Male HPV Vaccine Will Need Careful Promotion

BY KATE JOHNSON

MONTREAL — Although the prevalence of human papillomavirus is similar among females and males, physicians will need to be careful about promoting a vaccine that specifically targets men, according to a survey of male college students.

Efficacy trials suggest that the Gardasil HPV vaccine, which is currently approved for females only, is efficacious in males, and it could be approved for this population as early as the fall, said Mary Gerend, Ph.D., of Florida State University, Tallahassee.

However, her study of 221 young males suggests that their attitudes about the acceptability of the vaccine are only slightly positive, and depend partly on what it is called. On a scale of 1 (unlikely) to 6 (very likely) they indicated a 3.6 level of interest in receiving the vaccine, she reported.

"Marketing it as 'the cervical cancer' vaccine may not be the most effective strategy for this group," she said at the annual meeting of the Society of Behavioral Medicine.

The men in her group were aged 18-26 years, and 96% of them were heterosexual. Although only 47% had a current partner, 81% indicated that they had had sexual intercourse. The group reported a mean of 4.8 lifetime partners (range 0-34).

"Younger men were more interested, as were gay and bisexual men," Dr. Gerend said, adding that other predictors of interest were having already had sex, having a current partner, and ever being tested for a sexually transmitted infection.

Regarding a potential name for the vaccine, most of the group (76%) said they preferred "Gardasil" or "the HPV vaccine."

In a separate study of 356 heterosexual male college students, Dr. Gerend found that emphasizing the benefits of vaccination for a man's partner versus the personal benefits did not boost interest in vaccination (Sex. Transm. Dis. 2009;36:58-62).

Dr. Gerend did not disclose any conflicts of interest. ■

Widespread HPV Vaccination May Require School Mandate

BY DENISE NAPOLI

BALTIMORE — The notion that the future burden of human papillomavirus will be greatly decreased thanks to the HPV vaccine may be unrealistic without a national school mandate, according to a new model.

That's because voluntary vaccination among the target population of 11- to 17-year-old girls so far has been modest, with just 7% of this cohort receiving all three doses in the first year of the vaccine's availability, according to Dr. Amanda Dempsey of the University of Michigan, Ann Arbor.

"Under no-mandate conditions, our model suggests that vaccine utilization may be suboptimal and that coverage of even 70% could take decades to achieve," Dr. Dempsey and David Mendez, Ph.D., also of the university, wrote in a poster presented at the annual meeting of the Pediatric Academic Societies.

The researchers created a model of HPV vaccine uptake among 11- to 17-year-old girls based on census data, published literature on parental attitudes toward HPV vaccination, adolescent health care utilization patterns, and expert physician opinion. The model assumed that a school mandate would be applied on a national level, and would be such that vaccination would be required for school attendance, with exceptions similar to those of other vaccine mandates.

They adjusted their model to accurately predict the numbers reported by the Centers for Disease Control and Prevention during the first year of the vaccine's availability: 25% of U.S. 11- to 17-year-old girls received the first dose, 17% received the first and second dose, and 7% received all three recommended doses of the vaccine.

Without a mandate in place, the authors predicted that 70% utilization of the vaccine would be reached by year 23 of its availability, or 2030.

Under that model, by year 50 (in 2057) just 78% of the cohort will have received all three doses, they predicted.

With a mandate, 70% of the 11- to 17-year-old cohort would be vaccinated with all three doses by year 8 (in 2015). At year 41 (by 2048), 90% would be vaccinated.

In an interview, Dr. Dempsey added that she and Dr. Mendez did not account for vaccination of other groups, including those aged 18-26 years. "We plan on expanding our model in the future to be more comprehensive," she said. However, "because we were focusing specifically on school mandates, we limited our model to those who would be affected by the mandate in the current environment."

Dr. Dempsey said that at the time the study was done and at the time of its presentation, she had no ties to the pharmaceutical industry. However, shortly after the conclusion of the PAS meeting, she said that she agreed to serve on a Merck & Co. advisory board for male HPV vaccination. ■

FDA Strengthens Syncope Warning on Gardasil Label

BY MICHELE G. SULLIVAN

Patients who receive the Gardasil vaccine should sit or lie down in the office for at least 15 minutes after vaccination to prevent possible injury from falling during syncope, while being observed for paleness, sweating, dizziness, or other signs of a possible vasovagal reaction, the Food and Drug Administration recommended.

Because of continued reports of syncope and related traumatic injury, the FDA requested in June that Merck and Co. Inc., manufacturer of the vaccine, add this information to the warnings and precautions section of the label.

'The addition of syncope to the [label] emphasizes that health care providers and consumers should be alert that fainting may occur following vaccination with Gardasil.'

"The addition of syncope to the [label] emphasizes that health care providers and consumers should be alert that fainting may occur following vaccination with Gardasil, sometimes resulting in falling and injuries," the FDA said in a public information statement.

Up to 40% of adolescent syncope associated with Gardasil is also accompanied by tonic-clonic seizure-like activity, the FDA said. "If an individual faints and especially if seizure-like activity occurs, the individual should be placed in a position, such as lying down, to help restore blood flow to the brain."

Syncope has been listed on the label as a possible adverse event since October 2007, the statement said. However, the FDA's Vaccine Adverse Event Reporting System (VAERS) continues to receive reports of traumatic injuries related to fainting and falling after vaccination. In light of this, the agency decided to strengthen the label warning. Fainting doesn't appear to be unique to Gardasil, the statement added. "Syncope has been reported after administration of other adolescent and adult vaccines. ... It can also occur with certain medications, after blood donation, or in response to pain."

The fact sheet did not give details of the injuries associated with the events. However, 70 episodes of syncope in U.S. patients were reported (MMWR 2008;57;457-60). These events occurred from January 2005 to July 2007. The reports noted that about 5% of the spells were considered serious, 38 occurred on the same day as vaccination, and 37 required hospitalization.

As of May 1, 2009, there were 13,758 VAERS reports of adverse events following more than 24 million Gardasil vaccinations in the United States.

Of these reports, 93% were considered nonserious and 7% serious. Nonserious adverse events include fainting, pain and swelling at the injection site, headache, nausea, and fever.

Serious adverse events include Guillain-Barré Syndrome (GBS), transverse myelitis, and blood clots. Additionally, as of May 1, the FDA has received 39 reports of death among females who have received the vaccine. Twenty-six of these reports have been confirmed, six are still under investigation, and seven are unconfirmed. According to a fact sheet on the VAERS Web site, "In the 26 reports confirmed, there was no unusual pattern or clustering to the deaths that would suggest that they were caused by the vaccine."

The VAERS fact sheet did not give details of all these deaths. However, details of deaths that had occurred from June 30, 2006, to August 31, 2008, were reported during an October 2008 postlicensure safety update held by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

The committee reviewed 27 deaths following Gardasil vaccination; 17 of those had been confirmed. Deaths occurred in females aged 12-26 years with no discernible pattern to age or time since vaccine administration. Six occurred within 1 week of vaccination, five within 2-3 weeks, two within 3-9 weeks, and two within 9-17 weeks. One death occurred 288 days after vaccination, and one case had an unknown onset interval.

Other serious adverse events detailed during the committee meeting were syncope (70), venous thromboembolism (41), GBS (52), and transverse myelitis (10).

The vaccine is considered safe and effective, the FDA said in the public information statement. "Based on all of the information we have today, the Centers for Disease Control and Prevention continues to recommend Gardasil vaccination for the prevention of four types of human papillomavirus. As with all approved vaccines, CDC and FDA will continue to closely monitor the safety of Gardasil. Any problems detected with this vaccine will be reported to health officials, healthcare providers, and the public, and needed action will be taken to ensure the public's health and safety." ■

Information regarding adverse events associated with Gardasil is available on the FDA's VAERS Web site (www.cdc.gov/vaccinesafety/vaers/gardasil.htm).