

FDA Advisory Panel Backs Cervical Cancer Vaccine

The vaccine, called Gardasil, had been shown to be effective at blocking cervical cancers caused by certain strains of the human papillomavirus (HPV), a common sexually transmitted disease.

"This vaccine opens a new era in cancer prevention," said National Cancer Institute Acting Director John E. Niederhuber, MD, in an NCI news release following the vaccine's approval. "It has the potential to save women's lives, as well as to reduce health disparities in the United States and around the world."

There are over 80 different strains of HPV, affecting more than 40 million Americans. While the majority of HPV strains do not pose health risks, a few strains increase the risk for cervical cancer (such as HPV-16, HPV-18, HPV-31, and HPV-45). Clinical trial results presented to the FDA advisory panel in May 2006 showed that Gardasil blocked four strains of human papillomavirus. In studies of over 20,000 women ages 16 to 26, Gardasil prevented 100% of cervical, vaginal, and vulvar pre-cancers caused by HPV types 16 and 18. Gardasil was also shown to be highly effective at preventing cervical and external genital lesions due to one of four strains of HPV (6, 11, 16, 18).

"Gardasil is similar to other immunizations that guard against viral infection," said John Schiller, Ph.D., Deputy Chief of the Laboratory of Cellular Oncology at National Cancer Institute, in an NCI news release. Schiller's research helped pave the way for the vaccine's approval. "By preventing infection with two of the HPV types that can cause cervical cancer, this vaccine, if given prior to exposure to these sexually transmitted viruses, can protect women from ultimately developing cervical cancer."

According to Merck and Co. researchers, there does not appear to be any serious side effects to Gardasil. The most common side effect is soreness at the injection site. However, the FDA will study the safety of Gardasil before it makes a decision about whether to approve the vaccine for use in the United States.

In order to be effective, the vaccine must be administered to girls between the ages of 9 and 13—a requirement that has been somewhat controversial. Some conservative groups have voiced concern about giving a vaccine that blocks a sexually transmitted disease to young girls, worried that the vaccine could inadvertently encourage sexual activity. However, groups such as the Family Research Council have applauded the vaccine, noting that it will be a personal choice for parents and their daughters.

The Centers for Disease Control and Prevention is currently drafting a proposal recommending vaccination of all girls 11 and 12 years of age. However, actual regulation of the vaccine would be decided by states.

The vaccine does not eliminate the need for the Pap test because it only protects against four strains of HPV. Gardasil is administered to girls in three injections over a six-month period. The vaccine is expected to cost about \$500.

According to the American Cancer Society, in 2006, approximately 9,710 American women will be diagnosed with cervical cancer and about 3,700 will die from the disease. By contrast, the International Agency for Research on Cancer estimates that nearly 380,000 women are diagnosed with cervical cancer worldwide each year. The number of cases and number of deaths from cervical cancer are higher in less developed countries where routine screening is not widespread.

When detected early, the five-year survival rate for cervical cancer is approximately 92%. If cervical cancer is detected before it has invaded any surrounding tissues, the five-year survival rate is nearly 100%. The Pap test is highly effective at detecting cervical cancer. Between 1955 and 1992, the number of cervical cancer deaths in the United States dropped by 74% due largely to the increased use of the Pap test.

Risk factors for cervical cancer include age (the highest risk occurs between late teens and mid-thirties), early age at first sexual intercourse, multiple sexual partners, certain strains of the human papillomavirus (HPV, a sexually transmitted disease), smoking, and daughters of women who took DES (a hormonal drug prescribed between 1940 and 1971 to help prevent miscarriages).

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