

Gardasil Prevents HPV Infection in Teen Boys

BY MIRIAM E. TUCKER

ATLANTA — The human papillomavirus vaccine was efficacious in preventing persistent infections and genital warts caused by HPV strains 6, 11, 16, and 18 in a Merck-sponsored study of 4,065 males aged 16-26 years.

The findings were presented by Dr. Richard M. Haupt at a meeting of the Centers for Disease Control and Prevention's

Advisory Committee on Immunization Practices. Merck had previously reported immunogenicity and safety data for its HPV vaccine (Gardasil) in younger males aged 9-15 years, but these are the first data on efficacy in males and the first findings in older adolescent and adult males.

The rationale for use of Gardasil in males is twofold. There is intrinsic benefit to males themselves since HPV strain 18 causes penile, anal, and oropharyngeal

cancer and HPV 6 and 11 are associated with genital warts. There is also a public health benefit to vaccinating males against HPV since coverage among girls is likely to be incomplete, transition of HPV occurs efficiently between sexual partners, and "gender-neutral" vaccination would be expected to reduce overall viral transmission in the entire population, noted Dr. Haupt of Merck Research Laboratories, Whitehouse Station, N.J.

The ACIP is expected to recommend the vaccine for use in males aged 11-12 at the adolescent visit, just as it is now given to girls. This should simplify implementation, Dr. Doug Campos-Outcalt, of the University of Arizona, Phoenix, said in an interview.

"There are now four vaccines recommended for adolescents. I think there will be a period of time before we get high acceptance rates, but it will help to have other vaccines being offered at the same time," said Dr. Campos-Outcalt, who serves as the liaison to ACIP from the American Academy of Family Physicians.

In the randomized, double-blind, placebo-controlled trial, three doses of Gardasil or placebo were given at 0, 2, and 6 months. Mean follow-up for this analysis was 30 months of a planned total of 36. The study population, which came from 18 different countries, included 3,463 heterosexual males aged

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Vaccine efficacy was 90.4% against external genital lesions and 85.6% in preventing infection.

DR. HAUPT

16-23 years and 602 males aged 16-26 who have sex with men. Because of problems in enrollment, data collection for the latter group lags behind by about a year, Dr. Haupt noted.

At baseline, 12% of the entire group was polymerase chain reaction-positive to at least one of the four vaccine virus types. By serology, 8% were seropositive to at least one type. Combining the results of PCR and serology, 83% of the group was naive to all four types. Moreover, most who were infected had just one type, suggesting that "the vast majority would benefit from the vaccine," he said.

Per protocol, efficacy of the vaccine was 90.4% against external genital lesions, 85.6% in preventing persistent infection (from two or more consecutive visits), and 44.7% against DNA detection of a vaccine virus strain in anogenital specimen from one or more visits. All three results were statistically significant.

Safety analysis showed similar findings to those seen in females. Local site reactions were the most common adverse event, occurring in 60% of the 2,020 Gardasil recipients and 54% of the 2,029 placebo recipients. Systemic reactions, serious adverse events, and discontinuations due to adverse events were uncommon and were not different between the Gardasil and placebo groups, he reported.

Merck has filed an application with the Food and Drug Administration for licensure of Gardasil in males aged 9-26 years. A decision is expected in mid-October 2009. If the application is approved, ACIP anticipates addressing recommendations for its use in males at its meeting later that month, said Dr. Janet Englund, chair of the ACIP's HPV Vaccine Workgroup. ■