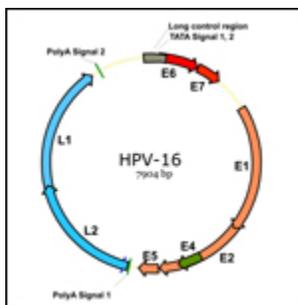


New HPV Vaccine Offers Protection Against Anal Cancer

By Rachel Warren | September 1, 2011
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A [study published](#) in *The Lancet Oncology* shows that an AS04-adjuvanted human papillomavirus (HPV) 16 and HPV 18 vaccine developed by GlaxoSmithKline Biologicals can offer protection against anal cancer (doi:10.1016/S1470-2045(11)70213-3). The study was carried out by Aimee Kreimer, a cancer epidemiologist, and her colleagues at the National Cancer Institute.



Genomic structure of human papillomavirus. Source: Wikimedia Commons, user Xmort

Anal cancer rates, while still quite low (1.5 per 100,000 women annually) are increasing both in developed and developing countries. It's estimated that roughly 90% of all anal cancer cases are caused by HPV 16 and 18 infections.

The Study

Between June 2004 and December 2005, women from Guanacaste and Puntarenas, Costa Rica who were between the ages of 18 to 25 and were basically healthy were enrolled in a randomized double-blind controlled trial. The women were randomly assigned to receive an HPV vaccine (Cervarix, GlaxoSmithKline, Rixensart, Belgium) or a control hepatitis A vaccine (Havrix, GlaxoSmithKline, Rixensart, Belgium).

The vaccines were administered in 0.5 ml doses: one at the time of enrollment, another at 1 month, and a third at 6 months. Four years after vaccination, the women provided anal specimens for assessment. The prevalence of anal HPV 16/18 infections was the primary endpoint of the study. Analyses were done in a restricted cohort of women who were negative for both cervical HPV 16 and HPV 18 DNA and who were HPV 16 and HPV 18 seronegative before enrollment, and also in the full cohort of women who provided an anal specimen.

Results

Of a total of 6,352 eligible women, 4,210 were included in the analysis. In the full cohort, the vaccine decreased incidence of HPV 16/18 at the anus (62.0%, 95% CI 47.1–73.1) and the cervix (76.4%, 67.0–83.5; *p* for interaction by anatomical site 0.031). In the restricted cohort (women with no likely previous exposure to HPV infection), vaccine efficacy against anal HPV 16/18 infection was 83.6% (66.7–92.8), which was similar to vaccine efficacy against cervical HPV 16/18 infection (87.9%, 77.4–94.0).

Late last year the U.S. Food and Drug Administration approved Merck's Gardasil, an HPV vaccine that, among other things, has been shown to be effective in preventing HPV transmission between men who have sex with men, a group known to have higher incidence of anal cancer. The Centers for Disease Control and Prevention (CDC) now recommends HPV vaccinations for females between the ages of 11 and 26 (for cervical cancer prevention); the CDC has not made a similar recommendation for males because of issues related to cost/benefit.