

# Newsletter New Vaccine Breakthroughs

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## 💡 Human Papilloma Virus vaccination (HPV): where we are in 2025

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### ✉ Editor's Note / Introduction

Welcome to this edition of Newsletter New Vaccine Breakthrough—your trusted source for insights into vaccine science, policy, and innovation.

### ⌚ This issue covers:

1. Reduced number of doses for HPV vaccination series studies.
2. HPV vaccination coverage.
3. HPV vaccination effectiveness
4. HPV vaccine ongoing clinical trials

Let's dive in. 

### 👉 1. Spotlight: Topic of the Month:

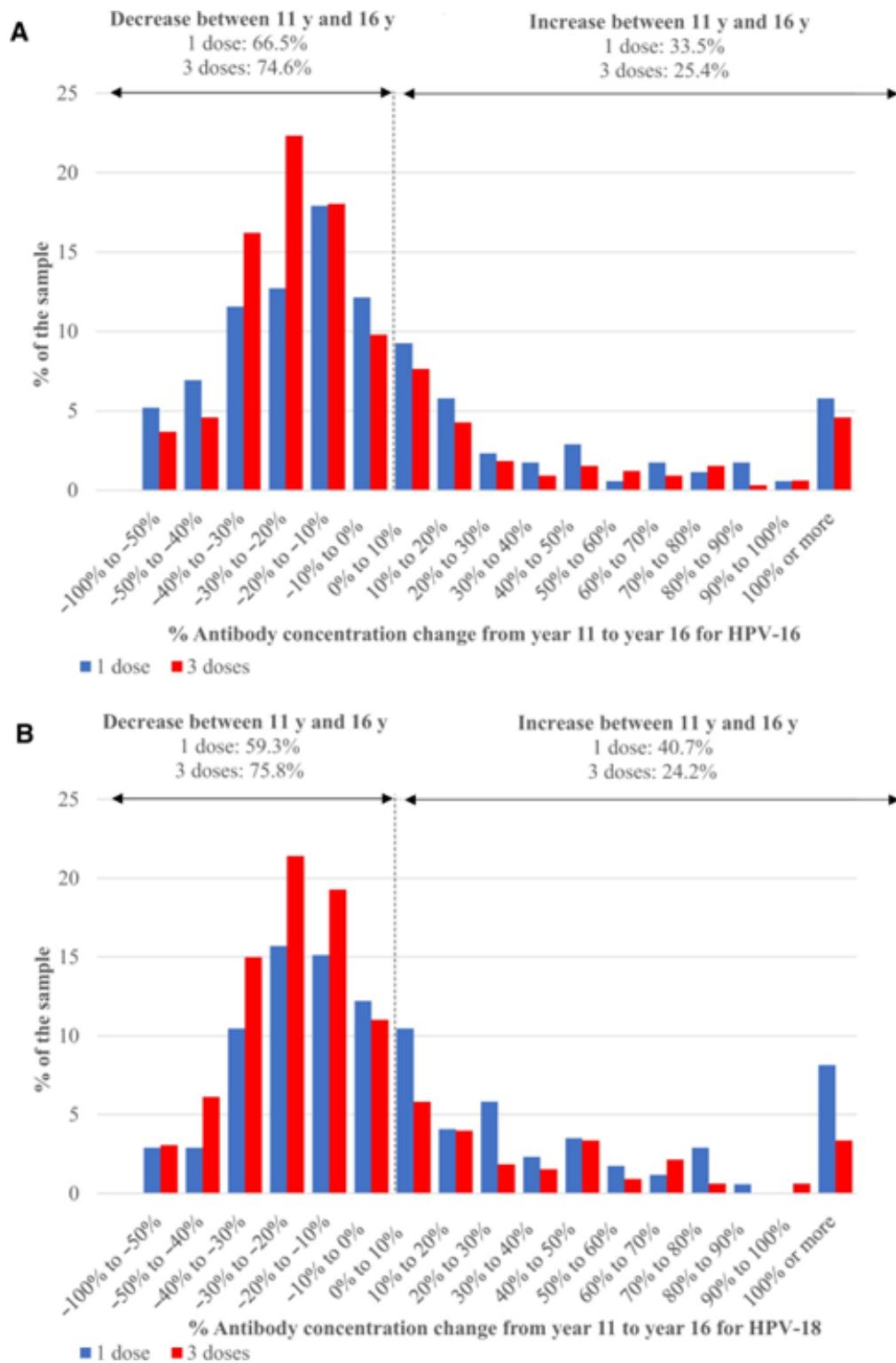
#### Reduced number of doses for HPV vaccination series studies: 1 dose efficacy data

##### ⌚ Summary:

##### ◊ PV16/18 antibodies 16-years after single dose of bivalent HPV vaccination : Costa Rica HPV vaccine trial.

This study provided initial evidence that 1 dose of the bivalent human papillomavirus (HPV) vaccine induces stabilizing antibody levels that may provide extended protection against HPV-16/18 infections. We report antibody seropositivity and stability 11 to 16 years after vaccination. By year 16, 99.4% (95% confidence interval [CI] ¼ 96.8% to 100.0%) and 100.0% (95% CI ¼ 98.9% to 100.0%) of 1-dose and 3-dose recipients, respectively, were HPV-16 seropositive and 98.8% (95% CI ¼ 95.9% to 99.9%) and 100% (95% CI ¼ 98.9% to 100.0%) of 1-dose and 3-dose recipients, respectively, were HPV-18 seropositive. Between years 11 and 16, women who had received 3 doses had a small but statistically significant decrease in the geometric mean concentration for HPV-16 of -12.4% (95% CI ¼ -16.3% to -8.4%) and HPV-18 of -13.4% (95% CI ¼ -17.2% to -9.4%). Among women who had received 1 dose, the decrease was statistically significant for HPV-16 at -8.9 (95% CI ¼ -14.2% to -3.1%) but nonsignificant for HPV-18. Geometric mean concentration ratios of 3:1 dose (year 16) were 3.0 and 2.2 for HPV-16 and HPV-18, respectively. HPV-16/18 seropositivity remained exceedingly high 16 years after vaccination. Over

5 years, small declines in antibodies were observed. Women should have protection for at least 20 years and likely much longer at the observed rate of decline.



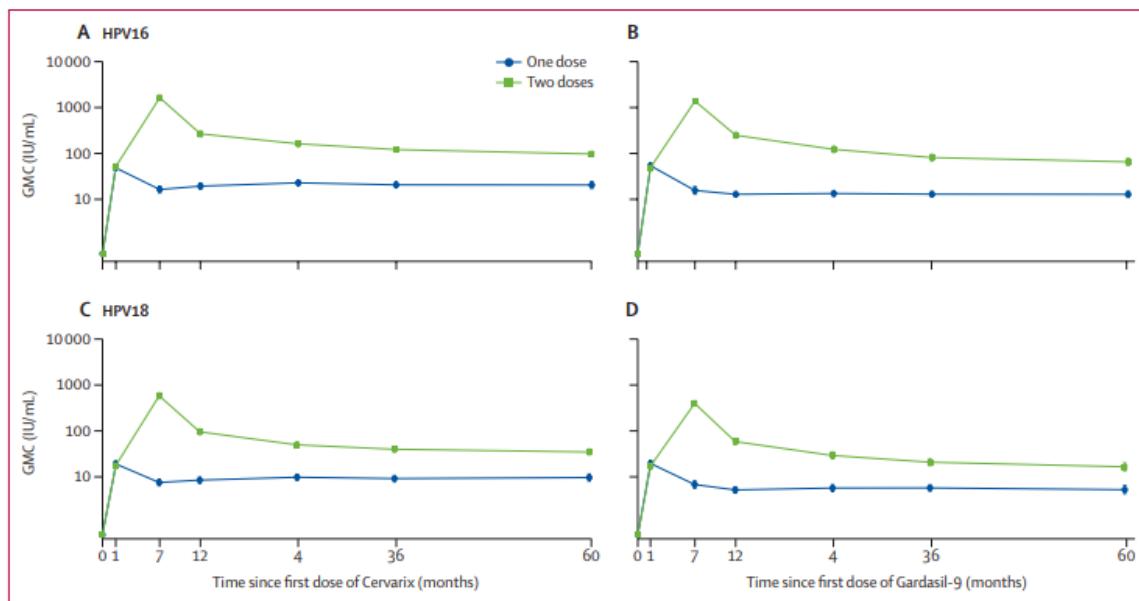
- ◊ **A prospective cohort study comparing efficacy of 1 dose of quadrivalent human papillomavirus vaccine to 2 and 3 doses at an average follow up of 12 years postvaccination.**

While recommending a human papillomavirus (HPV) single-dose vaccination schedule in 2022, the World Health Organization highlighted the need for long-term follow-up studies to monitor waning of protection. We report on vaccine efficacy against HPV infections in 1-, 2-, and 3-dose schedules and protection against cervical precancers at a median follow-up of 12 years postvaccination. This randomized multicenter study in India was originally designed to vaccinate unmarried girls aged 10-18 years with either 2 or 3 doses of quadrivalent HPV vaccine. A ministerial decree to halt vaccination in trials resulted in the creation of cohorts receiving different doses, including just a single dose. Cohorts were assessed for incident and persistent infections by genotyping cervical samples collected yearly for 4 consecutive years after participants were married. Cervical screening with an HPV test was initiated at age 25 years for married participants. Age- and site-matched unvaccinated married women were recruited to be compared with vaccinated cohorts. Vaccine efficacy was assessed using proportional incidence ratios. Vaccine efficacy against persistent HPV 16 and 18 infections was 92.0% (95% confidence interval [CI] = 87.0% to 95.0%) in 3022 recipients of the single dose ; and comparable with that observed in the 2-dose arm (94.8%, 95% CI = 90.0% to 97.3%) and the 3-dose arm (95.3%, 95% CI = 90.9% to 97.5%). No high-grade precancer associated with HPV 16 and 18 was detected among vaccinated participants compared with 8 precancers detected among the unvaccinated women. This observational cohort study has established that a single dose of HPV vaccine provides high protective efficacy against persistent HPV 16 and 18 infections and associated neoplasia 15 years postvaccination.

- ◊ **Durability of immunogenicity at 5 years after a single dose of human papillomavirus vaccine compared with two doses in Tanzanian girls aged 9–14 years.**

WHO has recommended that one dose of human papillomavirus (HPV) vaccine can be given to individuals aged 9–20 years to prevent HPV infection. Estimating durability of immune responses after a single dose in the target age for vaccination is important. We report immunogenicity results in Tanzanian girls up to 5 years after receiving a dose. In this open-label, randomised controlled trial (the Dose Reduction Immunobridging and Safety Study of Two HPV Vaccines in Tanzanian Girls [DoRIS] trial), 930 Tanzanian schoolgirls aged 9–14 years were enrolled and randomly allocated to receive one, two, or three doses of either the two-valent vaccine (Cervarix) ; or nine-valent vaccine (Gardasil-9; Merck Sharp & Dohme. Seropositivity specific to HPV16 or HPV18, antibody geometric mean concentrations (GMCs), and antibody avidity were measured annually up to month 36. Participants in the one-dose and two-dose groups were followed annually in a long-term extension of the DoRIS trial to month 60; the primary outcome was seropositivity specific to HPV16 or HPV18 comparing one dose with two doses. Single dose seropositivity for HPV16 IgG antibodies at month 60 with either vaccine was more than 99% and non-inferior to two doses. 98% of girls in the one-dose two-valent vaccine group and 93% in the one-dose nine-valent group were seropositive for HPV18 at month 60; however, the non-inferiority criteria for HPV18 seropositivity comparing one dose

with two doses were not met. Although HPV16 and HPV18 antibody GMCs after one dose were lower than those observed after two doses, antibody GMCs in the one-dose groups remained stable from month 12 to month 60. There was no evidence of a difference between the one-dose and two-dose groups in HPV16 or HPV18 antibody avidity at month 36 for either vaccine. A single dose of HPV vaccine in girls aged 9–14 years continues to provide stable immune responses 5 years after vaccination, although ongoing surveillance for potential waning immunity after a single dose is needed. Participants are being followed up to 9 years after vaccination.

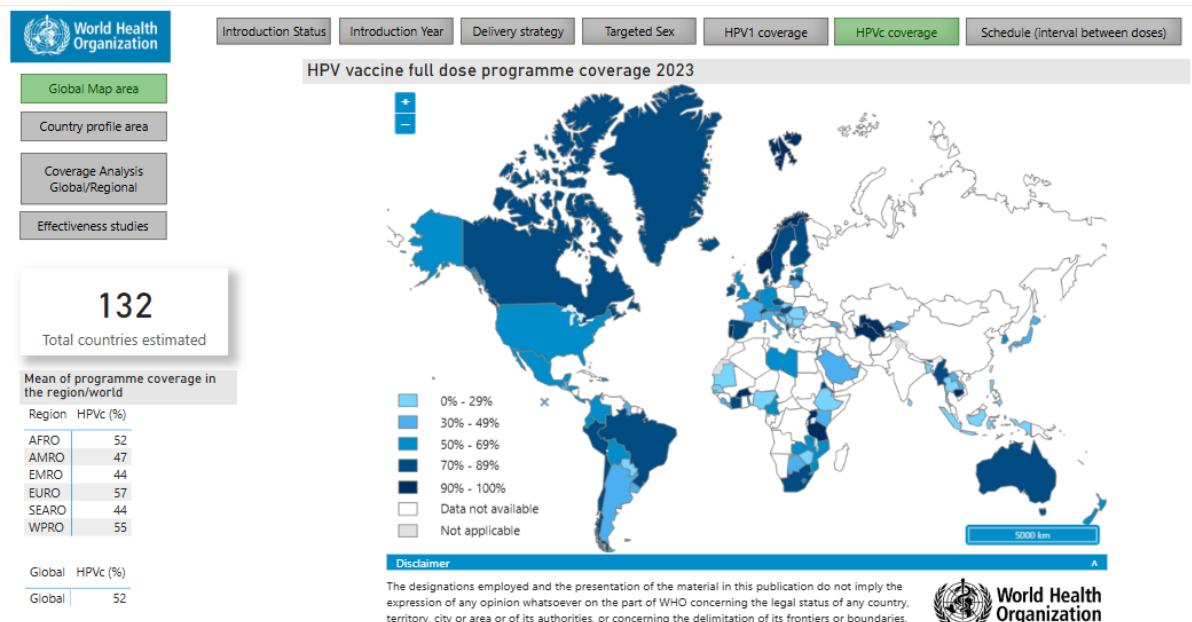


**Figure 2: Antibody GMCs over time by number of vaccine doses and study visit (per-protocol cohort)**  
HPV16-specific antibody GMCs with the two-valent (A) and nine-valent (B) vaccine, and HPV18-specific antibody GMCs with the two-valent (C) and nine-valent (D) vaccine. GMC=geometric mean concentration. HPV=human papillomavirus.

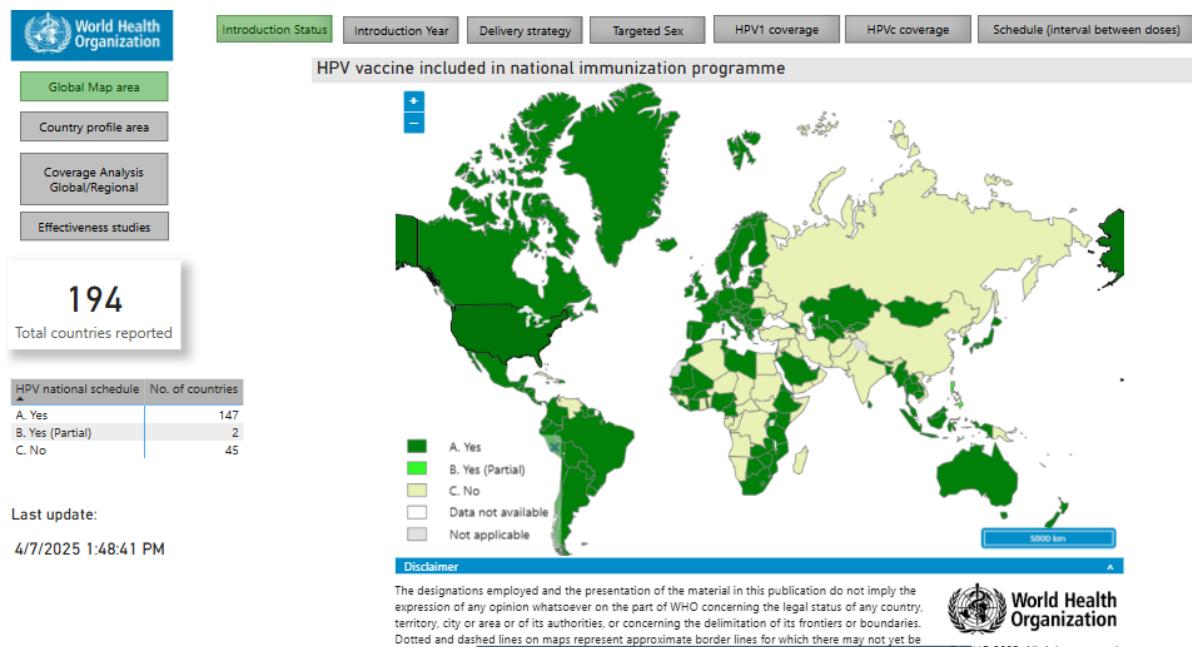
## 2. HPV Vaccination Coverage:

### ◇ Human Papilloma Virus vaccine (HPV) full dose programme coverage in 2023:

The HPV VCR is ranging from 44% in EMRO WHO region to 57 % in EURO WHO region.



As of April 7th, 2025, 147 countries worldwide included HPV vaccine in their nation immunization programme.



### 3. Science Simplified:

- ◊ [Effectiveness of quadrivalent human papillomavirus vaccination against high-grade cervical lesions by age and doses .](#)

One or two-dose schedule for human papillomavirus (HPV) vaccination has been recommended by the World Health Organization and used in many vaccination programs. This study aimed to comprehensively evaluate the effectiveness of quadrivalent HPV vaccine against high-grade cervical lesions by age at vaccination and number of doses received. This cohort study included 2,200,495 females aged 10–35 years old who were residents of Sweden between 2006 and 2022, with 584,676 (26.6%) receiving at least one dose of quadrivalent HPV vaccine. We used Poisson regression models to estimate the incidence rate ratios (IRR) comparing the incidence rate of high-grade cervical lesions in relation to age at vaccination and doses. In girls initiating vaccination before age 15, we observed IRRs of 0.42 (95% CI 0.33–0.52) after one-dose, 0.54 (0.47–0.63) after two-dose, and 0.50 (0.47–0.53) after three-dose. The IRRs were 0.60 (95% CI 0.52–0.70), 0.55 (0.49–0.62), and 0.54 (0.52–0.56) after one, two or three doses for girls who initiated vaccination age 15–17. For women who initiated vaccination after age 20, higher doses may be needed to achieve a statistically significant risk reduction. Receiving one or two doses of HPV vaccines prior to age 17, especially for those initiating before age 15, has comparable effectiveness against high-grade cervical lesions with those who received three doses.

### 4. Clinical Trials:

- ◊ [Comparing One or Two Doses of the Human Papillomavirus Vaccine for the Prevention of Human Papillomavirus Infection, ESCUDDO Study \(ESCUDDO\)](#)  
This ongoing phase IV trial investigates whether one dose of a human papillomavirus vaccine works as well as two doses in preventing human papillomavirus (HPV) infection. Researchers want to find out if one dose prevents HPV infection. If it does, more people might get the vaccine. Study completion estimated august 2025.

- ◊ [Global Burden Estimation of Human Papillomavirus](#)

This study is a multi-country and multi-site project to estimate the point-prevalence of high-risk (HR) HPV genotype infections among representative samples of girls and women aged 9–50 years, and among specific sub populations to estimate the incidence of persistent HPV infection among sexually active young women. The data to fulfill the objectives will be collected through a series of Cross-Sectional Surveys (CSS) and Longitudinal Studies (LS) in all 8

countries 3 South Asian countries including Bangladesh, Pakistan, Nepal and 5 sub-Saharan African countries including Sierra Leone, Tanzania, Ghana, Zambia and DR Congo. Qualitative sub-studies (QS) will be conducted in selected countries and populations following the CSS to further understand and unpack risk factors for HPV infection as well as to explore how gender-related dynamics including perceptions of gender norms and stigma, influence HPV burden and/or create barriers that shape girls/women access to and uptake of HPV prevention, screening, and treatment services. Specific study protocols and corresponding ethical applications for the qualitative sub-studies will be developed separately.

◊ **Extended Follow-up of Women Who Received One, Two, and Three Doses of the HPV Vaccine in the Costa Rica Vaccine Trial (CVT), ESCUDDO-CVT Study**

This study is extending follow up of women who participated in the Costa Rica Vaccine Trial (CVT) and received one dose or two doses of the human papillomavirus (HPV) vaccine, along with a group of women who received three doses. It also studies the stability of HPV defenses in these groups of women for up to 20 years after initial vaccination. Studying samples of blood in the laboratory may provide information on how long one, two, and three doses of the vaccine provide protection against HPV. The results of this study may also help researchers learn whether one dose of HPV vaccine is enough to protect against HPV.

## @@ **Thanks for reading!**

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