

# Study boosts support for single-dose HPV vaccine regimen

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Gardasil vaccine and box. Image: Wikipedia

A [randomized controlled trial](#) of 2,275 women in Kenya showed that a single dose of the human papillomavirus (HPV) vaccine was highly effective. The current standard for women is a three-dose regimen.

Dr. Ruanne Barnabas, principal investigator in the trial, said the trial results could help the World Health Organization reach its goal to have 90% of 15-year-old girls vaccinated against HPV by 2030. "The single-dose efficacy was the same as multiple doses," she said.

Currently, just 15% of women worldwide are vaccinated against HPV.

Barnabas was a professor of global health at the University of Washington School of Medicine in Seattle at the time of the study. She is now chief of the Division of Infectious Diseases at Massachusetts General Hospital in Boston.

The results of the "KEN-SHE" trial were to be published Monday, April 11, in the journal *NEJM Evidence*.

"These findings are a game-changer that may substantially reduce the incidence of HPV-attributable cervical [cancer](#) and positions single-dose HPV vaccination as a high-value and high-impact public health intervention that is within reach for us," said Professor Sam Kariuki, acting director general at the Kenya Medical Research Institute, where the study was conducted.

The findings add further support to the adoption of a single-dose HPV [vaccine](#), which could increase accessibility in low- and [middle-income countries](#), said Peter Dull, deputy director of vaccine development and surveillance at the Bill & Melinda Gates Foundation, which funded the study.

"HPV vaccines are a powerful tool to reduce cervical cancer, but too many women and girls in low- and middle-income countries don't have access to them," Dull said. "The KEN-SHE study results contribute to a growing body of evidence supporting the potential for a single-dose HPV vaccination."

Most sexually active women and men will be infected with HPV at some point in their lives and some will be repeatedly infected. The peak time for acquiring infection among both women and men is shortly after becoming sexually active.

While nine out of 10 HPV infections resolve on their own in two years, others lead to cancer of the reproductive system, mainly cervical cancer. HPV also can cause cancers of the cervix, vagina, vulva, penis, and oropharyngeal cancer (throat, tongue, and tonsils).

Worldwide, cervical cancer kills a women every two minutes. Most of those deaths are in Africa, which bears 80% of the cervical cancer burden. However, due to cost and limited vaccine supply, coverage has been low in areas with the highest cervical cancer burden.

In the trial, women 15 to 20 years old were randomly assigned a therapy and followed from December 2018 to June 2021. To be eligible, the women needed to be sexually active, have no more than five lifetime partners, be HIV-negative, and have no history of HPV vaccination. The most of those who enrolled (57%) were between 15 and 17 years old and most reported only one lifetime sexual partner (61%).

The participants were randomized into three treatment arms:

- 760 received a bivalent vaccine that covered two strains of HPV (16/18), which represent 70% of cases
- 758 received a nonavalent vaccine that covered seven strains of HPV (16/18/31/33/45/52/58), which represent 90% of cases
- 757 received a vaccine that protects against meningococcal meningitis.

After 18 months, the bivalent vaccine was 97.5% effective against HPV 16/18 and the nonavalent vaccine was 97.5% effective against HPV 16/18. The nonavalent vaccine was 89% effective against HPV 16/18/31/33/45/52/58. Even if women tested positive for one strain of HPV, the vaccine protected them from other strains of the virus.

Researchers said more studies need to be done to test how long the

vaccine lasts.

"This trial brings new energy to the elimination of cervical cancer. It brings great hope to the [women](#) living in countries like Kenya, who have a high burden of the disease," said Dr. Nelly Mugo, co-principal investigator on the study and senior principal clinical research scientist with the Center for Clinical Research at the Kenya Medical Research Institute in Nairobi. She also is a UW associate research professor of global health.

Researchers said one impetus for the trial was the cervical cancer ward at the Kenyatta National Hospital in Nairobi. They said they want the ward empty.

"I believe that I will see [cervical cancer](#) eliminated in my lifetime," said Dr. Maricianah Onono at the Kenya Medical Research Institute. "So, let's do this—one shot for every woman!"

**More information:** Efficacy of Single-Dose Human Papillomavirus Vaccination among Young African Women, *NEJM Evidence* (2022).  
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