



## Routine HPV vaccination recommended for all children at 11-12 years

by **Rodney E. Willoughby Jr., M.D., FAAP**

The Academy is recommending that both males and females be vaccinated routinely against oncogenic human papillomavirus (HPV) strains.

The recommendations are outlined in the policy statement *HPV Vaccine Recommendations* published in the March issue of *Pediatrics* (2012;129:602-605, <http://pediatrics.aappublications.org/cgi/doi/10.1542/peds.2011-3865>).

Since the last AAP policy statement on HPV vaccination was published in 2007, the Food and Drug Administration added indications for the quadrivalent human papillomavirus vaccine (HPV4 [Gardasil, Merck & Co. Inc.]) to include prevention of warts in adolescent males (2009) and prevention of anal cancers in males and females (2010).

In December 2011, the Centers for Disease Control and Prevention (CDC) recommended that males ages 11 or 12 years routinely receive a three-dose series of quadrivalent HPV vaccine. This recommendation closely parallels the 2006 CDC recommendation for HPV vaccination in females ages 11 or 12 years, using either bivalent or quadrivalent HPV vaccines. There are subtle differences between genders in catch-up strategies for vaccination.

### Burden of disease

HPV vaccination has been justified primarily to prevent adult cancers. Each year, HPV types 16 and 18 cause approximately 15,000 cases of cancer in U.S. females (in decreasing order: cervical, vulvar, anal, oropharyngeal and vaginal) and 7,000 cases of cancer in males (in decreasing order: oropharyngeal, anal and penile). Assuming 4 million children in each birth cohort, this is equivalent to one HPV-associated malignancy per 133 females and one per 286 males.

The highest prevalence of HPV infection is found in sexually active

adolescents and young adults. HPV vaccination is targeted at the pediatric population before onset of sexual activity to be maximally immunogenic and effective.

### Vaccine efficacy

In two large randomized clinical trials (RCTs) in females, the quadrivalent vaccine showed 98.2% per protocol efficacy in preventing precancerous lesions of the cervix or anus. In one large RCT in females, the bivalent vaccine showed 92.9% per protocol efficacy in preventing precancerous lesions of the cervix or anus.

In a substudy of high-risk males from one large RCT in males, the quadrivalent HPV vaccine showed 77.5% per protocol efficacy in preventing precancerous lesions of the anus. The quadrivalent HPV vaccine also showed high efficacy in preventing genital warts in males (89.3%) and females (99%).

No large study has evaluated HPV vaccine efficacy against HPV-associated oropharyngeal cancers, which are increasing.

### Vaccine safety

The safety of the quadrivalent HPV vaccine was evaluated in two large phase III clinical trials in females, one phase III clinical trial in males and several immunogenicity studies in adolescents.

There also is continued surveillance of potential adverse effects of HPV vaccine through the Vaccine Adverse Event Reporting System as well as real-time surveillance of large health maintenance organization practices via the Vaccine Safety Datalink. After more than 40 million doses administered in the first five years of routine administration in U.S. girls, no discernible, vaccine-specific adverse event, with the exception of rare anaphylaxis to vaccine components, has been detected.

### Differences in catch-up vaccination

HPV vaccination can be started at 9 years of age. HPV vaccine (bivalent or quadrivalent) is recommended for females ages 13 through 26 years and quadrivalent for males ages 13 through 21 years who have not initiated or completed the full vaccine series.

HPV vaccine may be given to males 22 through 26 years of age, and should be given to high-risk males through 26 years of age.



*Dr. Willoughby is a member of the AAP Committee on Infectious Diseases.*



## RESOURCES

The Academy has developed implementation guidance for the human papillomavirus (HPV) vaccine that covers supply, payment, coding and liability issues, as well as guidance for parents. These documents can be found on *Red Book Online* at [www.aapredbook.org/implementation](http://www.aapredbook.org/implementation).

A detailed discussion of quadrivalent HPV vaccine efficacy, safety, cost effectiveness and programmatic considerations for males is available in *Morbidity and Mortality Weekly Report*, [www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.htm?s\\_cid=mm6050a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.htm?s_cid=mm6050a3_w).