

CDC: Two-Dose Regimen of HPV Vaccine Sufficient Up to Age 15

Norra MacReady | December 15, 2016

Children aged 9 to 14 years can now receive the human papillomavirus (HPV) vaccine on a two-dose schedule, rather than a three-dose one, according to updated recommendations issued by the Centers for Disease Control and Prevention (CDC).

The recommendations are based on the findings of a year-long review of new clinical trial data conducted by the Advisory Committee on Immunization Practices (ACIP). The data show that among girls and boys in this age range, immunogenicity associated with the two-dose regimen was not inferior to, and in some cases was superior to, that seen with the three-dose regimen.

HPV infection causes cancer of the cervix, vulva, and vagina in women; in men, it causes cancer of the penis. In both sexes, it can cause anal and oropharyngeal cancer, as well as genital warts.

"HPV vaccines are highly effective and safe, and a powerful prevention tool for reducing HPV infections and HPV-associated cancers," lead author Elissa Meites, MD, and colleagues write in an article [published](#) in the December 16 issue of the *Morbidity and Mortality Weekly Report*.

Routine vaccination is recommended at 11 to 12 years of age for both sexes. However, vaccination as young as age 9 years is recommended if a child has been sexually abused or assaulted.

In addition, catch-up vaccinations are recommended through age 26 years for those not already vaccinated.

The agency continues to recommend three doses for people who are immunocompromised or who do not begin the vaccine series before their 15th birthday.

Prelicensure vaccine efficacy trials were conducted using the three-dose series. However, follow-up analyses and a large study comparing the two-dose and three-dose regimens suggested that, for some people, two doses might be as effective as three, prompting a reexamination of the original recommendations.

In October 2016, after considering the new evidence, both ACIP and the US Food and Drug Administration [approved](#) the two-dose series for individuals who receive the first vaccination dose on or after their ninth birthday and before their 15th birthday, with the second dose administered 6 to 12 months after the first.

"Assuming both efficacy and duration of protection are similar with either schedule, a 2-dose series would be cost-saving and have similar population impact to a 3-dose series," the authors point out. "Even if duration of protection is 20 years for a 2-dose series and lifelong for a 3-dose series, additional benefits of a 3-dose series would be relatively small, and a 2-dose series would be more cost-effective."

ACIP evaluated the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, supplemented with information from other studies, Dr Meites, from the Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, CDC, and colleagues write. CDC recommendations also are developed using the GRADE framework.

Two-Dose Regimen Noninferior

The committee revised its recommendations based on evidence from a clinical trial comparing the effects of the two-dose regimen in girls and boys 9 through 14 years of age to those of a three-dose

regimen in young women 16 through 26 years of age. Of the 1377 participants, 97.9% or more seroconverted to all of the vaccine-preventable HPV types within 4 weeks after receiving the last vaccine dose.

Individuals receiving the two-dose regimen met noninferiority criteria for seroconversion and geometric mean titers (GMTs) compared with participants receiving the three-dose regimen. This was seen whether the second dose was administered 6 or 12 months after the first.

In fact, GMTs were significantly higher "among persons aged 9 through 14 years who received 2 doses compared with females aged 16-26 years who received 3 doses [on a 0-, 2-month, and 6-month schedule]," the authors write.

No waning of protection has been seen in people followed for up to 10 years after receiving the three-dose series, they add. "Because antibody kinetics are similar with 2-dose and 3-dose series, duration of protection is also expected to be long-lasting after a 2-dose series."

The authors note that as of late 2016, the only type of HPV vaccine distributed in the United States is the 9-valent form (9vHPV [*Gardasil 9*, Merck and Co]). This vaccine targets HPV 16 and 18, which cause most HPV-associated cancers, as well as HPV 6, 11, 31, 33, 45, 52, and 58. It is licensed for use in both sexes from 9 through 26 years of age.

Until recently, bivalent (2vHPV) and quadrivalent (4vHPV) forms of the vaccine also were available in the United States and are still used in some countries, Dr Meites and coauthors point out. People who have started a vaccine series with either of these products can complete the series with 9vHPV, and if they have already received the full series of 2vHPV or 4vHPV, "there is no ACIP recommendation regarding additional vaccination with 9vHPV."

The authors have disclosed no relevant financial relationships.

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