



HPV Vaccines

What is HPV?

HPV is short for *human papilloma virus*. HPVs are a group of more than 150 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. But some types of HPV are known for causing cancer, especially of the cervix (the base of the womb at the top of the vagina).

The papilloma viruses are attracted to and are able to live only in certain cells in the body called squamous epithelial cells. These cells are found on the surface of the skin and on moist surfaces (called *mucosal surfaces*) like:

- the vagina, anus, cervix, vulva (around the outside of the vagina)
- the inner foreskin and urethra of the penis
- inner nose, mouth, throat
- trachea (the main breathing tube), bronchi (smaller breathing tubes branching off the trachea)
- the inner eyelids

Of the more than 150 known strains, about 3 out of 4 (75%) HPV types cause warts on the skin – often on the arms, chest, hands, and feet. These are common warts; they are not the genital type of wart.

The other 25% of the HPV types are considered mucosal types of HPV. “Mucosal” refers to the body’s mucous membranes, or the moist surface layers that line organs and cavities of the body that open to the outside. For example, the mouth, vagina, and anus have this moist mucosal layer. The mucosal HPV types are also called the *genital* (or *anogenital*) type HPVs because they often affect the anal and genital area.

Can a vaccine help prevent HPV?

Yes. Vaccines are available to help prevent infection by certain types of HPV and some of the cancers linked to those types: Gardasil[®], Gardasil 9[®], and Cervarix[®]. All of these vaccines help prevent infection by HPV-16 and HPV-18. These types cause 70% of all

cervical cancers and pre-cancers, as well as many cancers of the anus, vulva, vagina, and throat.

Gardasil also helps prevent infection by the 2 types of HPV (HPV-6 and HPV-11) that cause 90% of all genital warts.

Gardasil 9 helps prevent infection with the same 4 types of HPV as Gardasil, plus 5 other high risk types: 31, 33, 45, 52 and 58.

Cervarix may also provide some protection against some high-risk types of HPV besides 16 and 18.

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

Yes. Dr. Robert Rose at the University of Rochester was a member of 1 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.

Are the HPV vaccines safe?

Based on approval by the FDA, Gardasil and Gardasil 9 are safe for females ages 9 to 26 years, while Cervarix is safe for females ages 9 to 25 years.

Based on FDA approval, Gardasil is also safe for males ages 9 through 26 years, while Gardasil 9 is safe for males aged 9 through 15. Boys and young men may choose to get one of these vaccines to prevent anal cancer and genital warts.

All of the HPV vaccines were tested in thousands of people around the world before they were approved. These studies showed no serious side effects and no deaths have been linked to either vaccine. Common, mild side effects include pain where the shot was given, fever, dizziness, and nausea.

People may faint after getting any vaccine, including HPV vaccines. Fainting after getting a shot is more common in teens than in young children or adults. To keep people from getting hurt from fainting, a 15-minute waiting period for people of all ages is recommended after any vaccination.

All of the HPV vaccines are monitored for side effects, especially rare ones not seen in the study trials, even those approved several years ago. CDC and FDA doctors and scientists still review all reports of serious side effects reported to the Vaccine Adverse Event Reporting System (VAERS) to watch for potential new vaccine safety concerns that may need further study. (The VAERS is a national reporting system that looks at reports of side effects after vaccinations.) The American Cancer Society will watch those reviews and report any concerns about the safety of the vaccines.

Who should be vaccinated against HPV and when?

To work best, the HPV vaccine should be given before any type of sexual contact with another person. The vaccines are given as shots in a series of 3 doses within 6 months.

The American Cancer Society's recommendations for each age group

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 a 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. The American Cancer Society feels that there is not enough evidence of benefit to recommend vaccinating 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. This decision should be made after talking about their chance of previous HPV exposure and potential benefit from the vaccine.

Boys and young men

The American Cancer Society has no recommendation regarding the use of HPV vaccines in males. See the question below, "Can boys get the vaccine?"

Why do the vaccines have to be given at such a young age?

These vaccines will prevent the covered types of HPV only if they are given before exposure to the virus. According to the CDC, in 2011:

- About half of girls in high school have had vaginal sex.
- About 3% of high school students said they first had vaginal sex before age 13.

The vaccines are recommended for girls ages 11 to 12 because most girls at this age have not become sexually active. If they have been sexually active, most girls are likely have been exposed to only 1 or 2 types, so the vaccine will be partially protective. This is also an age when girls will still be seeing their doctors and getting other vaccinations.

What about women older than 26? Should they get one of the vaccines?

Women over age 26 were not included in the first studies that were done to test the vaccines. This means the FDA could not approve the vaccines for this age group. Since that time, the use of Gardasil in women between 27 and 45 has been studied. It was found that the vaccine helped protect against infection and disease from the HPV types contained in the vaccine. It only helped the women who weren't infected with those HPV types before vaccination. Because the risk of infection and disease from HPV is low in this age group, the vaccine didn't seem to benefit many women. When the FDA reviewed the data, it concluded that the vaccine didn't help enough women to justify giving it to all women up to age 45.

Are there any girls or women who should not get one of the HPV vaccines or who should wait?

Yes. Anyone with a severe allergy to latex should not get the Cervarix vaccine, and those with a severe allergy to yeast should not receive Gardasil or Gardasil 9. These vaccines should also not be given to anyone who has ever had a life-threatening allergic reaction to anything else contained in them, or anyone who has had a serious reaction to an earlier dose of HPV vaccine. Tell the doctor if the girl getting the vaccine has any severe allergies.

Pregnant women should not get any HPV vaccine at this time. Even though they appear to be safe for both mother and the unborn baby, this is still being studied. If a woman who is pregnant does get an HPV vaccine, it's not a reason to consider ending the pregnancy. Women who are breastfeeding may safely get either vaccine.

Any woman who finds out that she was pregnant when she got the vaccine is encouraged to call the Gardasil vaccine in pregnancy registry at 1-800-986-8999 or the Cervarix vaccine in pregnancy registry at 1-888-452-9622. Information from these registries will help doctors and scientists learn about pregnancy and infant outcomes after exposure to the vaccine. Women who started a vaccine series before they learned they were pregnant should complete the series after the pregnancy.

Can boys get the vaccine?

Yes. The FDA approved Gardasil and Gardasil 9 to protect boys from certain anal cancers and pre-cancers as well as to prevent anal and genital warts. These vaccine should be given before sexual activity begins, but are approved for different age ranges. Gardasil is approved for ages 9 to 26, while Gardasil 9 is approved for ages 9 to 15.

It's not yet known if these vaccine will keep boys from passing HPV to their partners. If they do, this will also reduce the risk of HPV-linked cancers in their sexual partners.

In 2011, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention recommended that boys and young men receive the

Gardasil vaccine routinely. The committee recommended that boys ages 11 and 12 be vaccinated. It also recommended vaccination of males ages 13 through 21 who had not already had all 3 shots. Vaccinations may also be given to boys as young as 9 and to men between the ages of 22 and 26. Gardasil 9 was not approved until late 2014, and so is not covered by these recommendations. ACIP is expected to release guidelines for Gardasil 9 in 2015.

The American Cancer Society has no recommendation about the use of any HPV vaccine in males at this time. The evidence for the use of HPV vaccines in males is being reviewed and updates to the American Cancer Society recommendations for the use of HPV vaccines will likely be published in 2015.

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

No. Testing is not needed and it's not recommended. A positive HPV test result doesn't always tell you which types of HPV are present. And even after infection with one type of HPV, the vaccine could still prevent other types of HPV infection. A negative test cannot tell you if you've had HPV in the past.

How long will the vaccines prevent HPV infection?

How long a new vaccine protects people is never known when the vaccine is first introduced. Current research (which includes about 6 years of follow-up data) shows that the vaccines are effective, and there's no sign that the protection decreases with time. Research will continue to find out how long protection against HPV lasts, and if booster vaccines will be needed.

What are the benefits of the HPV vaccines?

All the HPV vaccines help prevent infection by the HPV types 16 and 18, and can help prevent cervical cancer.

Gardasil and Gardasil 9 have been shown to prevent anal, vulvar, and vaginal cancers and pre-cancers linked to these 2 types of HPV. They also help prevent genital and anal warts by preventing infection with HPV types 6 and 11. Gardasil 9 also protects against 5 other high-risk types of HPV (31, 33, 45, 52 and 58) and so provides additional protection against cancers caused by these types of HPV.

Cervarix also seems to offer protection against some other high-risk types. It has also been found to help protect against HPV infection of the mouth and throat and the anus. Although in theory it could help protect against cancers caused by HPV besides cervical cancer, so far that hasn't been shown in studies.

The vaccines only work in people who have not already been exposed to these types of HPV. The vaccines will not prevent HPV in those who have already had these HPV types.

It's possible that the vaccines could also prevent some other HPV-related cancers, including some cancers of the penis and head and neck areas. It will be some time before studies can prove whether they will help prevent these cancers.

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

Yes. The Society has been involved in providing reliable and unbiased information to the public and to health care providers. The Society emphasizes the ongoing need to follow screening guidelines, such as getting regular Pap tests and HPV tests to find cervical cancers and pre-cancers early, and the critical need to ensure that the vaccines are available to the medically underserved.

How much do the HPV vaccines cost? Are they covered by health insurance plans?

The drug company price for either vaccine is around \$130 or \$140 per dose. This cost does not include the cost of giving the shots or the doctor's charge. So, it's possible that the cost for the series (3 shots over 6 months) could be \$500 or more. Insurance plans will probably cover the cost if the vaccine is given according to national guidelines. But check with your insurance plan to be sure.

The vaccines are included in the federal Vaccines for Children (VFC) program. This program covers vaccine costs for children and teens who don't have insurance and for some children and teens who are underinsured. The VFC program provides free vaccines to children and teens younger than 19 years of age, who are either Medicaid-eligible, American Indian or Alaska Native, or uninsured.

There are over 44,000 sites nationwide that provide VFC vaccines, including hospitals and private and public clinics. The VFC program also allows children and teens to get VFC vaccines through federally qualified health centers or rural health centers if their private health insurance does not cover vaccinations. For more on the VFC program or to find the VFC contact where you live, visit www.cdc.gov/vaccines/programs/vfc/contacts-state.html, or call 1-800-232-4636 (1-800-CDC-INFO).

Do women who have been vaccinated against HPV still need Pap tests?

Yes. Females who get vaccinated will still need to be tested regularly for cervical cancer because the vaccines do not prevent all types of HPV that can cause cervical cancer. If your daughter or granddaughter gets the vaccine, she will still need to have Pap tests at the scheduled times to check for cervical cancer.

See *Cervical Cancer: Prevention and Early Detection* for the American Cancer Society's screening guidelines.

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

Even though Pap tests are needed, the vaccines can prevent about 70% of cervical cancers. But there are still other types of HPV that can cause changes in the cervix cells. The Pap test does not keep these cells in the cervix from changing – but it can find them before they become cervical cancer. This means that if a woman has an abnormal Pap test, she will have other tests done and then treatment to keep the changed cells from becoming cancer. But because of the vaccine, many women won't have any abnormal cervical cancer screening tests, and won't need further tests and treatment for cervical cancer or pre-cancer.

Can cervical cancer be prevented without a HPV vaccine?

In most cases, yes, cervical cancer can be prevented even without a vaccine. Cervical cancer screening done according to American Cancer Society guidelines and with proper follow up will prevent most but not all cases of cervical cancer. Pap tests (with or without the HPV test) can find cervix cell changes early, before they become cervical cancer. These changed cervix cells can then be treated to keep them from becoming cancer.

When cancer screening guidelines are followed most, but not all, cervical cancers are found at an early enough stage that they are easily cured. 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 many years.

To learn more about the American Cancer Society's screening guidelines, see *Cervical Cancer: Prevention and Early Detection*.

To learn more

From your American Cancer Society

American Cancer Society Recommendations for Human Papilloma Virus (HPV) Vaccine Use to Prevent Cervical Cancer and Pre-Cancers (also in Spanish)

HPV Vaccine, Bivalent

HPV Vaccine, Quadrivalent

HPV and HPV Testing

What Women Should Know About Cervical Cancer and the Human Papilloma Virus

HPV and Cancer

Other organizations

The Centers for Disease Control and Prevention (CDC)

Toll-free number: 1-800-232-4636 (1-800-CDC-INFO)

Website: www.cdc.gov/vaccines/vpd-vac/hpv/default.htm.

The US Food and Drug Administration (FDA)

Toll-free number: 1-888-463-6332

Website:

www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm172678.htm

No matter who you are, we can help. Contact us anytime, day or night, for information and support. Call us at **1-800-227-2345** or visit www.cancer.org.

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