Gardasil®

Background

Gardasil® is the first vaccine developed to prevent cervical cancer and genital warts caused by a human papillomavirus (HPV). In June 2006, Gardasil® was licensed by the Food and Drug Administration (FDA). The Centers for Disease Control and Prevention and the FDA monitor the safety and effectiveness of the vaccine.

What is a human papillomavirus? An HPV is a common virus that is passed on through sexual contact. Most of the time, an HPV has no symptoms so people do not know they have it. There are many different strains or types of HPVs. Some types can cause cervical cancer in women and can also cause other kinds of cancer in both men and women. Other types of HPVs can cause genital warts in both males and females.
In most people, HPVs go away on their own and do not cause health problems. Experts do not know why HPVs go away in some cases, but not in others.

How common are HPVs? HPVs are the most common sexually transmitted infections in the United States, with about 20 million people currently infected. Women have an 80 percent chance of getting an HPV by the time they are 50. Every year in the United States, about 6.2 million people get a new HPV infection. HPVs are most common in young people who are in their late teens and early twenties.

How common is cervical cancer? The American Cancer Society estimates that in 2007 more than 11,000 women in the United States will be diagnosed with cervical cancer and approximately 3,600 will die from it.

What is the HPV vaccine? The vaccine Gardasil® is the first vaccine developed to prevent cervical cancer and genital warts from an HPV. It works by protecting against the four types of HPVs that most commonly cause these ailments. The vaccine is given as an injection into muscle in three doses. The vaccine is licensed by the FDA for girls and women ages 9 through 26.

How is the HPV vaccine made? Gardasil® is a recombinant protein that is produced by a strain of yeast that has been genetically engineered to produce virus-like particles (VLPs). The VLPs are similar enough to the actual human papillomavirus (which causes cervical cancer and genital warts) to cause your body to produce antibodies against it. The antibodies are then available to fight off the HPV if you are exposed to it at a later time. Because the VLPs are not an actual virus, they cannot cause any of the problems caused by an HPV, such as cervical cancer and genital warts.

Who should get the HPV vaccine? Doctors recommend this vaccine for 11- and 12-year-old girls. The vaccine can also be given to girls and women ages 13 through 26 who did not get the vaccine when they were younger or who did not complete the vaccination series.

Ideally, girls and women should get this vaccine before their first sexual contact when they could be exposed to the HPV. This timing is because the vaccine prevents disease in girls and women who have not previously acquired one or more types of HPVs prevented by the vaccine. It does not work as well for those who were exposed to the virus before getting the vaccine.

Is the HPV vaccine effective? This vaccine targets the types of HPVs that most commonly cause cervical cancer and genital warts. This vaccine is highly effective in preventing those types of HPVs in young women who have not been previously exposed to them. The vaccine will not treat existing HPV infections or existing diseases or conditions caused by HPVs. The vaccine will also not protect against diseases and infections caused by other HPV types that are not included in the vaccine.

Gardasil® (continued)

Is the HPV vaccine safe? The vaccine has been licensed as safe. Before it was approved by the FDA, the vaccine was studied in thousands of females ages 9 through 26 in the United States and around the world. The most common side effect is soreness at the injection site.

Are there other ways, besides the vaccine, to prevent HPV? The surest way to prevent genital HPVs is to avoid sexual contact. For individuals who are sexually active, condoms may lower their chances of getting an HPV, if used always and used correctly. Condoms may lower a person's chances of developing genital warts and cervical cancer. But an HPV can infect areas that are not covered by a condom–so condoms may not *fully* protect against HPVs.

Will girls and women be protected against HPVs and related diseases even if they don't get all three doses of the vaccine? The HPV vaccine is recommended as a three-dose vaccine. It is not yet known how much protection girls and women would receive if they get only one or two doses of the vaccine. For this reason, it is very important that they get all three doses of the vaccine.

Why is the vaccine indicated only for girls and women ages 9 through 26? The vaccine has been widely tested in females ages 9 through 26. But research on how well the vaccine works in older women has just recently begun. The FDA may license the vaccine for those women when research shows 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 being conducted to find out if the vaccine is effective in males. When more information is available, this vaccine may be licensed and recommended for boys and men as well.

Does the vaccine protect against other sexually transmitted diseases or pregnancy? No. Girls and women who have had all doses of this vaccine can still get other sexually transmitted diseases or get pregnant if they are sexually active.

Adapted from "HPV Vaccine–Questions & Answers for the Publicabout the Safety and Effectiveness of the Human Papillomavirus (HPV) Vaccine," Centers for Disease Control and Prevention, July 17, 2008, www.cdc.gov/vaccines/vpd-vac/hpv/hpv-vacsafe-effic.htm.