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Truth About the Human Papillomavirus Vaccine

The human papillomavirus (HPV) quadrivalent vaccine (Gardasil) was introduced to consumers in 2006. Administered as a series of 3 injections, it has been advertised as a method of preventing cervical cancer, and its use has grown in popularity.

HPVs have the ability to infect mucous membranes of the mouth, respiratory tract, anus, and genitals. There are over 100 different strains of HPV, and about 40 strains can put you at risk for developing cancer. These strains are transmitted through sexual contact with an infected partner. Over 90% of HPV infections clear up on their own within 2 years. However, in some patients, HPV may cause recurrent infections that can lead to genital warts or cancers of the cervix, vulva, vagina, or penis. Two strains, HPV 16 and 18, cause about 70% of cervical cancers worldwide. A routine Pap smear performed by your healthcare provider can identify changes in your cervix that might lead to cancer.

The HPV vaccine protects against 4 different kinds of HPV: strains 6, 11, 16, and 18. Strains 6 and 11 are common causes of genital warts, while strains 16 and 18 have been linked to cervical cancer. There is evidence that the vaccine may offer protection from precancerous changes related to strains 16 and 18. However, HPV strains 16 and 18 are responsible for only 1–8% of the 7.5 million HPV infections that occur in young women in the United States. Furthermore, most of these infections do not lead to cancer since over 90% heal on their own within 2 years.

Cancer of the cervix is the second leading cause of cancer death in women worldwide, but most deaths (over 80%) due to cervical cancer occur in developing countries. While HPV contributes to cervical cancer, the viruses alone are not sufficient to cause cancer. Other factors must also be present. Some of these risk factors include age of infection with HPV, number of sex partners, cigarette smoking, use of birth control pills, and infection with other sexually transmitted diseases.

FOR MORE INFORMATION

Centers for Disease Control and Prevention
www.cdc.gov/std/hpv/STDFact-HPV-vaccine-young-women.htm

Gardasil Vaccine Information Statement
www.immunize.org/vis/hpv.pdf

Medline Plus
www.nlm.nih.gov/medlineplus/hpv.html

Based on "The Human Papillomavirus Quadrivalent Vaccine: A Look Behind the Numbers" by Dennis K Flaherty and Fadi M Alkhateeb, ***The Annals of Pharmacotherapy***, **April 2009**, http://dx.doi.org/10.1345/aph.1L483. **For Our Patients** is provided by ***The Annals*** to help explain the latest research and information relating to your medications. These summaries are for informational purposes only and are not a substitute for professional advice from your personal medical provider. If you have questions about this material, you should discuss it with your physician or pharmacist.
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In clinical studies that were conducted for FDA approval of the HPV vaccine, the shots were 95–100% effective at preventing genital warts, but the studies were conducted for only 3 years—too short a time to determine whether the vaccine can truly prevent cervical cancer. In addition, when the vaccine was used by women in the general public, the vaccine reduced the incidence of precancerous changes by only 62% and the vaccine was 80% less effective in preventing genital warts compared to the earlier studies.

While the vaccine has been demonstrated to be safe in girls aged 9–15 years, the effectiveness of the shots has not been evaluated within this age group. Although the vaccine does protect against the 2 strains (HPV 16 and 18) that most commonly cause cervical cancer, it does so only among women who have not yet been exposed to these viruses. In addition, there are 21 other HPV strains that cause 30% of cervical cancers; these strains are not included in the vaccine, so the vaccine will not provide any protection against them. Finally, the length of protection offered by the vaccine is not known at this time.

An additional set of limitations to the vaccine involve storage, delivery, and cost. To be fully vaccinated against the 4 HPV strains, multiple shots are needed. The logistics of delivering multiple injections to healthy adolescents are challenging. The vaccine must also be stored in a refrigerated environment at all times. This limits the usefulness of the vaccine among women in developing countries, where death rates associated with cervical cancer are the highest. Furthermore, the full series of shots costs $250–350.

Regarding safety, nearly 10,000 adverse events have been reported with the vaccine. While most of these problems involved swelling or pain at the injection site, 4% of adverse events have been serious, including fainting, seizures, Guillain-Barre syndrome (a severe form of muscle paralysis that can affect the ability to breathe), and 21 deaths.

Currently, the Centers for Disease Control and Prevention recommends that girls aged 11–12 years be vaccinated (it is also safe in girls aged 9–10 years), as well as women aged 13–26 years who have not yet been vaccinated. Pregnant women should not receive the vaccine, and safety and efficacy have not been evaluated in women over 26 years of age.

Much about the HPV vaccine is still unknown, but it appears that the number of individuals affected by persistent infections attributed to cancer-causing HPV strains 16 and 18 is low in the United States. This means that the number of individuals at risk for developing cervical cancer has likely been overestimated. In addition, you should be aware that the vaccine efficacy in the "real world" is dramatically lower than that observed in early clinical trials, and its efficacy in young girls has not been proven. Finally, the duration of protection from the 4 HPV strains in the vaccine is unknown. As more long-term studies are completed, the usefulness of the vaccine can be better evaluated. Talk to your doctor if you would like to discuss whether you or your children should receive the HPV vaccine.