Cancer Reference Information

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Frequently Asked Questions About Human Papilloma Virus (HPV) Vaccines

Below is general information about HPV as well as information about the new HPV vaccine.

What are viruses?

Viruses are very small organisms -- most cannot even be seen with an ordinary microscope. They cannot reproduce on their own; they must enter a living cell, which becomes the host cell, and "hijack" the cell's machinery to make more viruses.

Viruses can enter the body through the nose, mouth, or breaks in the skin. Once inside, they find their specific type of host cell to infect. For example, cold and flu viruses specifically attack cells that line the respiratory or digestive tracts. The human immunodeficiency virus (HIV) infects the T-cells and macrophages of the immune system. HPV infects squamous epithelial cells in the body.

What is HPV?

HPV is short for human papilloma (pap-uh-LO-mah) virus. HPVs are a group of over 100 related viruses. Each HPV virus in the group is given a number, which is called an HPV type. HPVs are called papilloma viruses because some of the HPV types cause warts, or papillomas, which are non-cancerous tumors. The papilloma viruses are attracted to and are able to live only in squamous epithelial cells in the body. Squamous epithelial cells are thin, flat cells that are found on the surface of the skin, cervix, vagina, anus, vulva, head of the penis, mouth, and throat. HPVs will not grow in other parts of the body.

Of the more than 100 strains of HPV, about 60 HPV types cause warts on non-genital skin, such as on the hands and feet. These are the common warts.

The other 40 HPV types are mucosal types of HPV. "Mucosal" refers to the body's mucous membranes, or the moist skin-like layers that line organs and cavities of the body that open to the outside. For example, the vagina and anus have a moist skin-like layer. The mucosal HPV types are also called the genital (or anogenital) type HPVs because they typically affect the anal and genital area. The mucosal HPVs prefer the moist squamous cells found in this area. They do not prefer the skin of the hands and feet.

Some types of genital HPVs can cause cauliflower-shaped warts to appear on or around the genitals and anus of both men and women. In women, visible warts may also appear on the cervix and vagina. This type of "genital wart" is known technically as condyloma acuminatum and is most often caused by HPV-6 or HPV-11. Because these genital warts rarely develop into cancer, HPV-6 and HPV-11 are called "low-risk" viruses. These low-risk types can also cause low-grade cervix cell changes that do not develop into cancer.

Other genital type HPVs have been linked with genital or anal cancers in both men and women. They also cause low and high-grade cervix cell changes and pre-cancers. These are called "high-risk" HPV types and include HPV-16, HPV-18, HPV-31, HPV -35, HPV-39, HPV-45, HPV-51, HPV-52, and HPV-58, as well as some others.

How do you get HPV?

Genital HPV is transmitted mainly by direct genital contact during vaginal or anal intercourse. It is not spread through bodily fluids, nor does it live in blood, or any organs.

Infection is very common soon after a woman becomes sexually active. In one recent study, more than 50% of college age women were found to have acquired an HPV infection within 4 years of first having sex.

Transmission by genital contact without intercourse is not common, but infection has been reported in women who did not have a history of intercourse. Oral-genital and hand-genital transmission of some genital HPV types is possible and has been reported. Transmission from mother to newborn during delivery is rare. When it occurs, it can lead to development of warts in the infant’s throat called respiratory papillomatosis.

How common is HPV? Who gets it?

Genital HPV is a very common virus. Some doctors think it is almost as common as the common cold virus. In the United States, over 6 million people (men and women) get an HPV infection every year. Almost half of the infections are in people between 15 and 25 years of age. About one-half to three-fourths of the people who have ever had sex will have HPV at some time in their life.

What are the symptoms of HPV?

Genital HPV usually has no symptoms, unless it is a type that causes genital warts. Genital warts may occur within weeks or months after contact with a partner who has HPV. More rarely, genital warts may occur years after exposure.

Most people will never know they have HPV because they have no symptoms and the body's immune system causes the virus to become inactive. A small percentage of people with HPV will have the virus for a longer time and will develop cell changes that over many years may lead to cervical or other genital or anal cancers.

How is HPV related to cervical cancer?

Almost all (more than 99 %) cervical cancers are related to HPV. Of these, about 70% are caused by HPV types 16 or 18. About 500,000 pre-cancerous cell changes of the cervix, vagina, and vulva are diagnosed each year in the United States, and over half are related to HPV 16 and 18. Low-grade cervix cell changes are caused by a variety of HPV types, including 16, 18, 6, or 11.

Although nearly all cervical cancers are related to HPV, most genital HPV infections do not cause cervical cancer. Most people who test positive for genital HPV DNA in research studies eventually test negative, often within 6 to 12 months. Scientists are still not sure whether this means that a person's immune system has completely destroyed all of the HPV or has only suppressed the infection to an extremely low level (too low to be detected by available tests). If even a few cells of the cervix still contain HPV, it's possible that the virus may start to become active again if your immune system becomes very weakened.

It is possible that some low-grade cervix cell changes and some high-grade cervix cell changes may suddenly occur many years after first HPV exposure. This could help explain how a woman could get such changes after many years of normal Pap tests and no history of a partner change.

If cells stay infected with HPV, the virus may cause cervix cells to change and become pre-cancer cells. True pre-cancer cell changes are called high-grade SIL (squamous intraepithelial lesions), sometimes abbreviated as HSIL. Another term for HSIL is CIN 2 and CIN3. CIN is an abbreviation for cervical intraepithelial neoplasia.

Pre-cancer cells are not cancer. Although some pre-cancer changes may return to normal on their own, most cases of CIN 3 are likely to progress to cervical cancer over a period of time that probably takes about 10 years if not detected and treated. But very few HPV infections lead to cervical cancer. Pre-cancer cells are found by having regular Pap tests.

For more information on cervical cancer, please see the American Cancer Society document, *Cervical Cancer*.

What about other cancers and HPV?

Many anal cancers are caused by the same types of genital HPV that cause cervical cancer. A little less than half of cancers of the vulva are HPV-related. Several other genital cancers (cancers of the penis, vagina, and urethra) and some head and neck cancers (specifically of the tongue and tonsils) may be related to the high-risk types of HPV. Also, a high portion of skin cancers in people with weakened immune systems might be related to this virus.

What about other HPV-related diseases?

Over 500,000 new cases of anal and genital warts are diagnosed yearly in the United States, and about 9 out of 10 of these are caused by two specific HPV types.

Do men have the kinds of cancers that are related to HPV?

HPV is probably as common in men as in women. But HPV is not as easily diagnosed in men as in women. Genital HPV is passed to men through vaginal and anal sex -- the same way it is in women. Some types of HPV have been linked to cancer of the penis and anus in men. Although cancer of the penis is rare, anal cancer is now almost as common in men and women who have anal sex as cervical cancer was in women before the Pap test was introduced.

Like women, men do not have symptoms with HPV unless it is the type that causes genital warts. In men, genital warts can appear around the anus or on the penis, scrotum, groin, or thighs.

There is no test approved to detect HPV in men. But genital warts can be detected and treated. There are no tests approved to detect early HPV-related cancers in men, as there is in women with the Pap test. In gay, bisexual, and HIV-positive men, some doctors use anal Pap tests to detect and treat precancerous changes of the anus. Since anal testing is in the early stages of development and use, its effect on anal cancer rates will not be seen for many years.

For more information on sexually transmitted illnesses in men, please contact the American Social Health Organization (ASHA) at http://www.ashastd.org. You can get information on teen sexual health in English at http://www.iwannaknow.org or in Spanish at http://www.quierosaber.org.

Can HPV be treated?

No. Treatments cannot cure HPV. However, most genital HPV infections go away with the help of the body’s immune system. About 70% of HPV infections are gone within one year and 90% are gone within two years. Although HPV itself cannot be treated, the cell changes that come from an HPV infection can be treated. For example, genital warts can be treated; pre-cancer cell changes caused by HPV can be found by Pap tests and treated; and cervical, anal, and genital cancers can be treated.

Can HPV be prevented?

Getting the HPV vaccine before exposure will prevent some HPV. But the only sure way to prevent HPV is to abstain from all sexual activity. Limiting the number of sexual partners and avoiding sex with people who have had many other sex partners decreases a person's risk of exposure to HPV. HPV infection is so very common, though, that even these measures do not guarantee that a person will not get HPV. These measures are likely to reduce the number of times a person is exposed to HPV.

Condoms provide some, but not total, protection against HPV. The virus can spread during sexual skin-to-skin contact before the condom is put on, and the condom does not cover the entire genital area. Condoms are very helpful, though, in protecting from other infections that can be spread through sexual activity.

What are the risk factors for genital HPV?

People with the following risk factors are more likely to have genital HPV:

- having many sexual partners
- being younger than 25 years of age
- starting to have sexual intercourse at age 16 or younger
- having a male partner who has had several different sex partners

Is there a vaccine to prevent HPV?

In 2006, the Food and Drug Administration (FDA) approved a vaccine that prevents two types of HPV (HPV 16 and 18) that cause 70% of all cervical cancers. The vaccine also prevents two types of HPV (HPV 6 and 11) that cause 90% of all genital warts.

Did the American Cancer Society play a role in the development of the HPV vaccine?

Yes. Dr. Robert Rose at University of Rochester was a member of one of 4 teams that contributed to the development of a vaccine against HPV. The grant he received from the American Cancer Society in the mid-1990s enabled him to continue and confirm his important work studying the virus.

Is the HPV vaccine safe?

Before it was approved, the HPV vaccine was tested in thousands of people in many countries around the world. There were no serious side effects. The most common side effect was brief soreness at the injection site. The FDA determined that the vaccine is safe and effective for females aged 9 to 26 years.

By 2008, more than 8 million girls and women had received the vaccine. The Centers for Disease Control and Prevention (CDC) and the FDA monitor the safety of all U.S. vaccines. As of April 30, 2008, the Vaccine Adverse Event Reporting System (VAERS), a national reporting system that monitors reports of potential side effects following vaccination, had received a total of 7,802 reports of potential side effects following HPV vaccination. Less than 7 percent of those reports were serious side effects, about half of the average for vaccines overall.

There have been 15 reports of sudden death after vaccination. The CDC says after careful review of the 10 reports that had adequate information for analysis, CDC could not establish the causal relationship between vaccination and death.

In addition, there had been 31 reports of Guillain-Barré Syndrome (GBS) after Gardasil vaccination in the U.S, ten of which had been confirmed as GBS. Of those 10, 5 reported vaccination with Menactra, a vaccine against meningitis, at the same time. Of the remaining 21 reports, 7 did not meet the case definition for GBS, one had symptoms of GBS prior to vaccination, 4 were unconfirmed reports, and 9 were pending additional follow-up. The CDC says the number of GBS cases reported are within the range that could be expected to occur by chance alone after a vaccination. CDC and FDA physicians and scientists continue to

review all reports of serious side effects reported to VAERS to identify potential new vaccine safety concerns that may need further study. The American Cancer Society continues to monitor those reviews to ensure the safety of those who receive the vaccine, which has the potential to prevent the majority of the cases and deaths of cervical cancer.

Who should be vaccinated and when?

To be most effective, the HPV vaccine should be given before a female becomes sexually active and in a series of 3 doses within 6 months.

- girls ages 11 to 12 The vaccine should be given to girls ages 11 to 12 and as early as age 9.
- girls ages 13 to 18 girls ages 13 to 18 who have not yet started the vaccine series or who have started but have not completed the series should be vaccinated.
- young women ages 19 to 26

Some authorities recommend vaccination of women ages 19 to 26, but the American Cancer Society experts felt that there was not enough evidence of the benefit to recommend vaccination for all women in this age group. We do recommend that women ages 19 to 26 talk to their doctor or nurse about whether to get the vaccine based on their risk of previous HPV exposure and potential benefit from the vaccine.

What about women over 26 years of age? Should they get the vaccine?

Women over 26 years of age were not included in the studies that were done to test the vaccine. Therefore, the FDA could not approve the vaccine for this age group. Studies are now being done in women ages 27 to 55. When those study results are known, a decision can be made regarding vaccination in this age group.

Keep in mind that the risk of HPV exposure is highest soon after women become sexually active. Therefore, it is likely that women over 26 have already been exposed to HPV and would not benefit as much from the vaccine.

Are there some girls or women who should not get the HPV vaccine or who should wait?

Yes. Anyone who has ever had a life-threatening allergic reaction to yeast or any other component of the HPV vaccine, or anyone who has had a reaction to a previous dose of HPV vaccine should not get the vaccine. Tell your doctor if the girl getting the vaccine has any severe allergies.

Pregnant women should not get the vaccine. The vaccine appears to be safe for both mother and the unborn baby, but it is still being studied. If a woman who is pregnant does receive the vaccine, this is not a reason to consider terminating the pregnancy. Women who are breast-feeding may safely get the vaccine.

Any woman who finds out that she was pregnant when she got the vaccine is encouraged to call the HPV vaccine in pregnancy registry at 1-800-986-8999. Information from this registry will help us learn how pregnant women respond to the vaccine. Pregnant women who have started the vaccine series should complete the series after their baby is born.

Why does the vaccine have to be given at such a young age?

The vaccine will prevent HPV only if it is given before a girl has been exposed to HPV. The vaccine is recommended for girls ages 11 to 12 because most girls at this age have not become sexually active. This is also an age when girls will be seeing their doctor and getting other vaccinations.

Can boys get this vaccine?

Not at this time. Boys were included in part of the studies to see if the vaccine was safe in boys and to see if boys' immune systems responded to the vaccine. The vaccine was found to be safe and the boys' immune systems did respond to the vaccine. It is not known at this time if the vaccine will protect boys from genital warts or from passing HPV to their partners, which would also reduce cervical cancer. Studies are being done to find out if the vaccine will prevent HPV infection and genital warts in boys.

What are the benefits of the vaccine?

The vaccine will prevent 2 types of HPV that cause most cervical cancers (about 70%) and 2 types of HPV that cause most genital warts (about 90%) in women who have not been exposed to these types of HPV. It also helps prevent vulvar and vaginal cancers related to these 2 types of HPV. The vaccine will not prevent HPV in women who have already had these HPV types.

It is possible that the vaccine also could prevent some other HPV-related cancers, including some cancers of the anus, as well as some head and neck cancers. It will be some years before it can be proven to prevent these cancers.

How long will the vaccine prevent HPV infection?

How long a new vaccine protects people is never known when the vaccine is first introduced. Research is being done to find out how long protection against HPV will last, and if a booster vaccine will be needed.

How much does the HPV vaccine cost? Will it be covered by health insurance plans?

The drug company price is $120 per dose. This cost does not include the cost of giving the injections or the doctor's charge. So it is possible that the cost for the series (3 shots over 6 months) could be as much as $500 or more. Insurance plans will likely cover the cost. Check with your insurance plan.

The vaccination is included in the federal Vaccine for Children (VFC) entitlement program, which covers vaccine costs for children and teens who do not have insurance and for some children and teens who are underinsured. The VFC program provides free vaccines to children and adolescents younger than 19 years of age, who are either Medicaid-eligible, American Indian or Alaska Native, or uninsured. There are over 45,000 sites that provide VFC vaccines, including hospitals and private and public clinics. The VFC program also allows children and adolescents to get VFC vaccines through federally qualified health centers or rural health centers if their private health insurance does not cover vaccinations. For more information about the VFC program, visit http://www.cdc.gov/nip/vfc/Default.htm. Or call 1-800-CDC-Info (1-800-232-4636).

Some states have programs that will cover the vaccine costs.

Do you need to be tested for HPV before getting the vaccine?

No. Testing is not needed and it is not recommended. A positive HPV test result does not tell you which types of HPV are present. Even after infection with one type of HPV, the vaccine could still prevent the other types of HPV. A negative test does not tell you if you have had HPV but no longer have it.

Will women and girls who have been vaccinated still need Pap tests?

Yes. People who get vaccinated will still need Pap tests because the vaccine will not prevent all types of HPV that can cause cervical cancer. If your daughter or granddaughter receives the vaccine, she will still need to have Pap tests at the appropriate age.

If girls who are vaccinated will still need a Pap test, why should they get vaccinated?

The vaccine will actually prevent about 70% of cervical cancers from ever occurring. Those who have had the HPV vaccine can actually avoid cervix cell changes caused by HPV. The Pap test does not prevent the cervix cells from changing -- it can pick up changes in the cervix before they can become cervical cancer. This means that if a woman has an abnormal Pap test, she will have other tests and then treatment. Also, Pap tests are not perfect and can miss cervical changes and cancers. The vaccine will be helpful to those women who are unable to stay up to date on their Pap tests due to loss of health insurance or other reasons.

Can cervical cancer be prevented without a vaccine?

In some cases, yes. Pap tests done according to American Cancer Society guidelines and with proper follow up will prevent most but not all cases of cervical cancer. Pap tests can find cervix cell changes early before they become cervical cancer. These cervix cell changes can then be treated to prevent them from becoming cancer. The Pap test will find most but not all cervical cancers at an early, curable stage. Most cervical cancers in the United States are diagnosed in women who have never had a Pap test, or who haven't had a Pap test in 5 or more years.

If all sexually active women had regular Pap tests, most cervical cancers could be prevented by finding cervical cell changes early and treating them to prevent them from becoming cervical cancer.

Is the American Cancer Society in favor of vaccinating against HPV?

Yes. The Society is very much in favor of vaccinating against HPV. The Society will be actively involved in providing credible and unbiased information to the public and to health care providers, with an emphasis on the continued need to follow screening guidelines, such as getting regular Pap tests; and on the critical need to ensure that the vaccine is available to the medically underserved.

What is the American Cancer Society doing to promote the vaccine's use?

The Society is engaged in an active public education effort to ensure broad public awareness and acceptance of the new vaccine, recognizing the importance of building and sustaining the infrastructure to support successful implementation of the vaccine program.

Do you want more information?

For more information on cervical cancer, HPV, HPV testing, and the HPV vaccine, please call the American Cancer Society anytime, day or night, at 1-800-ACS-2345 or visit our Web site at www.cancer.org.

For more information on the HPV vaccine from the Centers for Disease Control (CDC), visit http://www.cdc.gov/Features/HPV.

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