Pediatricians can lay out evidence to allay fears over HPV vaccine
Michael T. Brady
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Pediatricians can lay out evidence to allay fears over HPV vaccine

by Michael T. Brady, M.D., FAAP

Recent media attention has some adolescents and parents wondering whether the human papillomavirus (HPV) vaccine is safe and effective. The discussions that have prompted all of this chatter are not based on available evidence. Unfortunately, a lack of validity does not prevent rapid transmission of rumors and innuendo, especially on television and the Internet.

Pediatricians can allay fears of patients and families and improve HPV vaccination rates if they are aware of the evidence and respond effectively to patient and parental questions. They also need to be as committed to HPV immunization as they are to all of the other AAP-recommended vaccines.

Following are some talking points that pediatricians can use to answer questions about effectiveness and safety of HPV vaccine.

Effectiveness

Clinical trials performed to achieve Food and Drug Administration approval showed the following:

- HPV 16/18-related cervical intraepithelial neoplasia grade 2/3 or adenocarcinoma in situ were reduced by 100%.
- Genital warts in females were reduced by 97%.
- Genital warts in males were reduced by 89% after three doses and 67% after one dose.

Post-marketing surveillance in “real world” settings showed dramatic benefit:

- 56% reduction in prevalence of HPV strains 6, 11, 16 and 18 in adolescent girls in the United States (National Health and Nutrition Examination Survey) despite the fact that only 33% of girls received three doses.
- 77% reduction in prevalence of HPV strains 6, 11, 16 and 18 in adolescent girls in Australia within three years of vaccine introduction (three-dose immunization rates of 70%).
- 75% reduction in low-grade cervical abnormalities in Australian girls younger than 18 years of age within three years of vaccine introduction.
- 45% reduction in genital warts in girls 16-17 years of age in Denmark.
- 36% reduction in genital warts in U.S. girls 15-19 years of age despite low HPV immunization rates.
- 88% reduction in genital warts in Australian females younger than 21 years of age.
- Data on cervical cancer reduction will take longer to obtain due to the time between HPV infection and development of cancer. But data on prevention of pre-cancerous lesions make it clear that the HPV vaccine is having its desired effect.

While it is important to administer the HPV vaccine prior to sexual debut, there is an additional advantage to providing HPV vaccine at the recommended age of 11 to 12 years. The antibody response is more robust, with higher levels of antibodies achieved when given at 11 to 12 years compared to after age 16 years. Data on persistence of antibody are optimistic, with high antibody levels maintained beyond seven years post-immunization. Continued follow-up is needed to determine how long the antibody persists at “protective” levels. However, it doesn’t appear that a booster will be needed.

Safety

- Nearly 60 million doses of HPV vaccine have been given in the United States through 2013.
- Post-marketing surveillance has not identified any new safety concerns in female or male HPV vaccine recipients.
- Injection site discomfort is the most common adverse event.
- Syncope is the most common safety concern. Adherence to a 15-minute observation period after vaccination should prevent significant adverse consequences due to syncope.
- Reports to the Vaccine Adverse Event Reporting System have declined dramatically since 2008 with no serious adverse events reported in 2013.
- Post-marketing surveillance has not shown any increased risk following HPV vaccine for the following conditions: Guillain-Barré syndrome, seizures, stroke, venous thromboembolism, appendicitis, anaphylaxis or other allergic reactions.
- While not approved to be given during pregnancy, no safety concerns have been identified in the HPV pregnancy registry, which includes reports of girls who have been immunized with HPV vaccine while pregnant.
- There is no evidence to suggest that HPV vaccine is responsible for ovarian failure. Genetic, infectious, inflammatory, autoimmune and toxin-related conditions are most likely responsible for ovarian failure in adolescent girls who have received HPV vaccine. (The relationship between ovarian failure and HPV vaccine is temporal but not causal.)
- As of June 2013, 85 deaths had been reported to the Vaccine Adverse Event Reporting System in individuals who have received HPV vaccine. A majority of these deaths have been reviewed...
by the Centers for Disease Control and Prevention, which found:
- There is no diagnosis at death that would suggest the HPV vaccine caused the death.
- There is no pattern of death occurring with respect to time after vaccination.
- There is no consistent vaccine dose number or combination of vaccines given and death.

The HPV vaccine has the potential to prevent tens of thousands of cases of cervical cancer. It truly is a cancer vaccine. Initial information strongly suggests efficacy and good safety. Acceptance of HPV vaccination can be enhanced by a strong recommendation from the health care professional.

Dr. Brady is chair of the AAP Committee on Infectious Diseases.
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