

Second vaccine to prevent cervical cancer approved by FDA

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Today, Cervarix became the second cervical cancer vaccine approved in the U.S. The FDA decided the vaccine, which is administered in three injections for females age 10 to 25, was safe and effective. It is recommended women receive the vaccine before becoming sexually active, which can expose them to human papillomavirus (HPV), a virus linked to cervical cancer and other diseases.

In clinical studies, Cervarix was found to be 93 percent effective in preventing pre-cancers associated with HPV types 16 and 18, which cause about 70-75 percent of cervical cancers. Cervarix may also protect against types 31 and 45, which account for another 10 percent.

Because there are more than 100 types of HPV--15 of which have been associated with cancer--the vaccine does not offer full protection from cervical cancer, and women vaccinated are recommended to continue cervical cancer screening.

In a phase II study in which more than 1,000 women age 15 to 25 were vaccinated with either three doses of Cervarix or placebo, the vaccine showed protection for more than five years and demonstrated 100 percent efficacy in precancers caused by types 16 and 18, as well as 68 percent efficacy against cervical precancerous lesions and 38 percent benefit against abnormal Pap tests, regardless of HPV type. Side effects reported in studies of the vaccine include pain, redness, and swelling at the site of the injection, as well as headache, fatigue, and weakness.

Cervarix has been playing a game of catch-up to Gardasil, which was initially approved in 2006 for prevention of cervical cancer in females ages 9 to 26 and has also been approved for vulvar and vaginal cancers and genital warts. Gardasil's maker has filed for additional indications for boys ages 9 to 26, because the virus can also cause genital warts in males (as well as penile and anal cancers), and for women older than 26. And although the two vaccines both protect against cervical pre-cancers and cancers associated with HPV types 16 and 18, studies have shown Gardasil also protects against types 6 and 11.

It's not known whether competition between the two vaccines may help bring down costs. Merck's Gardasil typically runs about \$360 for all three shots, but is usually covered by insurance, while GSK officials say pricing information for Cervarix will be released in the next week or so. But whether one is more effective than the other is not known. While one study has shown Cervarix produces a higher immune response against the virus than Gardasil, no head-to-head studies have been conducted.

Update: The [FDA](#) also announced today that the agency approved Gardasil for boys age 9 to 26 to prevent genital warts.