

Preventing
Cervical Cancer:

What Parents and Their Teens Should Know





ne of the most promising recent research developments in the fight against cancer has been the development and approval of a vaccine to fight the human papillomavirus (HPV) that causes cancer of the cervix in women.

“Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States,” state Richard E. Rupp, M.D., and Susan L. Rosenthal, Ph.D. in a recent clinical guide for pediatricians. “The vast majority of infections go unrecognized, but HPV is now implicated as a causative agent in more than 99 percent of cervical cancer cases.”

The Recommended Immunization Schedule for 2007 indicates that all adolescent girls should get a series of three HPV shots, preferably at age 11 to 12 years, to prevent cervical cancer and genital warts.

A new vaccine promises to virtually eliminate the virus that causes most cervical cancer in women. Talk to your pediatrician about this new HPV vaccine and your child.

The vaccine also is recommended for all females aged 13 to 26 years who have not yet been vaccinated.

Worldwide, cervical cancer is the third most common type of cancer in women, although less common in the United States because of routine use of Pap smears to screen for early stages of the cancer. Cervical cancers start in the cells on the surface of the cervix. The development of cervical cancer is very slow. It starts as a pre-cancerous condition called dysplasia. This pre-cancerous condition can be detected by a Pap smear and is 100 percent treatable. That is why it is so important for women to get regular Pap smears. Most women who are diagnosed with cervical cancer today have

not had regular Pap smears or they have not followed up on abnormal results.

Undetected, pre-cancerous changes can develop into cervical cancer and spread to the bladder, intestines, lungs, and liver. It can take years for pre-cancerous changes to turn into cervical cancer. Patients with cervical cancer do not usually have problems until the cancer is advanced and has spread.

Although a number of observers have been concerned that some parents might be reluctant to accept the new HPV vaccines because of their connection to sexual activity, Rupp and Rosenthal note that research indicates otherwise.

“Once educated about HPV, the majority of parents are interested in these vaccines for their children,” they state. “Thus, if parents are provided with accurate information in a calm and reassuring way, there is unlikely to be resistance to immunizing their children with a highly effective vaccine against a potentially devastating disease.”

[NOTE: For more detailed answers to questions about HPV vaccine, please read the Q&A information from the Centers for Disease Control and Prevention (CDC) on the following page.]

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. 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. 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.

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?

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.

Source: Centers for Disease Control and Prevention

THE POWER TO HELP PREVENT CERVICAL CANCER IS IN YOUR HANDS. AND ON YOUR DAUGHTER'S ARM.

A vaccine has been created for your daughter that may help protect her from 4 types of human papillomavirus. Those types may cause 70% of cervical cancer and 90% of genital warts. GARDASIL will not treat cervical cancer and genital warts. GARDASIL works by reaching your daughter before the virus can—by protecting her.

GARDASIL is for girls and young women ages 9 to 26. This vaccine is part of your daughter's recommended vaccination schedule, but only her doctor can decide if GARDASIL is right for her. Ask your daughter's doctor or healthcare professional about getting her vaccinated with GARDASIL. She could become one less life affected by cervical cancer.

SELECT SAFETY INFORMATION

GARDASIL may not fully protect everyone and does not prevent all types of cervical cancer, so future cervical cancer screenings will be important for your daughter. Anyone who is allergic to the ingredients of GARDASIL should not receive the vaccine, and GARDASIL is not for women who are pregnant. GARDASIL is given as 3 injections over 6 months and can cause pain, itching, swelling and redness at the injection site, fever, nausea, and dizziness.

Please see Patient Information on the next page.



GARDASIL[®]
[Quadrivalent Human Papillomavirus
(Types 6, 11, 16, 18) Recombinant Vaccine]

1-800-GARDASIL GARDASIL.com

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**Patient Information about
GARDASIL® (pronounced "gard-Ah-sill")**

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Generic name: [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine]

Read this information with care before you or your child gets GARDASIL®. You or your child will need 3 doses of the vaccine. It is important to read this leaflet when you receive each dose. This leaflet does not take the place of talking with your health care professional about GARDASIL.

What is GARDASIL and what is it used for?

GARDASIL is a vaccine (injection/shot) that helps protect against the following diseases caused by Human Papillomavirus (HPV) Types in the vaccine (6, 11, 16, and 18):

- Cervical cancer (cancer of the lower end of the uterus or womb).
- Abnormal and precancerous cervical lesions.
- Abnormal and precancerous vaginal lesions.
- Abnormal and precancerous vulvar lesions.
- Genital warts.

GARDASIL helps prevent these diseases – but it will not treat them.

You or your child cannot get these diseases from GARDASIL.

What other key information about GARDASIL should I know?

- Vaccination does not substitute for routine cervical cancer screening. Females who receive GARDASIL should continue cervical cancer screening.
- As with all vaccines, GARDASIL may not fully protect everyone who gets the vaccine.
- GARDASIL will not protect against diseases due to non-vaccine HPV types. There are more than 100 HPV types; GARDASIL helps protect against 4 types (6, 11, 16, and 18). These 4 types have been selected for GARDASIL because they cause approximately 70% of cervical cancers and 90% of genital warts.
- This vaccine will not protect you against HPV types to which you may have already been exposed.
- GARDASIL also will not protect against other diseases that are not caused by HPV.
- GARDASIL works best when given before you or your child has any contact with certain types of HPV (i.e., HPV types 6, 11, 16, and 18).

Who can receive GARDASIL?

GARDASIL is for girls and women 9 through 26 years of age.

See "Who should not receive GARDASIL?" below.

Who should not receive GARDASIL?

Anyone who:

- is allergic to any of the ingredients in the vaccine. A list of ingredients can be found at the end of this leaflet.
- has an allergic reaction after getting a dose of the vaccine.

What should I tell my health care professional before I am vaccinated or my child is vaccinated with GARDASIL?

It is very important to tell your health care professional if you or your child:

- has had an allergic reaction to the vaccine.
- has a bleeding disorder and cannot receive injections in the arm.
- has a weakened immune system, for example, due to a genetic defect or HIV infection.
- is pregnant or is planning to get pregnant. GARDASIL is not recommended for use in pregnant women.
- has any illness with a fever more than 100°F (37.8°C).
- takes or plans to take any medicines, even those you can buy over the counter.

Your health care professional will decide if you or your child should receive the vaccine.

How is GARDASIL given?

GARDASIL is given as an injection.

You or your child will receive 3 doses of the vaccine. Ideally the doses are given as:

- First dose: at a date you and your health care professional choose.
- Second dose: 2 months after the first dose.
- Third dose: 6 months after the first dose.

Make sure that you or your child gets all 3 doses. This allows you or your child to get the full benefits of GARDASIL. If you or your child misses a dose, your health care professional will decide when to give the missed dose.

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What are the possible side effects of GARDASIL?

As with all vaccines, there may be some side effects with GARDASIL. GARDASIL has been shown to be generally well tolerated in women and girls as young as 9 years of age.

The most commonly reported side effects included:

- pain, swelling, itching, and redness at the injection site.
- fever.
- nausea.
- dizziness.

Difficulty breathing (bronchospasm) has been reported very rarely.

If you or your child has any unusual or severe symptoms after receiving GARDASIL, contact your health care professional right away.

For a more complete list of side effects, ask your health care professional.

What are the ingredients in GARDASIL?

The main ingredients are purified inactive proteins that come from HPV Types 6, 11, 16, and 18.

It also contains amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, and water for injection.

What are cervical cancer, precancerous lesions, and genital warts?

Cancer of the cervix is a serious disease that can be life-threatening. This disease is caused by certain HPV types that can cause the cells in the lining of the cervix to change from normal to precancerous lesions. If these are not treated, they can turn cancerous.

Genital warts are caused by certain types of HPV. They often appear as skin-colored growths. They are found on the inside or outside of the genitals. They can hurt, itch, bleed, and cause discomfort. These lesions are usually not precancerous. Sometimes, it takes multiple treatments to eliminate these lesions.

What is Human Papillomavirus (HPV)?

HPV is a common virus. In 2005, the Centers for Disease Control and Prevention (CDC) estimated that 20 million people in the United States had this virus. There are many different types of HPV; some cause no harm. Others can cause diseases of the genital area. For most people the virus goes away on its own. When the virus does not go away it can develop into cervical cancer, precancerous lesions, or genital warts, depending on the HPV type. See "What other key information about GARDASIL should I know?"

Who is at risk for Human Papillomavirus?

In 2005, the CDC estimated that at least 50% of sexually active people catch HPV during their lifetime. A male or female of any age who takes part in any kind of sexual activity that involves genital contact is at risk.

Many people who have HPV may not show any signs or symptoms. This means that they can pass on the virus to others and not know it.

Will GARDASIL help me if I already have Human Papillomavirus?

You may benefit from GARDASIL if you already have HPV. This is because most people are not infected with all four types of HPV contained in the vaccine. In clinical trials, individuals with current or past infection with one or more vaccine-related HPV types prior to vaccination were protected from disease caused by the remaining vaccine HPV types. GARDASIL is not intended to be used for treatment for the above mentioned diseases. Talk to your health care professional for more information.

This leaflet is a summary of information about GARDASIL. If you would like more information, please talk to your health care professional or visit www.gardasil.com.

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