1 person in 10), itching at the injection site (1 person in 30), moderate fever (102°F) (1 person in 65). These symptoms do not last long and go away on their own. Like all vaccines, HPV vaccine will be monitored for more serious or unusual side effects.

**Do women still need to get a Pap test if they've been vaccinated against HPV?**

Yes! Women should continue to receive regular cervical cancer screening for three reasons. First, the vaccine does not provide protection against all types of HPV that cause cervical cancer. Second, women may not receive the full benefits of the vaccine if they do not complete the vaccine series. Third, women may not receive the full benefits of the vaccine if they receive the vaccine after they have already acquired HPV infection from one of the four types for which the vaccine is preventive.

In addition, vaccinated women should continue to practice protective sexual behaviors since the vaccine will not prevent all cases of genital warts or other sexually transmitted infections.

**Does the vaccine protect against all types of HPV?**

No, although there are more than 100 types of human papillomaviruses, only four are covered in the vaccine. These four viruses, however, are responsible for 70% of cervical cancers and 90% of genital warts. Because there will be 30% of cervical cancers not prevented by the vaccine, it is important for women to continue getting regular Pap tests.

**What if a person doesn't get all of the recommended three doses?**

It is not yet known how much protection girls/ women would get from receiving only one or two doses of the vaccine. For this reason, it is very important that individuals get all three doses of the vaccine. If there is a gap in the schedule longer than the recommended time, the series should just be continued from where it left off. There is no need to start the series over.

**Who should NOT receive HPV vaccine?**

Anyone who has ever had a life-threatening allergic reaction to yeast, any other component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine.

Pregnant women should not get the vaccine. Although the vaccine appears to be safe for both the mother and developing baby, this issue is still being studied. Inadvertently receiving HPV vaccine during pregnancy is not a reason to consider terminating the pregnancy. Any woman who learns she was pregnant when she got the HPV vaccine is encouraged to call the HPV Vaccine in Pregnancy Registry at (800) 986-8999. Information gathered from this registry will help experts learn how pregnant women respond to the vaccine.

Breast feeding women can safely get the vaccine.

Persons who are moderately or severely ill should wait until their condition improves to be vaccinated.

**Will the vaccine be covered by insurance plans?**

Most insurance plans and managed care plans cover recommended vaccines for children. However, there may be a lag time after a vaccine is recommended before it is available and covered by health plans.

The Vaccines for Children program provides free vaccines to children and adolescents younger than 19 years of age, who are either Medicaid-eligible, American Indian, or Alaska Native, uninsured, or receiving care in a Federally Qualified Health Clinic or Rural Health Center.

**Can the vaccine cause HPV?**

No. The vaccine is inactivated so it cannot cause disease- like symptoms or HPV disease.

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Adapted from [www.immunize.org/catg.d/p4207.pdf](http://www.immunize.org/catg.d/p4207.pdf) on 6/6/2008. We thank the [Immunization Action Coalition](#).

*This fact sheet is for information only and is not meant to be used for self-diagnosis or as a substitute for consultation with a health care provider. If you have any questions about the disease described above or think that you may have this infection, consult a health care provider.*

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