



HPV Vaccine Questions & Answers

In June 2006, the Advisory Committee on Immunization Practices (ACIP) voted to recommend 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®, protects against four HPV types, which together cause 70% of cervical cancers and 90% of genital warts.

The Food and Drug Administration (FDA) recently licensed this vaccine for use in girls/women, ages 9-26 years. The vaccine is given through a series of three shots over a six-month period.

WHO SHOULD GET THIS VACCINE

The HPV vaccine is recommended for 11-12 year-old girls, and can be given to girls as young as 9. The vaccine is also recommended for 13-26 year-old girls/women who have not yet received or completed the vaccine series.

These recommendations have been proposed by the ACIP—a national group of experts that advises the Centers for Disease Control and Prevention (CDC) on vaccine issues. These recommendations are now being considered by CDC.

Why is the HPV vaccine recommended for such young girls?
Ideally, females should get the vaccine before they are sexually active. 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.

Will sexually active females benefit from the vaccine?
Females who are sexually active may also benefit from the vaccine. But they may get less benefit from the vaccine since they may have already acquired one or more HPV type(s) covered by the vaccine. Few young women are infected with all four of these HPV types. So they would still get protection from those types they have not acquired. Currently, there is no test available to tell if a girl/woman has had any or all of these four HPV types.

Why is the HPV vaccine only recommended for girls/women ages 9 to 26?
The vaccine has been widely tested in 9-to-26 year-old girls/women. But research on the vaccine's safety and efficacy has only recently begun with women older than 26 years of age. 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 boys?
We do not yet know if the vaccine is effective in boys or men. It is possible that vaccinating males will have health benefits for them by preventing genital warts and rare cancers, such as penile and anal cancer. It is also possible that vaccinating boys/men will have indirect health benefits for girls/women. 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 boys/men as well.

Should pregnant women get the vaccine?
The vaccine is not recommended for pregnant women. There has been limited research looking at vaccine safety for pregnant women and their unborn babies. So far, studies suggest that the vaccine has not caused health problems during pregnancy, nor has it caused health problems for the infant-- but more research is still needed. For now, pregnant women should complete their pregnancy before getting the vaccine. If a woman finds out she is pregnant after she has started getting the vaccine series, she should complete her pregnancy before finishing the three-dose series.

EFFICACY OF THE HPV VACCINE



Studies have found the vaccine to be almost 100% effective in preventing diseases caused by the four HPV types covered by the vaccine— including precancers of the cervix, vulva and vagina, and genital warts. The vaccine has mainly been studied in young women who had not been exposed to any of the four HPV types in the vaccine.

The vaccine was less effective in young women who had already been exposed to one of the HPV types covered by the vaccine.

This vaccine does not treat existing HPV infections, genital warts, precancers or cancers.

How long does vaccine protection last? Will a booster shot be needed?
The length of vaccine protection (immunity) is usually not known when a vaccine is first introduced. So far, studies have followed women for five years and found that women are still protected. More research is being done to find out how long protection will last, and if a booster vaccine is needed years later.

What does the vaccine not protect against?
Because the vaccine does not protect against *all* types of HPV, it will not prevent all cases of cervical cancer or genital warts. About 30% of cervical cancers will *not* be prevented by the vaccine, so it will be important for women to continue getting screened for cervical cancer (regular Pap tests). Also, the vaccine does *not* prevent about 10% of genital warts—nor will it prevent other sexually transmitted infections (STIs). So it will still be important for sexually active adults to reduce exposure to HPV and other STIs.

Will girls/women be protected against HPV and related diseases, even if they don't get all 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 girls/women get *all three doses* of the vaccine.

SAFETY OF THE HPV VACCINE



The FDA has licensed the HPV vaccine as safe and effective. This vaccine has been tested in over 11,000 females (ages 9-26 years) around the world. These studies have shown no serious side effects. The most common side effect is soreness at the injection site. CDC, working with the FDA, will continue to monitor the safety of the vaccine after it is in general use.

Does this vaccine contain thimerosal or mercury?
No. There is no thimerosal or mercury in the HPV vaccine. It is made up of proteins from the outer coat of the virus (HPV). There is no infectious material in this vaccine.

COST AND COVERAGE OF THE HPV VACCINE

The retail price of the vaccine is \$120 per dose (\$360 for full series).

Will the HPV vaccine be covered by insurance plans?
While some insurance companies may cover the vaccine, others may not. Most large insurance plans usually cover the costs of recommended vaccines. However, there is often a short lag-time after a vaccine is recommended, before it is available and covered by health plans.

What kind of government programs may be available to cover HPV vaccine?
Federal health programs such as *Vaccines for Children* (VFC) will cover the HPV vaccine. The VFC program provides free vaccines to children and teens under 19 years of age, who are either uninsured, Medicaid-eligible, American Indian, or Alaska Native. There are over 45,000 sites that provide VFC vaccines, including hospitals, private clinics, 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 the vaccine. For more information about the VFC, visit www.cdc.gov/nip/vfc/Default.htm

Some states also provide free or low-cost vaccines at public health department clinics to people without health insurance coverage for vaccines.

WHAT VACCINATED GIRLS/WOMEN NEED TO KNOW



The HPV vaccine is given through a series of three shots over a 6-month period. The second and third doses should be given 2 and 6 months (respectively) after the first dose.

Will girls/women who have been vaccinated still need cervical cancer screening?

Yes. There are three reasons why women will still need regular cervical cancer screening. First, the vaccine will NOT protect against all types of HPV that cause cervical cancer, so vaccinated women will still be at risk for some cancers. Second, some women may not get all required doses of the vaccine (or they may not get them at the right times), so they may not get the vaccine's full benefits. Third, women may not get the full benefit of the vaccine if they receive it after they've already acquired one of the four HPV types.

Should girls/women 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 girls/women with one HPV type could get protection from the other vaccine HPV types they have not yet acquired.

Will girls be required to get vaccinated before they enter school?

There are no federal laws that require children or adolescents to get vaccinated. All school and daycare entry laws are state laws—so they vary from state to state. To find out what vaccines are needed for children or teens to enter school or daycare in your state, check with your state health department or board of education.



THE BASICS ABOUT HPV AND CERVICAL CANCER

Genital HPV is a common virus that is passed on through genital contact, most often during vaginal and anal sex. About

40 types of HPV can infect the genital areas of men and women. While most HPV types cause no symptoms and go away on their own, some types can cause cervical cancer in women. These types also have been linked to other less common genital cancers— including cancers of the anus, vagina, and vulva (area around the opening of the vagina). Other types of HPV can cause warts in the genital areas of men and women, called genital warts.

How is HPV related to cervical cancer?

Some types of HPV can infect a woman's cervix (lower part of the womb) and cause the cells to change. Most of the time, HPV goes away on its own. When HPV is gone, the cervix cells go back to normal. But sometimes, HPV does not go away. Instead, it lingers (persists) and continues to change the cells on a woman's cervix. These cell changes (or "precancers") can lead to cancer over time, if they are not treated.

How common is HPV?

At least 50% of sexually active people will get HPV at some time in their lives. Every year in the United States (U.S.), about 6.2 million people get HPV. HPV is most common in young women and men who are in their late teens and early 20s.

Anyone who has ever had genital contact with another person can get HPV. Both men and women can get it – and pass it on to their sex partners- without even realizing it.

How common is cervical cancer in the U.S.? How many women die from it?

The American Cancer Society estimates that in 2006, over 9,700 women will be diagnosed with cervical cancer and 3,700 women will die from this cancer in the U.S.

How common are Genital Warts?

About 1% of sexually active adults in the U.S. (about 1 million people) have visible genital warts at any point in time.

Is HPV the same thing as HIV or Herpes?

HPV is NOT the same as HIV or Herpes (Herpes simplex virus or HSV). While these are all viruses that can be sexually transmitted— HIV and HSV do not cause the same symptoms or health problems as HPV.

Can HPV and its associated diseases be treated?

There is no treatment for HPV. But 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.

OTHER WAYS TO PREVENT CERVICAL CANCER AND HPV

Another HPV vaccine is in the final stages of clinical testing, but it is not yet licensed. This vaccine would protect against the two types of HPV that cause most (70%) cervical cancers.

Are there other ways to prevent cervical cancer?

Regular Pap tests and follow-up can prevent most, but not all, cases of cervical cancer. Pap tests can detect cell changes in the cervix *before* they turn into cancer. Pap tests can also detect most, but not all, cervical cancers at an early, curable stage. Most women diagnosed with cervical cancer in the U.S. have either never had a Pap test, or have not had a Pap test in the last 5 years.

There is also an HPV DNA test available for use with the Pap test, as part of cervical cancer screening. This test is used for women over 30 or for women who get an unclear (borderline) Pap test result. While this test can tell if a woman has HPV on her cervix, it cannot tell *which* types of HPV she has.

Are there other ways to prevent HPV?

The only sure way to prevent HPV is to abstain from all sexual activity. Sexually active adults can reduce their risk by being in a mutually faithful relationship with someone who has had no other or few sex partners, or by limiting their number of sex partners. But even persons with only one lifetime sex partner can get HPV, if their partner has had previous 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. They can also reduce the risk of HIV and some other STIs, when used all the time and the right way.

WHERE CAN I GET MORE INFORMATION?

CDC HPV Information - <http://www.cdc.gov/std/hpv/>
Order Publications at <http://www.cdc.gov/std/pubs/>

STD information and referrals to STD Clinics
CDC-INFO
1-800-CDC-INFO (800-232-4636)
TTY: 1-888-232-6348
In English, en Español

American Cancer Society (ACS) - <http://www.cancer.org>

American Social Health Association (ASHA) - www.ashastd.org
P. O. Box 13827
Research Triangle Park, NC 27709-3827
1-800-783-9877

Printable versions of this and other STD fact sheets are available at: www.cdc.gov/std/healthcomm/fact_sheets.htm



August 2006

