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## **HPV Vaccine Provides Protection at Multiple Sites, Even Among Some *Previously Exposed***

PHILADELPHIA — Vaccination of women aged 18-25 with the human papillomavirus (HPV) vaccine resulted in strong protection against future infection at three anatomic sites among women without prior HPV exposure, and may still offer some protection in those with evidence of prior exposure, according to findings presented here at the [AACR Annual Meeting 2015](#), April 18-22.

“HPV is a local infection that can separately infect the cervical, anal, or oral sites where it can occasionally lead to cancer. This study demonstrates that the HPV16/18 vaccine provides protection at all three sites, particularly among women without evidence of HPV exposure prior to vaccination,” said Daniel C. Beachler, PhD, a postdoctoral fellow in the Infections and Immunoepidemiology Branch of the [National Cancer Institute \(NCI\)](#). “And while the HPV vaccine is not therapeutic and cannot help clear current infections, we did observe that it may help protect some women previously exposed to HPV against subsequent infection at their noninfected sites.”

Beachler emphasized that the results of this study support current U.S. guidelines that recommend routine vaccination for those aged 11 to 12, and vaccination through age 26 for those not vaccinated previously. He also pointed out that this was a post-hoc analysis and that the analysis was limited to a one-time sampling of oral and anal HPV infection four years after vaccination. “Further research and better understanding of HPV infection outside of the cervix is needed,” Beachler said.

The multisite vaccine efficacy, representing protection at all three sites, was evaluated in three subgroups. This efficacy was 83 percent among women without evidence of prior HPV exposure, 58 percent among women with HPV exposure prior to vaccination, and a nonsignificant 25 percent among women with active cervical HPV16/18 infection at vaccination. In all of these women combined, the overall multisite vaccine efficacy was 65 percent and increased to 91 percent for protection of at least two of the three sites.

According to Beachler, there are three HPV vaccines on the market that protect against HPV at different anatomic sites. However, only about 50 percent of women aged younger than 18 have

received the Centers for Disease Control and Prevention-recommended vaccine in the United States. With this analysis, the researchers examined the combined effect of the HPV16/18 vaccine on multiple sites among women who were aged 18-25 at vaccination.

Beachler and colleagues conducted this analysis in the Costa Rica Vaccine Trial, a randomized, controlled trial of women who were assigned to vaccination with the HPV16/18 vaccine or a control vaccine. Cervical samples were collected at each annual visit and oral and anal samples were collected at the four-year follow-up visit. There were 4,186 women who contributed samples for all three sites and were included in this analysis.

This study was funded by the intramural program of the NCI. Vaccines were provided by GlaxoSmithKline PLC. Beachler declares no conflicts of interest.

Press registration for the AACR Annual Meeting 2015 is free to qualified journalists and public information officers: [http://www.aacr.org/Documents/15AM\\_Press\\_Registration\\_Form.pdf](http://www.aacr.org/Documents/15AM_Press_Registration_Form.pdf).

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**Abstract Number:** 1088

**Title:** Efficacy of the HPV16/18 vaccine against cervical, anal, and oral HPV infection among women with and without previous HPV16/18 exposure

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**Abstract Body:**

**Background:** Previous reports from the Costa Rica Vaccine Trial demonstrated strong vaccine efficacy against HPV16/18 at the cervical, anal, and oral regions separately. However, the combined “woman-level” vaccine efficacy against infections at all three anatomic sites has not been examined in women with and without previous HPV16/18 exposure.

**Methods:** Women aged 18-25 from the Costa Rica Vaccine Trial were randomized to be vaccinated with the HPV16/18 Vaccine (Cervarix) or a Hepatitis A vaccine at enrollment. Cervical samples were collected at every annual visit, while oral and anal samples were collected only at the four year follow-up visit. Samples were tested for alpha mucosal HPV DNA types utilizing the SPF10 PCR-DEIA-LiPA25 version 1 method. An event in the multi-site woman-level vaccine efficacy analysis (n=4,186) was defined as a women with prevalent HPV16/18 DNA at the cervical, anal, or oral regions. Vaccine efficacies (VEs) and 95% confidence intervals (95% CIs) were computed for one-time detection of HPV16/18 in the cervical, anal, and oral regions in this intention-to-treat analysis.

**Results:** Four years following initial vaccination, the combined multi-site woman-level vaccine efficacy against HPV16/18 infections was 64.8%, 95%CI=54.8-72.8. Multi-site woman-level efficacy was stronger among women without evidence of previous HPV exposure (HPV16/18 seronegative and cervical HPV16/18 DNA negative at enrollment): VE=83.1%, 95%CI=72.6-89.6, but was also demonstrated among women with evidence of previous HPV16/18 exposure (HPV16/18 seropositive and cervical HPV16/18 DNA negative at baseline): VE=49.6%, 95%CI=2.7-73.9. Further supporting the partial protection of the vaccine in previously HPV16/18-exposed women, we observed a particularly strong vaccine efficacy against HPV16/18 at more than one anatomic site (VE=91.4%, 95%CI=81.4-96.6). Indeed, HPV16/18-infected women were significantly less likely to be HPV16/18-infected at two or more anatomic sites in the HPV vaccine arm than the control arm (6 of 81 (7%) vs. 70 of 230 (30%), p<0.01).

**Discussion:** This is the first study to present a combined multi-site woman-level HPV16/18 vaccine efficacy. This study found strong multi-site efficacy among those not previously exposed to cervical HPV16/18, but also suggests the vaccine may provide some protection against HPV16/18 at multiple anatomic sites among women previously exposed to HPV16/18. If confirmed, the partial protection against cervical, anal, and/or oral HPV16/18 in women previously exposed to HPV16/18 could be considered in HPV vaccination catch-up program decision-making.