HPV Vaccine Approval for Older Women Delayed

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The expanded approval of the currently marketed human papillomavirus vaccine to women aged 27-45 years is being held up, at least until the manufacturer addresses some outstanding issues.

In a statement issued in late June the manufacturer of Gardasil, Merck & Co., announced that the Food and Drug Administration had advised the company that there were issues that precluded approval of the vaccine for the older age group within the time frame that had been specified for the FDA's review to be completed.

The company has discussed the FDA's questions with the agency and at press time was expected to respond to the issues raised, according to Merck's statement. Neither the company nor the FDA elaborated on the specific issues.

In 2006, Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16, 18] Vaccine, Recombinant) was approved for girls and women aged 9-26 years for prevention of cervical cancer, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16, and 18.

The FDA designated the review of Gardasil in the older age group as a priority review in March. Data from clinical trials in older women were presented by Merck at the winter meeting of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. In placebo-controlled studies on Gardasil, including one study of almost 4,000 women aged 24-45 years, two-thirds of the women were negative for all four HPV serotypes in the vaccine, and about one-third were positive for one or more of the HPV vaccine serotypes; only 0.4% of the vaccine recipients and 0.3% of the controls were positive for all four.

Over a mean follow-up of 2.2 years, primary efficacy of the vaccine against persistent infection, cervical intraepithelial neoplasia, or external genital lesions caused by any of the four vaccine strains was 92% among subjects aged 24-34 years and 89% among 35- to 45-year-olds. Efficacy against cervical intraepithelial neoplasia or external genital lesions caused by any of the four vaccine serotypes was 92% (88% for 16 and 18, 100% for 6 and 11). Safety profiles were similar to those seen in the 16- to 26-year-old age group, with no serious vaccine-related adverse events among vaccine recipients. ■

Reimbursement Woes Loom Over HPV Vaccinations

New Orleans — Getting reimbursed is the top concern for physicians who offer the human papillomavirus vaccine, according to a survey by researchers at Brigham and Women's Hospital, Boston.

Using a Web-based tool, Brigham resident Dr. Emily M. Ko and colleagues surveyed 1,488 physicians who practiced with the Partners HealthCare System from May to July 2007. Overall, 424 physicians participated, of whom 87 (21%) were ob.gyns., 196 (46%) were internists, and 104 (25%) were pediatricians, said Dr. Ko in a poster at the annual meeting of the American College of Obstetricians and Gynecologists.

Of those who participated, 80% said they offer the HPV vaccine. That included 92% of pediatricians, 81% of ob.gyns., and 78% of internists. Male physicians were 54% less likely to provide the vaccine than were female physicians. The survey did not ask questions that would determine why some might be less likely to offer the vaccine, Dr. Ko said in an interview.

Physicians in community hospitals were twice as likely to offer the vaccine as were those at tertiary care facilities. Primary care physicians were 14 times more likely than specialists to offer it. Overall, the respondents cited reimbursement as the main hurdle to offering the vaccine. Most (95%) physicians said it would not promote promiscuity or decrease condom use, 3% were neutral, and 1.4% said it might promote promiscuity. There was no difference between genders or in specialties on the promiscuity issue, though 7% of physicians said parents might fear vaccination would promote promiscuity, and 19% of pediatricians said parental fear was a barrier.

Dr. Ko reported no conflicts of interest.

—Alicia Ault

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