CDC Mulls New HPV Vaccine Recommendations

BY SHARON WORCESTER

FROM A MEETING OF THE CDC'S ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

ATLANTA — The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices may soon consider whether routine human papillomavirus vaccination should be recommended for males aged 9-26 years, but it does not seem likely that a catch-up dose will be recommended for women who are older than 26.

The HPV vaccine (Gardasil, Merck & Co.) is licensed for males aged 9-26 years for prevention of genital warts associated with HPV-6 and -11, in addition to being routinely recommended for girls aged 11-12 years and for those aged 13-26 who have not already been vaccinated. Data also show that the vaccine has 75% efficacy for preventing anal intraepithelial neoplasia grades 2 and 3 in males, Dr. Lauri Markowitz of the center's HPV working group reported to the committee.

A review by the Food and Drug Administration, which is considering a supplemental biologic license application by Merck for the latter indication, is not expected to be complete before the next ACIP meeting in October, but the working group is reviewing vaccine trial data and cost-effectiveness data on male vaccination, and plans to present its findings at that meeting.

Specifically, the group is looking at cost-effectiveness based on different coverage assumptions. From currently available data, vaccination of males does not appear to be cost effective when female vaccination coverage is high, but it may be more cost effective if female vaccination coverage is low, said Dr. Markowitz, who is also with the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention at the CDC.

Vaccination of males does not appear to be cost effective when female vaccination coverage is high, but it may be more cost effective if female vaccination coverage is low.

The group is also looking at epidemiology and cost-effectiveness data in men who have sex with men, and at the feasibility of reaching men who have sex with men when they would benefit most from vaccination. These findings will also be presented at the October meeting.

Dr. Markowitz noted that ACIP had previously stated that the HPV vaccine "may be given" to males aged 9-26 years, but did not include the HPV vaccine in the routine vaccination schedule for this population.

She added that most working group members are opposed to a catch-up dose in women over age 26 on the basis of currently available data. ACIP first considered vaccination in women in this group in 2008, and Merck submitted a supplemental biologic license application to the FDA in 2009 for that indication. That application remains under review.

National Immunization Survey data show that 25% of girls aged 13-17 years received at least one HPV vaccine dose in 2007 and 37% received it in 2008. Additional data on vaccination rates, vaccine safety, and private insurance coverage will be presented at the October meeting, Dr. Markowitz said. ■

Disclosures: *Dr. Markowitz said that she has no relevant conflicts of interest.*

HPV Vaccine Reduced Risk of Abnormal Pap Test Results

BY SHERRY BOSCHERT

FROM THE ANNUAL MEETING OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS.

VITALS

Major Finding: The atropine sulfate–adjuvanted vaccine for human papillomavirus types 16 and 18 (Cervarix) significantly reduced the risk of abnormal Pap test results over a 3-year period by 56%-68% depending on the type of abnormality.

Data Source: Secondary analysis of data on 17,347 women from a phase III efficacy trial in 14 countries.

Disclosures: Dr. Martens has been a consultant for and received research funds, honoraria, and conference sponsorship from Merck & Co. and from GlaxoSmithKline Biologicals, which makes the vaccine and funded the study.

SAN FRANCISCO — A vaccine for human papillomavirus decreased the risk for cytologic abnormalities over a 3-year period by 56%-68%, compared with placebo vaccine, a secondary analysis of data on 17,347 women in a phase III clinical trial found.

The analysis looked at vaccination with all three doses of Cervarix, the atropine sulfate–adjuvanted vaccine for human papillomavirus types 16 and 18 (HPV-16/18), in 8,665 young, predominantly sexually active women compared with a control group of 8,682 women who got hepatitis A vaccine.

In one state—Ohio—each physician performing Pap smears would see 20 fewer cases of grade II/III cervical intraepithelial neoplasia per year if patients were vaccinated.

The primary results of the Papilloma Trial Against Cancer in Young Adults (PATRICIA), reported last year, showed that the vaccine was highly prophylactic against grade II cervical intraepithelial neoplasia (CIN2) associated with HPV-16/18 and against several oncogenic nonvaccine types of HPV (Lancet 2009;374:301-14).

Dr. Mark G. Martens reported at the meeting on a secondary end point built into the PATRICIA trial to assess vaccine efficacy in preventing abnormal Pap smear results and subsequent reduction in colposcopy referrals and cervical excision procedures.

Cervical samples were collected every 6 months for HPV DNA genotyping, and the women underwent yearly gynecology and cytologic examinations. The rate of atypical squamous cells of undetermined significance (ASCUS) with HPV-16/18 was 57% lower in the vaccine group compared with the control group during 3 years of follow-up, said Dr. Martens, who conducted the analysis while at Oklahoma State University, Tulsa, and now practices at Jersey Shore University Medical Center, Neptune, N.J.

The rate of low-grade squamous intraepithelial lesions (LSILs) with HPV-16/18 was 68% lower than in the control group, and the rate of high-grade squamous intraepithelial lesions (HSILs) with HPV-16/18 was 56% lower than in the control group, he said.

Absolute rates of ASCUS with HPV-16/18 were 2% in the vaccine group and 4% in the control group (percentages are rounded). LSILs with HPV-16/18 were detected in 2% of the vaccine group and 6% of the control group. HSILs with HPV-16/18 were present in 0.2% of the vaccine group and 0.5% of the control group.

There was a statistically significant difference between groups for HSILs with HPV-16 (0.1% in the vaccine group vs. 0.4% in the control group) but not for HSILs with HPV-18 (0.05% and 0.1%).

Irrespective of HPV type, the vaccine reduced the risk for ASCUS by 8%, the risk for LSILs by 14%, and the risk for HSILs by 41%, he added.

The risk for CIN2 and CIN3 was 30% and 33% lower than in the control group. "That means the lesions we're going to act upon"—HSILs, CIN2, and CIN3—"were 30%-40% lower with the vaccine," Dr. Martens said.

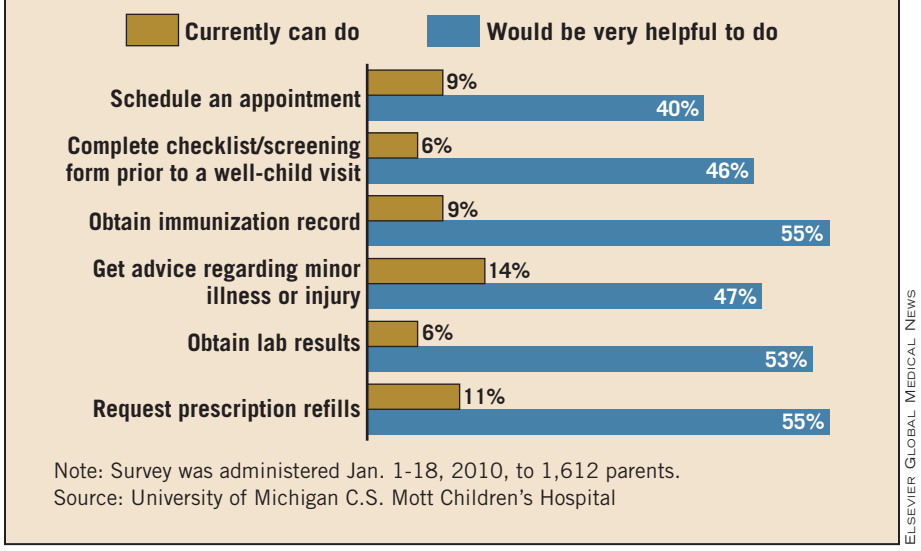
HSILs were found in 0.5% of the vaccine group, irrespective of HPV type, and 0.9% of the control group. CIN2 was detected in 2.5% of the vaccine group and 3.7% of the control group. The rate of CIN3 was 0.8% in the vaccine group and 1.3% in the control group.

Compared with the control group, colposcopy referrals were reduced by 10% and cervical excision procedures were reduced by 25% in the vaccine group, he reported.

Dr. Martens said he did an extra calculation for one state—Ohio—and estimated that each physician performing Pap smears in the state would see 20 fewer cases of CIN2/3 per year if patients were vaccinated. Nationally, the vaccine could result in 5 million fewer Pap smears per year because there would be less abnormal cytology, he added.

Women were included in the analysis regardless of their HPV DNA status, HPV serostatus, or cytology at baseline. Evidence of past or current infection with HPV-16/18 was present at baseline in 26% of women, but only 98 participants (less than 1%) were DNA positive for both HPV-16 and HPV-18. ■

DATA WATCH



ELSEVIER GLOBAL MEDICAL NEWS