HPV Cancer Vaccine Effective for Heterosexual, Gay and Bisexual Men

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Gardasil, an approved vaccine active against four strains of human papillomavirus (HPV), can substantially reduce the risk of cancerous and non-cancerous varieties of anal and penile lesions in men, according to data from a large clinical trial reported Friday, July 23, at the XVIII International AIDS Conference in Vienna. Importantly, the study enrolled a sizeable number of men who have sex with men (MSM) and demonstrated a significant reduction in the number of pre-cancerous anal lesions caused by HPV.

According to the U.S. Centers for Disease Control and Prevention (CDC), about 100 HPV types have been identified, over 40 of which infect the anogenital (anus and genital) area. Anogenital HPV types are categorized according to their cancer-causing potential. Infections with low-risk types, such as HPV types 6 and 11, can cause anogenital warts, along with benign cell changes of the cervix, vagina, vulva, anus and penis. Conversely, high-risk forms of the virus such as HPV types 16 and 18 can cause high-grade changes to certain anogenital cells and ultimately increase the risk of cancer.

Two vaccines—Merck's Gardasil and GlaxoSmithKline's Cervarix—are available to protect females against HPV types 16 and 18; Gardasil also protects against HPV types 6 and 11. The CDC's Advisory Committee on Immunization Practices (ACIP) recommends that all girls who are 11 or 12 years old get the three injectable doses of either brand of HPV vaccine to protect against cervical cancer and pre-cancerous lesions. In addition, the CDC recommends that girls and young women ages 13 through 26 get all three doses of an HPV vaccine if they have not received all doses yet.

Though Gardasil—but not Cervarix—is also approved for males ages 9 through 26, ACIP has not yet advised routine immunization for boys and young men, despite a great deal of epidemiological data indicating that men who ultimately enter into sexual relationships with other men are at a substantial risk for HPV infection and its associated diseases. Whether the newest data—from a large international study involving men by Heiko Jessen, MD, of Praxis, a private medical clinic in Berlin, and his colleagues, and reported on at Vienna—will sway ACIP's recommendations remains a matter of conjecture.

Jessen's group randomized 4,065 men—3,463 heterosexual men between 16 and 23 years old and 602 MSM between 16 and 26 years old—to receive three doses (a first injection, followed by a second two months later and a third four months after that) of Gardasil or placebo and were followed for about 36 months. The men were enrolled at sites in 18 countries on five continents.

To qualify for the study, volunteers had to have no evidence of genital lesions or history of genital warts. Heterosexual men were only permitted in the study if they had a history of one to five sexual partners; MSM could only participate if they had five or fewer sexual partners, identified themselves as MSM and had engaged in oral sex or anal intercourse within the year before enrollment.

None of the male volunteers were infected with HIV.

Safety data were available for 1,945 men in the Gardasil group and 1,950 men in the placebo group. About 64 percent of Gardasil recipients experienced one or more vaccine-related adverse event—including injection-site problems and systemic complaints—in the study, but so did 58.2 percent of those in the placebo group.

Serious adverse events—including appendicitis, cellulitis, chest pain and peanut allergy—were documented in 0.3 percent and 0.1 percent of those in the Gardasil and placebo groups, respectively. However, when the researchers looked for serious adverse events clearly attributed to vaccination, the rates were 0 percent in both groups.

Follow-up data at month 36 evaluating the effects of vaccination on the rate of extra-genital lesions (EGLs are lesions visible outside the body, on the penis or around the anus) were available for 1,397 men in the Gardasil group and 1,408 men in the placebo group. EGLs were documented in three Gardasil recipients compared with 31 placebo recipients, with a suggested efficacy of 90.4 percent in Gardasil's favor. Genital warts, in particular, were documented in three Gardasil recipients versus 28 placebo recipients, boasting 89.4 percent efficacy.

MSM in the study underwent more invasive follow-up testing to look for warts, low-grade lesions and potentially pre-cancerous lesions (anal intraepithelial neoplasia, or AIN) inside the anus. Jessen reviewed data involving 194 MSM in the Gardasil group and 208 MSM in the placebo group.

In the Gardasil group, HPV type 6-, 11-, 16- or 18-related AIN or anal cancer occurred in five MSM volunteers, compared with 24 in the placebo group. Jessen said this equated to 77.5 percent reduction in the incidence of anal lesions among those who received Gardasil. Looking only at cases of moderate- or high-grade anal dysplasia (AIN 2, AIN 3 or anal cancer), the efficacy of Gardasil was 74.9 percent—three cases in the Gardasil group compared with 13 cases in the placebo group.

Rates of persistent HPV infection—defined as the same HPV type found at least four months apart in a study volunteer—were also significantly reduced in the Gardasil group. Among those receiving placebo, there were 101 cases of persistent HPV infection, compared with 15 cases in the Gardasil group, for an efficacy of 85.6 percent.

In summing up these encouraging results, Jessen said that Gardasil was not only well tolerated, but also highly efficacious in reducing the incidence of external genital lesions in all male recipients between 16 and 26 years old. The results, he said, also demonstrate that Gardasil is efficacious in preventing pre-cancerous lesions and anal cancer related to HPV in MSM—at least those who have not yet been exposed to HPV types 6, 11, 16 and 18.

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