HPV Vaccine Approved for Women and Men up to Age 45

Human papillomavirus vaccine can prevent cervical, anal and oral cancers.

October 8, 2018 By Liz Highleyman

On October 5, the Food and Drug Administration (FDA) expanded its approval of the Gardasil 9 vaccine, which protects against nine difference strains of human papillomavirus (HPV), to cover women and men ages 27 to 45.

HPV is primarily a sexually transmitted disease, and most sexually active people carry some of the more than 100 known types. HPV can come and go over time as the immune system clears it and reinfection occurs. HPV triggers abnormal cell growth, including warts and precancerous tissue changes known as dysplasia.

If left untreated, these abnormal changes can progress to cervical, anal, genital and mouth and throat cancers. Oral cancer is becoming more common and a growing proportion is attributable to HPV. Cervical Pap screening has dramatically lowered cervical cancer mortality by detecting precancerous changes before they progress to invasive cancer. Anal Pap smears are not routinely done, but some experts recommend them for men who have sex with men, who are at greater risk.

Vaccines can prevent people from becoming infected with HPV in the first place. Over the past decade, HPV vaccines have expanded to cover more virus types, and their approval has extended to larger segments of the population.

The original Gardasil vaccine (approved in 2006) and the Cervarix vaccine (approved in 2009) offered protection against two high-risk, or cancer-causing, HPV types 16 and 18. Gardasil also protects against HPV types 6 and 11, which cause genital warts. Gardasil 9, approved in 2014, wards off five additional high-risk HPV types (31, 33, 45, 52 and 58).

HPV vaccines were previously approved only for young women ages 9 to 26, as immunization is more likely to be effective if given prior to becoming sexually active. The approval was later extended to young men in the same age group. The Centers for Disease Control and Prevention now recommends HPV vaccination for both boys and girls at age 11 or 12.

Last week’s expanded approval covers people from age 27 up to age 45. With the latest vaccine

protecting against nine HPV types, there is a greater likelihood that older adults have not been infected with all of them and could therefore benefit from immunization.

This approval was supported by a study of more than 3,000 women ages 27 to 45. Over 3.5 years of follow-up, Gardasil 9 was 88 percent effective against persistent HPV infection, genital warts, cervical, vulvar and vaginal precancerous lesions, and cervical cancer caused by the nine covered HPV types. There is less research on outcomes among men, but studies show the vaccine stimulates immune responses in men as well as women.

Gardasil 9 is generally safe and well tolerated, with the most common side effect being mild to moderate injection-site reactions.

"Today's approval represents an important opportunity to help prevent HPV-related diseases and cancers in a broader age range," Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, said in a news release. "The Centers for Disease Control and Prevention has stated that HPV vaccination prior to becoming infected with the HPV types covered by the vaccine has the potential to prevent more than 90 percent of these cancers, or 31,200 cases every year, from ever developing."

Click here for full prescribing information for Gardasil 9.

Learn more about cervical, anal and oral cancers.

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