Gardasil Prevents Warts, HPV Infection in Males

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. Merck Research Laboratories, Whitehouse Station, N.J.

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 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. With the results of PCR and serology combined, 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,” Dr. Haupt said.

Per protocol, efficacy of the vaccine was 90.4% against external genital lesions and 85.6% in preventing infection. Dr. HAUPT

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The finding was presented by Dr. Richard M. Haupt at a meeting of the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices. The study was funded by the U.S. Department of Health and Human Services, CDC. Dr. Haupt is a consultant to Merck, the manufacturer of Gardasil.

On the other hand, it raises questions about what the impact will be in many other studies about cultural norms, such as things like machismo and the way we’ve traditionally interpreted this concept,” she said. “As we saw in these focus groups, there’s sort of an initial reaction, but then people talked about standing by their partner.”

Clues about these cultural norms and beliefs are essential to the design and implementation of successful and badly needed interventions for HPV prevention. “You have to be very cautious in terms of generalizing these findings, but many of the populations that are suffering increased incidence of HPV and cervical cancer and increased mortality are in this area,” Dr. Fernandez said.

The study was funded by the National Institutes of Health. The authors reported no conflicts of interest.

New Smallpox Vaccine Found Safer Than Existing Vaccines

BY MARY ANN MOON

The third-generation smallpox vaccine LC16m8 was found to be as immunogenic as existing smallpox vaccines but appeared to be safer in a study of over 3,000 Japanese adults.

The live, attenuated, tissue-cultured vaccine (LC16m8) was found to be as immunogenic as existing smallpox vaccines, as were serum skin reactions to a single intraepidermal scarification—was comparable to that seen with other vaccines, as were serum skin reactions to a single intraepidermal scarification, according to a small, prospective study.

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The study was funded by the National Institutes of Health. The authors reported no conflicts of interest.

HPV Misunderstood, Feared In One Border Community

BY PATRICE WENDLING

Hispanic men and women living on the United States–Mexico border have little understanding about the human papillomavirus and its role in the etiology of cervical cancer, according to a small, prospective study.

Not only were there very low levels of knowledge among these residents, but their misconceptions and confusion continued even after they were given some basic information about HPV and cervical cancer, Maria Fernandez, Ph.D., said in Carefree, Ariz., during a press conference sponsored by the American Association for Cancer Research. For example, participants tended to compare HPV with HIV and other sexually transmitted infections, and were confused or unaware that men could have HPV and transmit it.

She reported on 30 Hispanic women and 11 Hispanic men with- out a diagnosis of HPV who lived in Rio Grande Valley colonias (un incorporated border settlements) and participated in focus groups in Brownsville, Tex. The mean age was 41 years among the women (range, 20-74 years) and 39 years among the men (range, 19-76 years). The average annual income for a family of four in these semi-rural neighborhoods was $13,000. About 60% of participants had not completed grade school.

Analysis of the Spanish-language focus group transcripts revealed that attitudes and concerns about HPV differed by gender, said Dr. Fernandez. Of the 30 Hispanic men, all expressed fear of contamination, whereas more than half of the 60 Hispanic women believed that HPV was not serious and that it could be cured with medication. They defined contamination as physical contact or as things like machismo and the way we’ve traditionally interpreted this concept,” she said. “As we saw in these focus groups, there’s sort of an initial reaction, but then people talked about standing by their partner.”

Clues about these cultural norms and beliefs are essential to the design and implementation of successful and badly needed interventions for HPV prevention. “You have to be very cautious in terms of generalizing these findings, but many of the populations that are suffering increased incidence of HPV and cervical cancer and increased mortality are in this area,” Dr. Fernandez said.

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