

Human Papillomavirus (HPV): Questions and Answers

INFORMATION ABOUT THE DISEASE AND VACCINES

How common is HPV in the United States?

HPV is the most common sexually transmitted infection in the United States. About 79 million Americans are currently infected with HPV. About 14 million people become newly infected each year. HPV is so common that most sexually active men and women will get at least one type of HPV at some point in their lives.

An estimated 30,700 cancers attributed to HPV occur annually in the U.S., including an estimated 11,500 HPV-attributed cancers in males. Of the HPV-attributed cancer, approximately 64% are caused by HPV types 16 and 18, which are included in all three HPV vaccines that have been available in the United States and about 12% are caused by the 5 HPV types included in Gardasil 9.

How does HPV spread?

HPV is spread through contact with infected skin, usually through sexual contact. Most infected people have no symptoms and are unaware they are infected and can 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 develop 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 short-term HPV infections may develop mild Pap test abnormalities that go away with time.

A small percentage of people infected with HPV develop persistent (chronic) 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.

What are possible complications from HPV?

Cancer is the most serious possible complication from HPV infection. Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. The American Cancer Society (ACS) estimates that in 2016, approximately 12,990 new cases of invasive cervical cancer will occur in the U.S. and about 4,120 women will die from the disease. 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. For example, ACS estimates that this year there will be about 2,030 new cases of penile cancer in the U.S. and 340 men will die from it. 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. It is estimated that approximately 360,000 cases of genital warts occur each year in the U.S. among sexually active people.

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. In April 2014 the U.S. Food and Drug Administration approved the first HPV DNA test for women age 25 years and older that can be used alone to help

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a health care professional assess the need for additional diagnostic testing for cervical cancer. The test also can provide information about the patient's risk for developing cervical cancer in the future.

No HPV tests are available for men.

Can genital HPV infection be cured?

There is no cure for HPV infection, although the immune system usually eliminates the virus from the body. Approximately 90% of women with HPV infection become HPV-negative within two years. However, a small percentage of infected people remain infected for many years, which may result in genital warts or cancer.

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 health-care 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 with another partner in the past is currently infected.

It is not known how much protection a condom provides against HPV, since skin that is not covered by a condom can be exposed to the virus. However, condoms may reduce the risk of genital warts and cervical cancer. People can also reduce their risk by getting the HPV vaccine.

When were the HPV vaccines licensed?

The first HPV vaccine (Gardasil, Merck) was licensed for females in 2006. Gardasil protected against four HPV types: 16, 18, 6, and 11. About 80% of cervical cancers are caused by HPV types 16 and 18, and more than 90% of genital warts are associated with HPV

types 6 and 11. In 2009, Gardasil was licensed for use in males. In 2009, a second HPV vaccine was licensed (Cervarix, GlaxoSmithKline) for use in females. Cervarix protected against HPV types 16 and 18. In 2014, a new version of Gardasil was licensed. This vaccine, called Gardasil 9, protects against the four HPV types included in the original Gardasil as well as 5 additional cancer-causing HPV types. These 5 additional types account for about 11% of all HPV-associated cancer in the United States (14% of HPV-associated cancers in females and 4% in males). As of late 2016, only Gardasil 9 is distributed in the United States.

What kind of vaccine is it?

HPV vaccine is an inactivated (not live) vaccine.

How is this vaccine given?

This vaccine is given as an injection in the deltoid muscle of the arm.

Who should get this vaccine?

The CDC's Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of boys and girls at age 11 or 12 years with catch-up vaccination for females through age 26 years, and for males through age 21 years; males age 22 through 26 years may be vaccinated. In addition, vaccination is recommended for men age 22 through 26 years who have sex with men or are immunocompromised as a result of disease (including HIV) or medication. The vaccination series can also be started as young as age 9 years, at the clinician's discretion.

How many doses are needed and on what schedule?

The schedule for HPV vaccine depends on the age at which the first dose is given. For people starting the vaccine series before age 15 years, the recommended schedule is 2 doses, separated by 6 to 12 months. If vaccination is started at age 15 years or older, the schedule is 3 doses. The second dose should be given one to two months after the first dose and the third dose should be given six months after the first dose and at least 12 weeks after the second dose. The vaccine can be administered at the same visit as other needed vaccines.

The vaccine provides the best protection when given before onset of sexual activity. However, people who are sexually active also may benefit from vaccination. People who have not been infected with any vaccine HPV type

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would receive the full benefit of vaccination. Those who already have been infected with one or more HPV types would still get protection from the vaccine types they have not acquired. HPV vaccine can be given to females who have had 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 (that is, the vaccine is not a treatment for HPV infection or HPV-related disease).

Why is HPV vaccine not licensed for adults older than 26 years?

HPV vaccine was tested in people age 9 through 26 years. Although Gardasil has been tested in women age 27 through 45 years and found to be safe, data on the effectiveness of the vaccine in this age group was inconclusive, mainly because many of the participants in the trial had already been infected with HPV types included in the vaccine. The FDA will consider licensing the vaccines for older people if additional research shows that it is effective for them.

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.

How effective are the HPV vaccines?

All three HPV vaccines are highly effective in preventing infection with types of HPV included in the vaccines. Studies have shown that all three vaccines prevent nearly 100 percent of the precancerous cervical cell changes caused by the types of HPV included in the vaccine for more than 10 years after vaccination. Among males, efficacy of Gardasil for prevention of genital warts was 89% and efficacy for the prevention of precancerous lesions of the anus was 78%.

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 people to still be protected after more than 10 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 HPV vaccine?

The Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG) all recommend routine HPV vaccination of boys and girls at 11 or 12 years of age.

What side effects have been reported from HPV vaccine?

Mild problems may occur with HPV vaccine, including pain, redness, swelling, and itching at the injection site. These problems do not last long and go away on their own. Fainting has been reported among adolescents who receive HPV vaccine (and other recommended vaccines as well). It's best for the patient to sit during vaccine administration and remain seated for 15–20 minutes after receiving the vaccine.

Like all vaccines, HPV vaccine is being monitored for more serious or unusual side effects.

Can HPV vaccine cause HPV?

No. HPV vaccines are inactivated so they cannot cause disease-like symptoms or HPV disease.

We've heard stories in the media lately about severe reactions to HPV vaccine. Is there any substance to these stories?

No. While serious events, including death and Guillain-Barre syndrome, have been reported among women who had recently received HPV vaccine, CDC and FDA follow-up on these reports has not found that the events occurred more frequently among vaccinees than among the general population, and has detected no pattern that would indicate an association with the vaccine. You can find complete information on this and other vaccine safety issues at www.cdc.gov/vaccinesafety/index.html.

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 were infected with HPV before receiving the vaccine.

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In addition, vaccinated people 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 (HPV 6, 11, 16, and 18) were included in Gardasil, 9 are included in Gardasil 9 (HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58) and only two (HPV 16 and 18) were included in Cervarix. HPV 16 and 18 (included in all three vaccines) are responsible for 66% of cervical cancers; HPV 6 and 11 causes approximately 90% of genital warts.

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

It is not known how much protection people would get from receiving fewer than the recommended number of doses of the vaccine. For this reason, it is very important to receive all recommended doses of the vaccine. If there is a gap in the schedule longer than the recommended time, the series should be continued from where it left off – there is no need to restart the series. A person who starts the series before the 27th birthday should complete the series even if he or she is now older than age 26 years.

Can an HPV vaccine series begun with Cervarix or Gardasil be completed with Gardasil 9?

Yes. Any HPV vaccine may be used to continue or complete the series.

Does CDC recommend revaccination with Gardasil 9 for people who previously received a series of Cervarix or Gardasil?

CDC has not recommended routine revaccination with Gardasil 9 for persons who have completed a series of another HPV vaccine. There are data that indicate revaccination with Gardasil 9 after a series of Gardasil is safe. Discuss this issue with your healthcare provider to decide if the benefit of immunity against 5 additional oncogenic strains of HPV is worth the time and expense of revaccination.

My 12-year-old received the first 2 doses of the HPV series 2 months apart according to the 3-dose schedule. Is his HPV vaccine series complete or does he need a third dose?

Adolescents age 9 through 14 years who received 2 doses of HPV vaccine separated by less than 5 months should receive a third dose 6–12 months after dose #1 and at least 12 weeks after dose #2.

Do women and men whose sexual orientation is same-sex need HPV vaccine?

Yes. HPV vaccine is recommended for females and males regardless of their sexual orientation.

Who should NOT receive HPV vaccine?

Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine (such as baker's yeast), 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 woman and developing baby, this issue is still being studied. Inadvertently receiving HPV vaccine during pregnancy is not a reason to consider terminating the pregnancy. Patients and healthcare providers should report any exposure to HPV vaccine during pregnancy to the manufacturer of the vaccine, at (800) 986-8999.

Breast-feeding women can safely get the vaccine.

People who have a moderate or severe acute illness should wait until their condition improves to be vaccinated.

Is HPV vaccine covered by insurance plans?

Many health insurance plans cover vaccines recommended for children and adolescents. The Vaccines for Children (VFC) program provides free vaccines to children and adolescents younger than 19 years of age, who are Medicaid-eligible, American Indian, or Alaska Native, uninsured, or receiving care in a Federally Qualified Health Clinic or Rural Health Center. This includes boys as well as girls. For adults, if you're not certain about your healthcare coverage, contact your health insurance plan for further information. If you don't have health insurance or if your plan doesn't cover this vaccine, ask your doctor or your local health department how you can obtain this vaccine.