

# Gardasil Blocks HPV Types Not Included in Vaccine

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CHICAGO — The quadrivalent human papillomavirus vaccine Gardasil offers cross-protection against cancer-causing HPV types that are not included in the vaccine, according to data reported in a late-breaking poster at the annual Inter-science Conference on Antimicrobial Agents and Chemotherapy.

A three-dose regimen of the human pa-

pillomavirus (HPV) type 6/11/16/18 vaccine demonstrated 62% efficacy in preventing cervical intraepithelial neoplasia (CIN) grades 2 and 3 or adenocarcinoma in situ (AIS) caused by HPV 31 or 45, the two most common HPV types found in cervical cancer after HPV 16 and 18.

Efficacy was 43% against CIN 2/3 or AIS due to HPV 31, 33, 45, 52, or 58, the five most common types found in cervical cancer after HPV 16 and 18.

Efficacy was 38% for 10 nonvaccine

oncogenic types (HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, or 59), which cause more than 20% of cervical cancers worldwide, Dr. Darron Brown reported on behalf of the FUTURE Study Group.

In all, 38 cases of CIN 2/3 or AIS due to the 10 cancer-causing HPV types were reported among 4,616 Gardasil-vaccinated women, who were participants in the Merck-sponsored phase III Females United To Unilaterally Reduce Endo/Ectocervical Disease (FUTURE) I and II trials,

which led to the approval of Gardasil in June 2006.

They underwent cervicovaginal sampling and Pap testing at day 1 and 6-12 month intervals for up to 48 months.

The data have been submitted to the Food and Drug Administration for review.

Kelley P. Dougherty, who is the director of public affairs for Merck & Co., West Point, Pa., said in an interview that it is too early to say if the indication for Gardasil or its marketing campaign will be expanded.

"We expect to hear from them by the end of the first quarter of '08, and once we determine collectively what these data mean as far as long-term impact, we'll look at that," she said.

Reductions in disease with Gardasil vaccination were most apparent for the A9 species, which includes HPV 16. CIN 2/3 or AIS due to nonvaccine A9 species (types 31, 33, 35, 52, and 58) was reported in 26 vaccinated women and 48 placebo-treated women, demonstrating a 45% efficacy for Gardasil.

Efficacy was 46% against disease due to nonvaccine A7 species (types 39, 45, and 59), with 8 and 15 cases reported for vaccinated and placebo-treated women, respectively. HPV 18 is the prototype of the A7 species.

Efficacy data were not available for types 51 and 56 because the study was not powered to look at efficacy for individual HPV types.

Data were available on cross-protection for persistent infection. Among 1,036 vaccinated women and 1,029 placebo-treated women, Gardasil had a 45% efficacy against persistent infection with HPV 31 or 45, and 28% efficacy against persistent infection with HPV 31, 33, 45, 52, or 58.

Dr. Brown suggested that HPV 16 and 18 neutralizing antibodies generated by vaccination may bind and neutralize virions of nonvaccine HPV types, thereby preventing them from entering the cervical cell. "By preventing infection, we can prevent disease," he said.

As for whether Gardasil may provide similar efficacy in men, Dr. Brown said during the presentation, which was sponsored by the American Society for Microbiology, that there is reason to suspect protection might be different because the male and female epithelia are quite different, especially when comparing penile and cervical lesions. The penile epithelium is a stratified squamous epithelium about 20-30 cells thick, whereas the cervical epithelium is a mucosal epithelium, 6-8 cells thick.

"The good news is that the penile epithelium and the vulvar epithelium are actually quite similar, and in our studies, vulvar lesions were nearly 100% prevented in women, giving us hope that analogous penile lesions will be similarly protected against. But that is still being analyzed," he said.

Indiana University and Merck have an intellectual property agreement for the development of the vaccine, and Dr. Brown receives a portion of his income from that agreement, he disclosed. ■

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