ACIP Votes for Second HPV Vaccine to Prevent Cervical Ca

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ATLANTA — The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommended a bivalent human papillomavirus vaccine as an alternative to the quadrivalent vaccine for the prevention of cervical cancer and related precancerous conditions in women and girls aged 9-26 years. ACIP made the recommendation at its annual fall meeting

The bivalent human papillomavirus (HPV) vaccine (GlaxoSmithKline's Cervarix) was recently approved by the Food and Drug Administration. The vaccine provides clinicians with another option to vaccinate adolescent girls and young women against diseases caused by HPV types 16 and 18. But unlike the quadrivalent vaccine, the bivalent vaccine is not designed to protect against genital warts, noted Dr. Lauri Markowitz of the CDC, who presented the ACIP recommendations for the use of the bivalent vaccine.

The quadrivalent vaccine (Merck & Co.'s Gardasil) protects against genital warts associated with HPV types 6 and 11, in addition to protecting against diseases caused by HPV types 16 and 18.

ACIP recommended against a statement of no preference between the bivalent and quadrivalent vaccines after a lively debate. Instead, the recommendations will present the information about the two vaccines without a statement of preference or a statement of nonpreference. The recommendations state that the two vaccines can be used interchangeably to complete the three-dose series, but that using the same vaccine for the entire series is preferable. The bivalent vaccine, like the quadrivalent vaccine, is not a live vaccine, and it can be given simultaneously with other vaccines.

"Now women have two choices when it comes to a cervical cancer vaccine," Dr. Sandra Fryhofer, an internist in private practice in Atlanta, Georgia, and the American College of Physicians liaison to ACIP, said in an interview. The bivalent vaccine contains an adjuvant, AS04, that "adds a little immunogenic punch," she said. And now that clinicians have the option to choose between two vaccines, "we hope that the cost will come down," Dr. Fryhofer added.

ACIP also voted to harmonize the age ranges for the two vaccines, with first doses given at ages 11-12 years and recommended second and third doses at 1-2 months and 6 months after the first dose. The recommended minimum dosing intervals remained as 4 weeks between the first and second dose and 12 weeks between the second and third doses. The vaccine can be initiated as young as 9 years, and catch-up vaccination is recommended for females aged 13-26 years.

The committee voted to add the bivalent vaccine to the CDC's Vaccines for Children program. For more information, visit www.cdc.gov/vaccines/recs/acip. ■

ACIP Votes to Make HPV Vaccine Available for Boys

ATLANTA — The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices voted in favor of a permissive recommendation to vaccinate males aged 9-26 years with the quadrivalent human papillomavirus vaccine.

ACIP also approved the statement that the human papillomavirus (HPV) vaccine would be most effective if given before young men become sexually active. Research has suggested that the vaccine "would be most effective if given prior to sexual debut," said the CDC's Dr. Eileen Dunne, who presented background data and considerations for the quadrivalent HPV vaccine (Gardasil) in males.

Studies have shown that men have a similar prevalence of HPV compared with women, and that approximately 70% of men will have had vaginal sex by 19 years of age, Dr. Dunne said.

In clinical trials, the vaccine showed a 93% efficacy against HPV type 11 and 88% efficacy against HPV type 6, the two types of virus that have been associated with more than 90% of cases of genital warts in men.

The CDC's Harrell Chesson, Ph.D., presented cost-effectiveness data on male HPV vaccination, which suggested that vaccinating males would be most cost effective if HPV vaccination coverage in females was relatively low. In Dr. Chesson's model, the incremental cost per quality-of-life year gained was $47,500 for all outcomes, including cervical cancer and genital warts, if female vaccine coverage was 45% vs. $161,500 if coverage in women was 70%.

Adverse events were similar in the vaccine group vs. the placebo group. The most common adverse event was pain at the injection site, reported in 64% of the vaccine group and 53% of the placebo group.

Several studies have shown that HPV vaccination for boys and young men would be accepted by most health care providers, boys and men in the target age group, and parents, Dr. Dunne said.

The relatively high cost of the vaccine remains a challenge, at $130 per dose for private insurerers, but the estimated direct medical costs of genital warts in the United States is more than $2 million annually, Dr. Dunne said.

"Now boys and men aged 9-26 years can get the HPV4 vaccine," Dr. Sandra Fryhofer, an internist in private practice in Atlanta, and the American College of Physicians liaison to ACIP, said in an interview. ACIP approved permissive, rather than routine, use of the vaccine, which means, she said, that the vaccine "won't be promoted" for males, "but it will be available," and parents who ask can get it for their children.

The committee voted in favor of adding the quadrivalent HPV vaccine for males to the CDC's Vaccines for Children program.

For the latest information on ACIP vaccine recommendations, visit www.cdc.gov/vaccines/recs/acip. ■

PCV13 Replacing PCV7 Doses

Draft Guidelines *from page 1*

dren who have completed the PCV7 schedule, and immunocompromised children or children with chronic illness.

For unvaccinated infants and children, the recommendations are the same as for PCV7, with PCV13 replacing PCV 7 for all doses, said Dr. Nuorti.

The draft recommendations also state that children who began their vaccination series with PCV7 can complete the series with PCV13 at any point in the schedule, and children who have completed the primary infant series with PCV7 should receive a single PCV13 dose during the second year of life to provide protection against the six additional serotypes.

In addition, the draft recommendations propose a fifth "catch-up" dose for all children aged 12 through 59 months who have received all four PCV7 doses. The catch-up dose will provide protection against the six additional serotypes, Dr. Nuorti said.

Dr. Nuorti added that the proposed recommendations for the 23-valent pneumococcal polysaccharide vaccine (PPSV23) after PCV13 for individuals aged 2 years and older with underlying medical conditions are the same as those currently recommended for the use of PPSV23 after PCV7, although no safety and immunogenicity data are yet available for this vaccine sequence.

Dr. Paradiso of Wyeth reviewed safety and immunogenicity data presented at an ACIP meeting earlier this year, including comparison data from a study including 125 children aged 15 months to 2 years, and 182 children aged 2-5 years.

The studies suggest that the safety profiles and immune responses were similar to those seen with PCV7. ■

ACIP Working Group Suggests Waiting on Infant Vaccination

ATLANTA — The meningococcal working group of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices believes that "ACIP should consider not adding meningococcal conjugate vaccines to the routine infant vaccine schedule at this time," said working group member Dr. Amanda Cohn.

At its fall meeting, ACIP discussed safety and epidemiology data on meningococcal vaccines in development for infants. These products have not yet been licensed.

The low burden of meningococcal disease in infants raises the question of whether every vaccine that is shown to be safe and effective should be recommended if the burden of disease is low, said Dr. H. Cody Meissner, chair of the working group.

The last ACIP recommendations for meningococcal vaccines were published in May 2005, and an update is planned for 2010, he noted.

ACIP heard information about three potential meningococcal vaccines in development that would involve either a two-dose or four-dose series.

Early data have shown that the vaccine is highly immunogenic, but concerns persist about the already crowded infant vaccination schedule and catch-up recommendations, and the need for boosters to maintain protection until adolescence, Dr. Cohn commented.

ACIP will hear data about cost-effectiveness and vaccine acceptability at its February 2010 meeting, she noted. ■