Fewer than three doses of cervical cancer vaccine effective

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Fewer than three doses of the human papillomavirus (HPV) vaccine Cervarix may be just as effective as the standard three-dose regimen when it comes to preventive measures against cervical cancer, according to a new study published September 9 in the *Journal of the National Cancer Institute*.

Across the globe, cervical cancer is the third most common cancer among women, and HPV types 16 and 18 are a large contributor to the development of the disease. The HPV 16/18 vaccine is currently given in three doses over six months, making it an expensive and sometimes difficult to complete. No previous study has reported on the efficacy of fewer doses of the vaccine in protecting women against the HPV infections that lead to cervical cancer.

To determine whether a lower number of doses of the Cervarix vaccine would be efficacious, Aimée R. Kreimer, Ph.D., of the Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, and a team of researchers conducted an analysis of data from the NCI-sponsored Costa Rica Vaccine Trial, where women received either three doses of Cervarix or the control vaccine. Of the 7,466 women enrolled, 20% received fewer than three doses due to involuntary factors, such as pregnancy or referrals to colposcopy during routine patient management. The researchers compared the frequency of persistent infection with HPV 16 or 18 in the HPV and control arms of the trial during 4 years of follow-up in women who received one or two doses of the vaccine and in women who received 3 doses.
Once researchers excluded women who had no follow-up or who were HPV16 and HPV18 DNA positive at the time of enrollment, 5,967 women received three doses of the treatment, 802 received two doses and 384 women received only one dose.

The researchers found similar levels of protection against HPV16 and HPV18 from the vaccine among women receiving one, two, and three doses of the vaccine. For settings in which the cost of vaccine and logistics of implementation are important factors, they write, "Our clinical efficacy data provide suggestive evidence that an HPV vaccine program that provides fewer doses to more women could potentially reduce cervical cancer incidence more than a standard three-dose program that uses the same total number of doses but in fewer women." They add that they were surprised by the evidence of protection from one dose, since other subunit vaccines typically require at least two shots. They caution that it remains to be determined whether fewer than three doses will provide strong protection for substantially longer periods than the 4 years of the current study.

They conclude, "If randomized studies and cost-effectiveness analyses confirm the benefits of administering fewer doses, and the duration of protection is sufficient, then the need for fewer doses may help make primary prevention of cervical cancer a reality."

In an accompanying editorial, Cosette Marie Wheeler, Ph.D., of the Department of Pathology and Department of Obstetrics and Gynecology at the University of New Mexico writes that there is a need for additional, larger studies specifically designed to evaluate the efficacy of one, two and three doses of the vaccine for adolescent girls. However, because of the high cost of clinical trials, she writes that phase IV effectiveness studies and population-based surveillance programs may be useful.
In any case, the Kreimer study represents a step in the right direction, Wheeler writes. "The age old adage of less is more may apply to HPV vaccination, and if so, the report of Kreimer et al. represents an important step on the road to more effective and sustainable cervical cancer prevention programs.

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