FREQUENTLY ASKED QUESTIONS

Human papilloma virus (HPV) causes almost all cases of cervical cancer. HPV vaccines are highly effective in preventing HPV-associated cervical cancer, but worldwide vaccine coverage is low (only 31 percent of girls less than 15 years old in 2024). Most deaths from cervical cancer occur in low- and middle-income countries.

In December 2022, the World Health Organization (WHO) endorsed an alternative single-dose HPV vaccination schedule in women and girls ages 9-20. The Pan American Health Organization (PAHO) Technical Advisory Group (TAG) and the WHO Africa Regional Immunization Technical Advisory Group (RITAG) endorsed the global recommendation in 2023 and 2024, respectively.

High-quality evidence assessing single-dose HPV vaccination suggests that implementing a single-dose schedule is scientifically sound and provides the greatest public health benefit. As of March 2026, more than 90 countries have implemented a single-dose schedule.

Below are frequently asked questions and answers about the evidence around single-dose HPV vaccination and the current policy landscape.

EVIDENCE

WHAT INFORMED WHO'S ENDORSEMENT OF A SINGLE-DOSE HPV VACCINE SCHEDULE? CAN A SINGLE-DOSE HPV VACCINATION SCHEDULE PREVENT CERVICAL CANCER?

- Immunization schedule updates are driven by scientific evidence.
- Data accumulated to date from clinical trials and high-quality observational clinical studies provide strong evidence of comparable efficacy and effectiveness between single and multidose schedules in preventing HPV infections, causing almost all cases of cervical cancer.
- For a detailed review of the evidence that informed WHO's recommendation, along with additional data that has accumulated since the recommendation, view the Trials Summary (in the Appendix below) or download the Consortium slide deck.[1]

WHAT DO WE KNOW ABOUT THE DURATION OF PROTECTION OF A SINGLE-DOSE HPV VACCINE?

[1] PATH. *Current evidence on single-dose HPV vaccination*. PATH; December 2025. https://www.path.org/our-impact/resources/presentations-on-single-dose-hpv-vaccination/.

- Data available for more than a decade (14 years post-vaccination in India[2]; 11 years post-vaccination in Costa Rica[3]) show comparable rates of HPV infection prevention between single and multidose schedules.
- Data available from 10 years post-vaccination in India[2] and 16 years post-vaccination in Costa Rica[3] show persistent antibody response, with no evidence of waning.
- Based on large body of evidence on the durability of HPV antibodies generated by virus-like particle vaccines[4], protection is likely to persist throughout life.
- In December 2025, results were published from the first randomized control trial (RCT) to directly compare a single-dose cohort with a two-dose cohort within the same study. The study found a single dose to be non-inferior to two doses in reducing persistent infections (assessed at five years post-vaccination) and highly effective compared to the unvaccinated cohort. A single dose was also highly effective compared to the unvaccinated cohort in the KEN SHE study (assessed at 4.5 years post-vaccination).[5]
- For a detailed review of the evidence, view the Trials Summary (in the Appendix below) or download the Consortium slide deck.[1]

IS THERE MORE EVIDENCE COMING?

- KEN-SHE, IARC, CVT, and DoRIS studies will continue to collect data on their respective efficacy and/or immunogenicity endpoints.
- Additional studies are underway to assess a single-dose regimen in varying age groups, HIV-positive populations, and recently licensed products.

WHY SHOULD COUNTRIES CONSIDER SWITCHING TO A SINGLE-DOSE SCHEDULE?

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[2] Basu P, Malvi SG, Joshi S, et al. Vaccine efficacy against persistent human papillomavirus (HPV) 16/18 infection at 10 years after one, two, and three doses of quadrivalent HPV vaccine in girls in India: a multicentre, prospective, cohort study [published correction appears in *Lancet Oncology*. 2022 Jan;23(1):e16]. *Lancet Oncology*. 2021;22(11):1518-1529. doi:10.1016/S1470-2045(21)00453-8.

[3] Kreimer AR, Sampson JN, Porras C, et al. Evaluation of Durability of a Single Dose of the Bivalent HPV Vaccine: The CVT Trial. *Journal of the National Cancer Institute*. 2020;112(10):1038-1046. doi:10.1093/jnci/djaa011.

[4] Schiller J, Lowy D. Explanations for the high potency of HPV prophylactic vaccines. *Vaccine*. 2018;36(32 Pt A):4768-4773. doi:10.1016/j.vaccine.2017.12.079.

[5] Kreimer AR, Porras C, Liu D, Hildesheim A, Carvajal LJ, Ocampo R, Romero B, Gail MH, Cortes B, Sierra MS, Coronado K, Sampson J, Coto C, Dagnall CL, Mora D, Kemp TJ, Zuniga M, Pinto LA, Barrientos G, Schussler J, Estrada Y, Montero C, Avila C, Ruggieri D, Cyr JT, Chanock S, Lowy DR, Schiller JT, Herrero R. Noninferiority of One HPV Vaccine Dose to Two Doses. N Engl J Med. 2025 Dec 3. doi: 10.1056/NEJMoa2506765. Epub ahead of print. PMID: 41337735.

- Scientific data show that one dose provides sufficient protection against HPV.
- Modeling based on a high-quality evidence base suggests that reaching a greater number of girls with one dose of HPV vaccine will prevent a much higher number of cervical cancer cases than vaccinating fewer girls with two doses.[6]
- In 2023-2024, an additional 18.5 million girls were reached due to the adoption of single-dose, averting about 300,000 cervical cancer cases.[7]

IS THERE ONE PRODUCT MORE EFFECTIVE AS A SINGLE DOSE THAN ANOTHER?

- In RCTs assessing the performance of single-dose HPV vaccination, Gardasil, Gardasil 9, Cervarix, and Cecolin and provided comparably high levels of protection against persistent HPV infection.

[6] Prem K, Choi YH, Bénard É, et al. Global impact and cost-effectiveness of one-dose versus two-dose human papillomavirus vaccination schedules: a comparative modelling analysis. *BMC Med*. 2023;21(1):313. Published 2023 Aug 28. doi:10.1186/s12916-023-02988-3.

[7] Stuart R, Theopold N, Miall N, Kobayashi E, Vernam S, Taskin T, Dull PM. The role of HPV single-dose vaccination in expanding access in GAVI-supported countries during a period of supply constraints. Vaccine. 2026 Jan 22;75:128187. doi: 10.1016/j.vaccine.2025.128187. Epub ahead of print. PMID: 41576708.

POLICY LANDSCAPE

DOES WHO RECOMMEND SINGLE-DOSE HPV?

- In December 2022, the WHO Position Paper on HPV was updated to recommend a one or two-dose schedule for the primary target of girls aged 9-14 years, for young women aged 15-20 years, and boys/men aged 9-20 years. Women over 21 years old should have two doses with at least six-month interval. The PAHO TAG and the WHO Africa RITAG endorsed the global recommendation in 2023 and 2024, respectively.
- Immunocompromised individuals, including those with HIV, should receive at least two doses and, ideally, three doses.
- See the WHO updated position paper on HPV vaccination schedules[8] and the PAHO and WHO Africa RITAG endorsements of single-dose regimens.

WHY DOES WHO RECOMMEND EITHER A SINGLE DOSE OR A TWO-DOSE SCHEDULE?

- Based on the strength of the evidence available at the time, WHO recommended one or two doses to expand HPV vaccine schedule options available to countries and enable stronger vaccine coverage.
- In December 2025, results from an anticipated RCT, the first to directly compare vaccine efficacy in a single-dose cohort to a two-dose cohort within the same study, confirmed a single-dose is non-inferior in reducing HPV infections.

WHY IS IT RECOMMENDED BOYS MAY USE THE SAME SCHEDULES AS GIRLS IF THERE IS LIMITED DATA ON BOYS?

- While data in boys are limited, a single-dose HPV vaccine elicits a similar immune response in girls and boys aged 9-14 years.
- Males can transmit HPV infection to females, and HPV is the main cause of cervical cancer in women. Protecting boys is another way to protect girls.

WHAT ARE THE RECOMMENDATIONS FOR THOSE LIVING WITH HIV?

[8] World Health Organization. Human papillomavirus vaccines: WHO position paper (2022 update). Weekly epidemiological record. *World Health Organization – Weekly epidemiological record*. 2022;97(50):645-672. https://iris.who.int/bitstream/handle/10665/365350/WER9750-eng-fre.pdf.

- Evidence is still being collected on the performance of single-dose HPV in immunocompromised individuals, including those living with HIV. For now, WHO recommends women and girls living with HIV receive at least two doses and, where possible, three doses.

WHAT ARE THE POTENTIAL PROGRAMMATIC BENEFITS OF A SINGLE-DOSE HPV VACCINATION SCHEDULE?

- Single-dose HPV vaccination schedule can accelerate broader access to HPV vaccines by:
  - Lowering vaccine costs for programs.
  - Reducing potential risks for global supply shortages.
  - Leading to new distribution options, such as co-delivery with other vaccine campaigns, which could reduce overall costs, or a shift gender-neutral programming without major cost implications.
- The programmatic benefits are especially pronounced given the historically poor coverage of HPV vaccination.

CAN NATIONAL PROGRAMS ADOPT A SINGLE-DOSE SCHEDULE EVEN THOUGH THIS CONSTITUTES AN OFF-LABEL USE?

- Science moves faster than label updates. Due to the high-quality evidence base supporting the use of single-dose HPV vaccine, WHO includes in their recommendations the off-label use of a single-dose regimen as an alternative to a multi-dose schedule.
- WHO has previously made off-label recommendations when the evidence supports it. Previous vaccine examples of WHO off-label recommendations include pneumonia conjugate vaccine and hepatitis A vaccine.
- It is ultimately up to national regulatory authorities to decide to implement an off-label recommendation.

WHAT NATIONAL POLICY-LEVEL CHANGES ARE NEEDED TO PROCEED WITH THE SHIFT TO SINGLE-DOSE?

- Each country has its own national immunization advisory authorities, who ultimately will review evidence and decide on implementing a single-dose schedule according to their country-specific processes.

WILL GAVI SUPPORT COSTS ASSOCIATED WITH SWITCHING FROM TWO- TO ONE-DOSE SCHEDULES?

- Gavi provides financial support for existing routine programs and new vaccine introductions and campaigns within Country Vaccine Budget allocations.

WILL MORE RECENTLY LICENSED HPV VACCINES BE CONSIDERED FOR THE SINGLE-DOSE REGIMEN?

- For new vaccine products to be considered effective in a single-dose schedule, they must demonstrate single-dose efficacy or immunological non-inferiority compared to vaccines for which one-dose efficacy data exists. WHO has indicated that two years post-vaccination immunobridging data for recently licensed products is required. Some studies assessing recently licensed products are already underway.

To access the full review of current evidence, visit the Single-Dose HPV Vaccine Evaluation Consortium landing page.[9] For information about implementing single-dose HPV vaccination programs, including decision-making, Gavi applications, planning, communication, implementation and monitoring, visit the TechNet-21 toolkit.[10]

APPENDIX: TRIALS SUMMARY

- The most impactful RCT evidence to date on single-dose HPV vaccination is from the ESCUDDO Study, the first randomized control trial (RCT) to directly compare a single-dose cohort with a two-dose cohort within the same study. The study found a single dose to be non-inferior to two doses in reducing persistent infections (assessed at five years post-vaccination) and highly effective compared to the unvaccinated cohort.
- The KENya Single-dose HPV vaccine Efficacy (KEN SHE) RCT[11] in African adolescent girls and young women launched in 2018. It showed that a single dose of HPV vaccination was ~98% effective in preventing new onset persistent HPV 16/18 (the strains that cause the majority of cervical cancer cases) in a sexually active population (15-20 year-olds), assessed at 4.5 years post-vaccination.
    - The KEN SHE RCT builds on follow-up studies using previous RCTs that sought to measure performance of two- or three-dose HPV vaccine schedules, but which inadvertently generated single-dose cohorts when participants didn't receive subsequent doses for various reasons unrelated to the study objectives.

[9] PATH. Accessed March 18, 2024. https://www.path.org/who-we-are/programs/center-for-vaccine-innovation-and-access/single-dose-hpv-vaccine-evaluation-consortium/.
[10] TechNet-21. Accessed March 18, 2024. https://www.technet-21.org/en/topics/programme-management/hpv-intro.
[11] Barnabas RV, Brown ER, Onono M, et al. Single-dose HPV vaccination efficacy among adolescent girls and young women in Kenya (the KEN SHE Study): study protocol for a randomized controlled trial. *Trials*. 2021;22(1):661. doi:10.1186/s13063-021-05608-8.

    - One such example of a high-quality observational study is the International Agency for Research on Cancer's (IARC) HPV vaccine trial in India launched in 2009. The incidence of HPV infections was comparable among the one-, two-, and three-dose groups 14 years after vaccination.
    - The other example is the Costa Rica HPV Vaccine trial (CVT) launched in 2004 that provides evidence that following one dose of HPV vaccine the level of protection against HPV infections is similar to two or three doses in healthy young females up to 11 years post-vaccination.
- The RCT Dose Reduction Immunobridging and Safety study (DoRIS) of two HPV vaccines in Tanzanian girls provides single-dose immunogenicity data.
    - An immunobridging analysis found that the immune response 24 months post-vaccination of a single dose of HPV in girls aged 9–14 years was non-inferior to a single dose in historical cohorts for which single-dose efficacy was shown (ages 15-20 in Kenya; ages 18–25 in Costa Rica; and ages 10–18 in India).
- While immune responses following a single dose have shown to be lower than after two or three doses, single-dose vaccination elicits higher levels of antibodies than those induced after natural infection that remains stable through 10 and 16 years of post-vaccination data collection (in the India IARC trial and the Costa Rica HPV Vaccine trial, respectively).