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Is One HPV Vaccine Dose Enough?

— NHANES data suggest yes, but researchers urge caution

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A single-dose vaccination regimen for human papillomavirus (HPV) had similar efficacy against HPV infection compared with the recommended two- or three-dose series, although researchers caution that more research is needed.

Analysis of 2009-2016 data from 1,620 women in the National Health and Nutritional Examination Survey (NHANES) showed infection with strains covered by the quadrivalent vaccine (types 6, 11, 16, or 18) in 2.4% of those who received one dose of the vaccine compared with 5.1% in those given two doses and 3.1% who received three doses.

Among unvaccinated women, prevalence of infection with HPV type 6, 11, 16, or 18 was 12.5%, reported Kalyani Sonawane, PhD, of the University of Texas Health Science Center at Houston, and colleagues in *JAMA Network Open*.

"Our study suggests that US women who received 1 dose of the HPV vaccine may have gained similar protection against vaccine-type infections compared with those who received additional doses," the study authors wrote. "These findings support previous observational studies and post hoc analyses of vaccine trials that demonstrated comparable effectiveness of one dose to two or three doses."

Sonawane and colleagues emphasized, however, that the study's limitations precluded firm conclusions about the efficacy of one versus multiple vaccine doses. All data on immunization history and sexual behavior were patient-reported and at risk of recall bias, they noted. In addition, the timing of HPV vaccination could not be evaluated or compared with potential HPV exposure because of the cross-sectional study design.

"If ongoing trials confirm sufficient efficacy and sustained duration of protection from a single-dose regimen, vaccine initiation (as opposed to the series completion) will become a more achievable metric of population coverage," they wrote.

The CDC has estimated that each year, 33,700 cancers are caused by HPV. These include oropharyngeal, anal, cervical, vaginal, vulvar, and penile cancer.

The current HPV vaccination program for adolescents -- which has been routinely recommended for girls since 2006 and for boys since 2011 -- has the potential to prevent the majority of these cancers, according to the CDC's Advisory Committee on Immunization Practices (ACIP). Routine vaccination is recommended at age 11 or 12, but can begin as early as 9. Catch-up HPV vaccination is recommended through age 26 with shared clinical decision-making in adults ages 27 to 45.

Simplifying HPV vaccination with a single-dose strategy could go a long way towards reducing the burden of HPV-related cancers, not just in the U.S. but globally, Sonawane and colleagues said. To date, HPV vaccine coverage worldwide is less than 10%, they pointed out.

"The rates of HPV-associated cancers, including anal cancer and throat cancer, are increasing rapidly in the U.S. both in men and women," Sonawane told *MedPage Today*. "Currently, there are no other ways to prevent these cancers, and thus, improving HPV vaccination rates is the only hope to reverse the rising burden of these cancers in future generations."

In the current study, 1,004 women were unvaccinated and 106 received one dose, 126 received two doses, and 384 received three doses of the HPV vaccine. Mean patient age was 22.2 years.

Differences in HPV infection rates by the number of doses received were not statistically significant for cross-protection against HPV types 31, 33, and 45 or against eight other high-risk HPV types, the results showed. In adjusted analyses, unvaccinated women had a 7.4% predicted probability of infection with HPV 6, 11, 16, or 18 compared with women who received one (2.3%), two (5.7%), or three doses (3.1%) of the HPV vaccine.

Black women had a higher predicted probability of HPV infection than white women (10.8% vs 6.6%), and women with more than five lifetime male sexual partners had a higher predicted probability of infection compared to women with five or fewer lifetime male sexual partners (11.6% vs 3.3%).

In the 10-plus years since the HPV vaccine was introduced in the U.S., coverage among adolescents ages 13 to 17 has increased steadily but remains suboptimal, the researchers noted. In 2018, 51.1% of adolescents nationwide completed a full vaccination series

compared to 49% in 2017. These rate increases were only seen in boys, and fall far below the 80% Healthy People 2020 target for HPV vaccination coverage.

Barriers to optimizing HPV vaccination include a lack of awareness or forgetfulness on the part of patients about subsequent doses in the series, the investigators said. Lack of health insurance coverage or contact with the medical system can also prevent initiation or completion of vaccination.

Clinicians who do not recommend HPV vaccination have also contributed to suboptimal coverage, Sonawane and colleagues asserted. In an earlier national U.S. survey study, the same group found that more than half of the vaccine-eligible patients did not receive a recommendation for the HPV vaccine from a clinician. The study also showed that fewer men (19%) than women (31.5%) received an HPV vaccine recommendation ($P< 0.001$), and there was a 10% difference in vaccination coverage between boys and girls (44.3% vs 53.1%, respectively).

Notably, more than 70% of men and women age 27 years and older did not know that HPV causes oral, anal, and penile cancers. These are the people who will be making future decisions about immunization of adolescent children, the researchers noted.

Adolescents whose parents received a provider recommendation "were more likely to receive HPV vaccination compared with adolescents whose parents did not report a provider recommendation," the CDC confirmed in a recent report.

Results from a literature review of barriers to HPV vaccination revealed that parents often lacked the information they needed to consent to having their child vaccinated. Chief concerns included cost of the vaccine and its effect on adolescent sexual behavior. In addition, many parents perceived that HPV infection was low risk and that vaccination carried no direct benefit for male children.

Since decisions about immunization for patients younger than age 15 are made by a parent or caregiver, "communicating the importance of HPV vaccine is critical to parental decision-making," Sonawane emphasized. Addressing parents' concerns about vaccine safety and efficacy, making strong provider recommendations for vaccination, and supporting public health campaigns that increase awareness about the importance of HPV vaccination may improve coverage in the U.S., she said.

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