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More Data on HPV Vaccines

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Cervarix joins Gardasil to become the second vaccine to show protection against two types of cervical cancer-causing human papillomavirus. HPV types 16 and 18 are responsible for about 70 percent of all cervical cancers, and Cervarix may also protect against types 31 and 45, which account for another 10 percent of all cervical cancers. About 10 other strains of the virus can also cause the disease, which affects 11,000 American women each year.

For the 1,113 women ages 15 to 25 who were vaccinated in a phase II study with either three doses of Cervarix or placebo, the vaccine offered 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. The Food and Drug Administration is currently reviewing GlaxoSmithKline's Cervarix for approval.

Merck, maker of Gardasil (the only vaccine currently approved to prevent cervical cancer), is now seeking an additional approval from the FDA for its vaccine based on new data that show it is effective in preventing vaginal and vulvar cancers. Two phase II studies published in the May 10 issue of the *New England Journal of Medicine* report Gardasil is 100 percent effective in preventing vulvar and vaginal precancer and genital warts caused by HPV types 6, 11, 16, and 18.

The trials found near-perfect efficacy (98 to 100 percent) for at least three years against cervical precancerous lesions related to HPV types 16 and 18 in women with no prior exposure to those two strains. Gardasil provided only slight protection in women infected with at least one cancer-causing strain of HPV, which led some researchers to theorize other cancer-causing strains of the virus may be filling the gap left open by types 16 and 18. These results stress the importance of vaccination before HPV exposure.