

AAP updates HPV vaccine recommendations after licensure of HPV9

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

The recently licensed 9-valent human papillomavirus (HPV9) vaccine is one of three HPV vaccines now recommended by the Academy.

The Food and Drug Administration approved HPV9 (Gardasil 9, Merck & Co. Inc.) in December 2014 for use in females ages 9 through 26 years and males ages 9 through 15 years. The vaccine provides close to 97% protection against five additional types of HPV not covered by quadrivalent HPV (HPV4, Gardasil), also manufactured by Merck.

The Academy's recommendations do not reflect a preference for HPV9, HPV4 or bivalent HPV vaccine (HPV2, Cervarix, GlaxoSmithKline), which is approved only for females. It is much more important to initiate and complete the HPV vaccine series using any available HPV vaccine because more than half of vaccine-eligible children are not being protected against HPV-associated cancers.

Safety, efficacy of HPV9

The efficacy and immunogenicity of HPV9 vaccine was compared to HPV4 in 14,000 women ages 16-26 years (Joura EA, et al. *N Engl J Med.* 2015;372:711-723). Results showed HPV9 prevented infection and disease related to HPV types 31, 33, 45, 52 and 58 in a susceptible population and generated an antibody response to HPV types 6, 11, 16 and 18 that was noninferior to that generated by the HPV4 vaccine.

Systemic adverse events were comparable between HPV4 and HPV9, while adverse events related to injection site were more common in the HPV9 group than in the HPV4 group (90.7% vs. 84.9%, respectively).

AAP recommendations

All 11- and 12-year-old children should receive HPV vaccine as part of the adolescent immunization platform.

The Academy recommends three doses of HPV9, HPV4 (as availabilities last) or HPV2 for routine immunization of females 11 or 12 years of age. Three doses of either HPV9 or HPV4 (as availabilities last) are recommended for routine immunization of males 11 or 12 years of age. The second dose should be administered at least one to two months after the first dose, and the third



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Although HPV9 protects against five additional types of HPV, revaccination is not recommended for people who received HPV4 or HPV2 but may be done safely.

dose should be administered at least six months after the first dose.

The vaccination series can be started as young as 9 years of age. In the case of sexual abuse, HPV vaccination is recommended beginning at 9 years of age.

Any of the three vaccines are recommended for females 13 through 26 years of age who have not been immunized or have not completed the series.

Either HPV9 or HPV4 is recommended for immunization of males 13 through 21 years of age who have not been immunized or have not completed the series as well as for men who have sex with men and people who are immunocompromised (including those with HIV infection) through 26 years of age. Men 22

through 26 years of age who have not been immunized or have not completed the vaccine series may receive HPV9 or HPV4 vaccine. Cost-efficacy models do not justify a stronger recommendation in this age group.

Revaccination of people vaccinated with HPV4 or HPV2 is not recommended but may be done safely.

The Academy's recommendations mirror those of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (1.usa.gov/1FMKrTv).

Additional recommendations

- Dose(s) of vaccine received after a shorter-than-recommended interval should be repeated.
- If the vaccine schedule is interrupted, the series does not need to be restarted.
- Whenever feasible, the same HPV vaccine should be used for the entire series. Immunization should not be deferred if an alternate HPV vaccine is available.
- Prior sexual activity is not a contraindication to HPV immunization or completion of the immunization series. Patients infected with one HPV type still may benefit from protection against remaining HPV types in the vaccine.
- Testing for prior exposure to HPV is not recommended.
- HPV vaccine can be administered when a female patient has an abnormal or equivocal Papanicolaou test result. There is no known therapeutic (as opposed to prophylactic) benefit from

the HPV vaccines.

- HPV vaccine can be administered when a patient is immunocompromised because of disease or medication or when a female patient is breastfeeding.
- Because HPV vaccine will not prevent infection attributable to all high-risk HPV types, cervical cancer screening recommendations (i.e., Papanicolaou testing) should continue to be conducted in women older than 21 years.
- HPV immunization of children 9 years of age and older should be covered by all public and private health insurers. All HPV vaccines are covered by the Vaccines for Children Program.

Contraindications

- HPV vaccines should not be given to pregnant women, 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.
- HPV4 and HPV9 should not be given to people with a history of immediate hypersensitivity to yeast.
- HPV2 should not be used in persons with anaphylactic latex allergy.

Precautions

- Immunizations should be deferred for people with moderate or severe acute illness.
- Because syncope can occur in adolescents after injections and has been reported after HPV vaccine, recipients should sit or lie down for 15 minutes after administration.

Rationale for immunization

The rationale for routine HPV immunization at 11 or 12 years of age is twofold. First, optimal vaccine efficacy requires that the vaccine be administered before onset of sexual activity. The vaccine is inactive against HPV types previously acquired by the vaccine recipient. Second, antibody responses are highest at ages 9 through 15 years.

Uptake of the HPV vaccine lags behind other vaccines offered in adolescence. In 2013, only 57% of females and 35% of males ages 13-17 years had initiated HPV immunization. This means that

one in 350 girls and one in 390 boys in each year's immunization cohort will continue to develop HPV-associated cancers despite available prevention.

Research has shown that a personal recommendation by primary care professionals in favor of HPV vaccination matters most to parents. When speaking with parents, pediatricians can focus on how the HPV vaccine can prevent cancer. Tell parents that this is a three-dose series. Schedule the patient before leaving the office. Recall patients using an electronic medical record, immunization registry, postcards or phone/text messages. Standing orders are effective and efficient.



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

RESOURCES

- Red Book Online chapter on HPV, http://redbook.solutions.aap.org/data/books/1484/RBO2015.sec3_094.en.pdf (available 5-29)
- HPV implementation guidance, <http://redbook.solutions.aap.org/ss/vaccine-policy-guidance.aspx>
- HPV vaccine resources for health care professionals, www.cdc.gov/vaccines/YouAreTheKey
- Tips for talking with parents about the HPV vaccine, www.cdc.gov/vaccines/hpv-tipsheet
- PediaLink continuing medical education courses (free): Adolescent Immunizations: Strongly Recommending the HPV Vaccine and Adolescent Immunizations: Office Strategies, <http://bit.ly/1E5RypU>

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