Single Dose of HPV Vaccine Provides Lasting Cancer Protection

This makes a big difference in preventing the more than half a million new cervical cancer cases and over 300,000 deaths globally each year.

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Single Dose of HPV Vaccine Yields Long-Term Protection from Many Cancer-Causing Types

More than a decade after vaccination, women who had received a single dose of human papillomavirus (HPV) vaccine continued to be protected against cervical infection with the two cancer-causing HPV types targeted by the vaccine, HPV16 and 18. The new findings are from an extended follow-up of the NCI-sponsored Costa Rica HPV Vaccine Trial.

In a second, related analysis, the trial's researchers found that a single vaccine dose also provided long-lasting protection against three other cancer-causing HPV types not targeted by the vaccine—a phenomenon known as cross-protection. The vaccine also provided lesser cross-protection against two additional cancer-causing HPV types.

The findings, which confirm and extend earlier results from a 7-year follow-up study of the Costa Rica Trial, "provide more data to support a one-dose schedule with this particular HPV vaccine," said Lauri Markowitz, MD, associate director of science for HPV at the Centers for Disease Control and Prevention (CDC), who was not involved with the new analyses. Results from both were published February 24 in the Journal of the National Cancer Institute.

The vaccine used in the trial, known as Cervarix, is no longer available in the United States, but it is still used in some countries. It is one of three World Health Organization–recommended HPV vaccines that protect against sexually transmitted infections with disease-causing HPV types.

The ability to protect against many cancer-causing HPV infections with just one vaccine dose—rather than the two or three doses currently recommended—"would make a very big difference" in preventing the more than half a million new cervical cancer cases and more than 300,000 deaths from the disease worldwide each year, said Costa Rica Trial investigator Aimée Kreimer, PhD, of NCI's Division of Cancer Epidemiology and Genetics (DCEG).

However, Kreimer and Markowitz cautioned, data from several other ongoing studies, including the large, randomized NCI-led ESCUDDO study in Costa Rica, are needed to confirm that a single dose of HPV vaccine is sufficiently protective and determine if a single dose is as effective as two or

three doses. Such findings could support changes in worldwide vaccination guidelines, they said.

Public Health Benefits of a One-Dose Schedule

Persistent infections with HPV types 16 and 18 cause about 70% of all cervical cancers. Three other HPV types (31, 33, and 45) account for another 13% of cervical cancer cases, said DCEG postdoctoral fellow Sabrina Tsang, PhD, MPH, who led the complementary analysis of vaccine cross-protection. HPV infections (primarily HPV16) can also cause other cancers of the genital and anal regions, as well as throat cancers, in both men and women.

Cervical cancer is a leading cause of cancer and cancer deaths in women worldwide. A combination of HPV vaccination and cervical cancer screening can greatly reduce cervical cancer incidence and deaths. But global HPV vaccination rates remain low, and many low-resource countries do not have HPV vaccination programs or routine screening.

“If we needed only one dose of the vaccine, that would make it logistically easier and less expensive to administer,” Markowitz said. And as Kreimer explained, “There aren’t many vaccines that we give to adolescents globally.”

The infrastructure needed to administer multiple doses, including tracking when each person received their first dose, is a significant barrier to achieving widespread vaccination, she added. “A vaccine where you can give everyone one dose and they’re done is a much simpler approach.”

In addition, Kreimer said, there is currently a global HPV vaccine shortage, and needing only one dose would allow more people to be vaccinated.

Insights from Long-Term Follow-Up

The Costa Rica Trial was a 4-year randomized clinical trial of three doses of the HPV vaccine. Kreimer and her colleagues continued following most HPV-vaccinated women from the trial beyond 4 years. About 20% of women in the trial received fewer than three vaccine doses. So, the investigators were able to evaluate the efficacy of one and two doses. The main reasons for not receiving all three doses were pregnancy or abnormal cervical findings from routine cervical cancer screening.

To understand the duration of the vaccine’s protection, the researchers continued to follow women in the trial in a long-term follow-up study, obtaining cervical and blood samples 7, 9, and 11 years after vaccination.

“In this most recent analysis, we found that HPV-vaccinated women had very few cervical HPV16 or 18 infections even 11 years after vaccination, whereas a group of unvaccinated women we followed had higher rates of infection,” Kreimer said.

The reduction in HPV infections was similar no matter how many vaccine doses were received, with an estimated vaccine efficacy of 82%, 84 %, and 80%, respectively, for one, two, and three doses. (Vaccine efficacy is the reduction in infections in vaccinated versus unvaccinated women.)

HPV-vaccinated women had antibodies to HPV16 and 18 in their blood at 11 years, the researchers found. Antibody levels were comparable to those seen in the early years following vaccination, regardless of the number of doses received, an indication of long-lasting immune response to the vaccine, they explained.

Stable Cross-Protection Over Time

In the companion analysis on cross-protection led by Tsang, the researchers compared rates of infections with cancer-causing HPV types not targeted by the vaccine among vaccinated and unvaccinated women.

Consistent with previous findings from this study, which had 7 years of follow-up, the updated analysis showed that women who received three doses experienced protection against new infections with HPV types 31, 33, and 45, with an average vaccine efficacy of 64% that remained stable over 11 years. Although limited by sample size, the data suggested that vaccine efficacy against these three HPV types was similar in women who received only one vaccine dose, said Kreimer. The vaccine also provided a lesser degree of cross-protection against HPV types 35 and 58.

Researchers believe cross-protection occurs because the cross-protected types of HPV are genetically similar to the vaccine-targeted HPV types 16 and 18, Tsang said.

These findings suggest that the HPV16/18 vaccine may protect against a greater percentage of cervical cancers than researchers had anticipated, Tsang continued.

Strengths, Limitations, and Future Studies

Although Markowitz called the results of the two new studies “very encouraging,” she noted some limitations, including that relatively few women in the Costa Rica Trial received one or two vaccine doses, and they were not randomly assigned to the specific dosing schedule. She noted that some other, shorter-term studies have suggested that one dose of the HPV 16/18 vaccine will work as well as two or three doses.

None of the published studies to date have randomly assigned women to receive a single vaccine dose. It is possible that women in the Costa Rica Trial who received a single dose “were different in some way,” Markowitz said. However, she continued, “the trial investigators have done extensive analyses to look at how comparable the single-dose women were to the women who received three doses.”

Indeed, Kreimer said, “we launched the ESCUDDO study to directly evaluate the question of single-dose protection of HPV vaccines in a new randomized clinical trial.”

The ESCUDDO study enrolled more than 20,000 adolescent girls, randomly assigned to receive one or two doses of Cervarix or Gardasil 9, which protects against nine HPV types. More than 4,000 young adult women were also enrolled to document HPV rates in the population at the start

of the study.

Together, the new findings of long-lasting protection “give us a first glimpse of hope that these vaccines will last as long as we need them to,” Kreimer explained.

The goal is to vaccinate girls when they are 10–12 years old and protect them for at least 20 years. “HPV infections acquired in the late teens and twenties, when women are most sexually active, are the most important ones to protect [against] in terms of controlling cervical cancer,” she said.

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