

Study compares effectiveness of 2 vs. 3 doses of HPV vaccine for girls and young women

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With the number of doses and cost of human papillomavirus (HPV) vaccines a barrier to global implementation, researchers have found that girls who received two doses of HPV vaccine had immune responses to HPV-16 and HPV-18 infection that were noninferior to (not worse than) the responses for young women who received three doses, according to a study in the May 1 issue of *JAMA*, a theme issue on child health. The authors note that more data on the duration of protection are needed before reduced-dose schedules can be recommended.

"Globally, [cervical cancer](#) is the second most common cause of cancer morbidity and mortality in women. [Human papillomavirus](#) infection has been identified as a necessary cause for the development of cervical cancer, with HPV genotypes 16 and 18 accounting for approximately 70 percent of cervical cancer cases," according to background information in the article. "Global use of HPV vaccines to prevent cervical cancer is impeded by cost. A 2-dose schedule for [girls](#) may be possible."

Dr. Dobson and colleagues conducted a study to determine whether average antibody levels to HPV-16 and HPV-18 among girls receiving 2 doses were noninferior to women receiving 3 doses. The authors also looked at antibody levels to HPV-6 and HPV-11, and compared girls given 2 or 3 doses. The randomized, phase 3, multicenter study included 830 Canadian females from August 2007 through February 2011. Follow-up blood samples were provided by 675 participants (81 percent). Girls (9-13 years of age) were randomized 1:1 to receive 3 doses of quadrivalent [HPV vaccine](#) at 0, 2, and 6 months (n=261) or 2

doses at 0 and 6 months (n=259). [Young women](#) (16-26 years of age) received 3 doses at 0, 2, and 6 months (n=310). Antibody levels were measured at 0, 7, 18, 24, and 36 months.

The researchers found that the geometric mean titer (GMT) [antibody levels](#) in girls receiving 2 doses were noninferior to the respective GMTs in women receiving 3 doses for all 4 genotypes, with GMT ratios of 2.07 for HPV-16 and 1.76 for HPV-18. "Girls given 2 doses vs. 3 doses had a noninferior antibody response for all 4 [vaccine](#) genotypes," with GMT ratios of 0.95 for HPV-16 and 0.68 for HPV-18.

"The GMT ratios for girls (2 doses) to women (3 doses) remained noninferior for all genotypes to 36 months. Antibody responses in girls were noninferior after 2 doses vs. 3 doses for all 4 vaccine genotypes at month 7, but not for HPV-18 by month 24 or HPV-6 by month 36."

The authors write that these are the first data, to their knowledge, "on the duration of the [immune response](#) of young adolescent girls to a reduced-dose schedule of quadrivalent HPV vaccine out to 3 years." However, "The clinically meaningful difference between the 2- and 3-dose schedules cannot yet be determined."

"Reducing the number of doses affects vaccine and administration costs as well as potentially improving uptake rates. Evidence-based decision making in public health has led to reduced-dose schedules for hepatitis B, pneumococcal, and meningococcal serogroup C vaccine programs. There is a balance to be found between the incremental value of an additional dose on population effectiveness and the opportunity costs of using the resources required for the extra dose in other public health programs. This is especially the case for HPV vaccines at their present cost."

"... the study by Dobson et al provides encouraging preliminary

evidence that a 2-dose quadrivalent HPV vaccine series in girls may be as immunogenic as a 3-dose series in women, although the duration of protection may be less," writes Jessica A. Kahn, M.D., M.P.H., and David I. Bernstein, M.D., M.A., of the Cincinnati Children's Hospital Medical Center and the University of Cincinnati College of Medicine, in an accompanying editorial.

"If future studies establish that a 2-dose series leads to a durable immune response and effectively prevents HPV-related cancers in both women and men, the benefits would be substantial for reducing the global burden of cervical cancer and other HPV-related diseases. The potential to further reduce morbidity and mortality due to HPV-related cancers would be especially significant in less developed regions of the world, where the cost of vaccination and implementation of adolescent vaccination programs present significant barriers, but where primary prevention strategies are most urgently needed."

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