American Academy of Pediatrics
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POLICY STATEMENT

Prevention of Human Papillomavirus Infection: Provisional Recommendations for Immunization of Girls and Women With Quadrivalent Human Papillomavirus Vaccine

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

Committee on Infectious Diseases

ABSTRACT

This policy statement contains provisional recommendations for use of the quadrivalent human papillomavirus vaccine in girls and women. A full policy statement from the American Academy of Pediatrics is forthcoming.

INTRODUCTION

On June 8, 2006, the US Food and Drug Administration licensed a quadrivalent human papillomavirus (HPV) vaccine (Gardasil; Merck & Co Inc, Whitehouse Station, NJ) for use in girls and women 9 through 26 years of age. The recommendations of the Centers for Disease Control and Prevention for use of the HPV vaccine have been published.[1]

The American Academy of Pediatrics has developed provisional recommendations for the use of this vaccine in the pediatric population that are consistent with its "Recommended Immunization Schedules for Children and Adolescents: United States, 2007."[2] A full American Academy of Pediatrics policy statement from the Committee on Infectious Diseases is in preparation. In the interim, these provisional recommendations are intended to give the pediatrician guidance for the use of this vaccine.

BRIEF BACKGROUND AND RATIONALE

HPV is the most common sexually transmitted infection in the United States. The highest prevalence of HPV infection is seen in sexually active adolescents and young adults, most of whom initially acquire HPV shortly after they become sexually active. Most HPV infections are subclinical (asymptomatic) and resolve without sequelae within 1 to 2 years. However, persistent infection with high-risk HPV types is responsible for virtually all cervical cancer and precancerous lesions of the cervix as well as a large percentage of precancerous lesions and malignancies at other anogenital sites in both women and men. Low-risk HPV types cause anogenital warts, low-grade cervical cytologic changes, and juvenile recurrent respiratory papillomatosis.

The quadrivalent HPV vaccine is a bioengineered, component vaccine made up

www.pediatrics.org/cgi/doi/10.1542/peds.2007-1735

doi:10.1542/peds.2007-1735

Key Words
human papillomavirus, HPV, sexually transmitted infection, adolescents, Gardasil

Abbreviation
HPV— human papillomavirus

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

of virus-like particles produced from the surface proteins of HPV types 16 and 18, which are responsible for 70% of cases of cervical cancer, and types 6 and 11, which are responsible for 90% of cases of genital warts and almost all cases of juvenile recurrent respiratory papillomatosis. The vaccine contains no viral DNA and is not infectious.

Clinical trials have shown the vaccine to be highly immunogenic, safe, and well tolerated in female subjects 9 through 26 years of age. Antibody responses are highest in girls aged 9 to 15 years. In sexually active female subjects 16 to 26 years of age, protection has been demonstrated against persistent infection, precancerous lesions, and genital warts caused by HPV types within the vaccine.

The rationale for routine immunization at 11 to 12 years of age is that, to be most effective, the vaccine should be given before a female becomes sexually active. Although effective in preventing infection with the 4 types of HPV included in it, the vaccine does not seem to alter the outcome of an established HPV infection caused by a vaccine type. Catch-up HPV immunization is also recommended for older females who have not been previously immunized even if they already have been sexually active. Most sexually active females are expected to receive some benefit from immunization, because available data indicate that they are not likely to have been infected with all 4 of the HPV types included in the vaccine.

PROVISIONAL RECOMMENDATIONS

1. Girls 11 to 12 years of age should be immunized routinely with 3 doses of quadrivalent HPV vaccine administered intramuscularly at 0, 2, and 6 months. The vaccine can be given to girls as young as 9 years of age at the discretion of the physician.
2. All girls and women 13 through 26 years of age who have not been immunized previously or who have not completed the full vaccine series should receive quadrivalent HPV vaccine.
3. For individuals who receive a dose of vaccine earlier than the recommended interval from the previous dose, the minimum interval within which the dose can be counted in the series is 4 weeks between doses 1 and 2 and 12 weeks between doses 2 and 3.
4. HPV vaccine can be administered at the same visit as all other recommended vaccines.
5. HPV vaccine can be given in these special circumstances:
   a. when a patient has an abnormal or equivocal Papanicolaou test result;
   b. when a patient is breastfeeding; or
   c. when a patient is immunocompromised because of disease or medication.
6. HPV vaccine is not recommended for use during pregnancy. The practitioner should inquire about pregnancy in sexually active patients, but a pregnancy test is not required before starting the immunization series. If a vaccine recipient becomes pregnant, subsequent doses should be postponed until completion of the pregnancy. It is recommended that women who become pregnant while receiving HPV vaccine be reported to a registry that has been developed to record data on outcomes (1-800-986-8999).
7. Because HPV vaccine is not expected to prevent infection attributable to all high-risk HPV types, cervical cancer–screening recommendations (ie, Papanicolaou testing) should continue to be followed for patients who have received HPV vaccine.
8. Administration of HPV vaccine does not change current counseling recommendations for use of barrier methods for the prevention of HPV and other sexually transmitted infections as well as discussion of healthy choices about sexual activity, including abstinence.

CONTRAINDICATIONS

The vaccine should not be given to people with a history of immediate hypersensitivity to yeast or any vaccine component.

PRECAUTIONS

Immunization should be deferred for people with moderate or severe acute illness. Because syncope can occur in adolescents after injections, consider having vaccine recipients sit or lie down for 15 minutes after administration.[3]

USE OF QUADRIVALENT HPV VACCINE IN BOYS AND YOUNG MEN

Quadrivalent HPV vaccine currently is not recommended for males. Safety and immunogenicity studies have been completed in 11- to 15-year-old boys, and clinical trials are underway to evaluate its efficacy in sexually active males. Recommendations for the use of quadrivalent HPV vaccine in boys and men will be considered on the basis of the outcome of these trials and licensure decisions by the US Food and Drug Administration.

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REFERENCES

1. Markowitz LE, Dunne EF, Saraiya M, et al. Quadrivalent human papillomavirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2007;56(RR-2):1–24. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm
2. American Academy of Pediatrics, Committee on Infectious Diseases. Recommended immunization schedules for children and adolescents: United States, 2007 [published correction appears in *Pediatrics*. 2007;119:659]. *Pediatrics.* 2007;119:207–208
3. American Academy of Pediatrics. Vaccine administration. In: Pickering LK, Baker CJ, Long SS, McMillan JA, eds. *Red Book: 2006 Report of the Committee on Infectious Diseases.* 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006:18–22

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Pediatrics 2007;120;666
DOI: 10.1542/peds.2007-1735

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OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

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