Evidence to inform decision-making on single-dose HPV vaccination policy

Cervical cancer is a leading cause of cancer death among women in low- and middle-income countries (LMICs), and almost all cases can be attributed to human papillomavirus (HPV). Over half a million new cases and 350,000 deaths occur annually, with more than 90% of deaths occurring in LMICs.[1] HPV vaccines are highly effective, and vaccination is the primary tool for preventing and eliminating cervical cancer.

As of March 2026, more than half of the countries with national HPV vaccination programs have adopted a single-dose HPV vaccination schedule.[2] This brief summarizes critical study findings, estimated public health impacts, and current recommendations to assist policymakers and program implementers with decision-making.

HPV vaccines are safe and highly effective. Since their introduction, they have significantly reduced vaccine-type HPV infections, precancerous cervical lesions, and cervical cancers. Efficacy and robust and durable antibody responses to the five licensed and WHO-prequalified HPV vaccines (Cervarix®, Cecolin®, Gardasil®, Gardasil 9, and Walrinvax®) are well documented. In healthy young women, seroconversion rates are virtually 100%. Immune responses in preadolescents are stronger than in adults. The durability of protection and stability of antibody responses have been observed for more than 14 years post-vaccination; this pattern is evident even after a single dose of HPV vaccine.

Single-Dose HPV Vaccine
EVALUATION CONSORTIUM

Clinical studies

Data from clinical studies across multiple geographies, in addition to those listed in the chart below, continue to reinforce the World Health Organization's recommendation[3] of a single-dose HPV vaccination schedule.

Study	KEN SHE[4]	DoRIS[5]	Estudio de Comparacion de Una y Dos Dosis de Vacunas Contra el Virus de Papiloma Humano (ESCUDDO)[6]	International Agency for Research on Cancer (IARC)[7]	Costa Rica HPV Vaccine Trial (CVT)[8]
Study type	Randomized, controlled	Randomized, controlled	Randomized, controlled	High-quality observational*	High-quality observational
Study start	2018	2017	2017	2009	2004
Clinical endpoints	Vaccine type-specific HPV infection; vaccine immunogenicity	Vaccine immunogenicity	Vaccine type-specific HPV infection; vaccine immunogenicity	Vaccine type-specific HPV infection; vaccine immunogenicity	Vaccine type-specific HPV infection; vaccine immunogenicity
Location	Kenya	Tanzania	Costa Rica	India	Costa Rica
Key findings	Single-dose vaccination with HPV9 (Gardasil 9, MSD) or Cervarix was >95% effective in preventing new onset persistent HPV 16/18 infection in African adolescent girls and young women as of 54 months post- vaccination.	Antibody levels among girls receiving a single dose of HPV9 (Gardasil 9, MSD) or HPV2 (Cervarix, GSK) were at least as high as those in women from the KEN SHE, CVT, or IARC studies where single-dose efficacy was shown. Data suggest the efficacy of a single dose of HPV vaccine can be inferred to the targeted 9–14-year-old age group.	Single-dose of HPV9 (Gardasil 9, MSD) or HPV2 (Cervarix, GSK) is non-inferior to a 2-dose regimen in preventing persistent HPV-16/18 infection among adolescent girls. Either HPV vaccine provides >97% protection against HPV16/18 infection over 5 years.	Single dose showed 92% efficacy with HPV4 (Gardasil, MSD) against persistent HPV 16/18 infection for at least 14 years. Vaccine efficacy was comparable regardless of the dose regimen with Gardasil (one, two, or three doses).	Efficacy from one and three doses of HPV2 (Cervarix, GSK) were comparable in protecting against HPV 16/18 infection as of 10 years post-vaccination. The level of antibody induced after a single dose was 10X above the natural infection level as of 16 years post- vaccination.[9]

** The IARC and CVT studies are randomized, controlled trials designed to assess multi-dose schedules that generated single-dose cohorts for reasons unrelated to study objectives. This provided an opportunity for long-term follow-up of participants who received a single dose of HPV vaccine.*

Level of protection

In December 2025, results became available from the randomized, controlled Study Comparing One and Two Doses of HPV Vaccines (Estudio de Comparacion de Una y Dos Dosis de Vacunas Contra el Virus de Papiloma Humano, or ESCUDDO).[6] Researchers assessed participants five years post-vaccination and found a single-dose regimen to be >97% effective and non-inferior to two doses. It is the first trial to conduct a head-to-head comparison of one- and two-dose regimens within the same study and represents a critical addition to the evidence base. In the randomized, controlled KEN SHE study, a single dose was highly effective in preventing persistent vaccine-type related oncogenic HPV infections as of 54 months post-vaccination.

The ESCUDDO and KEN SHE studies were designed to answer scientific questions about the efficacy of single-dose HPV vaccination, and thus provide evidence based on scientific rigor that builds upon high-quality observational data from the IARC and CVT studies. In the controlled, high-quality observational IARC and CVT studies, rates of incident or prevalent and persistent infections with HPV 16/18 were extremely low in single-dose recipients and significantly lower than in participants who either were unvaccinated or received a control vaccine and comparable to two- or three-dose cohorts. In the DoRIS study, single-dose effectiveness was inferred in 9–14-year-olds based on immunobridging to KEN SHE, IARC, and CVT trials. The immunobridging analyses found that single-dose immunogenicity two years post-vaccination in this age group was non-inferior to the reference single-dose cohorts, i.e., cohorts with proven single-dose efficacy (KEN SHE for Cervarix and GARDASIL 9, 15–20 years of age; CVT for Cervarix, 18–25 years of age; and IARC for GARDASIL, 10–18 years of age).[10]

Durability of protection

Data confirming durability of protection are available up to 5 years in the ESCUDDO study and 4.5 years post-vaccination in the KEN SHE study, 10 years post-vaccination in the CVT study, and 14 years post-vaccination in the IARC study. Additionally, the IARC and CVT studies showed that the level of antibody remained stable and above the level induced by natural infection, with no evidence of waning as of 10 and 16 years, respectively.

Data available in 9–11-year-old boys suggests that single-dose HPV vaccination elicits a similar immune response as in girls,[11] and a population-based effectiveness study in South Africa suggests single-dose vaccination impact on HPV 16/18 prevalence in an adolescent population, irrespective of HIV status.

Estimated public health impact

It can take decades for an HPV infection to cause cervical cancer. This prolonged natural history process makes mathematical modeling a critical complementary tool to aid in decision-making. Models synthesize clinical and epidemiological data to estimate and compare health impacts (e.g., the number of cervical cancer cases prevented) and economic impacts across a range of scenarios. Taken together, results point to a positive public health impact of a single-dose schedule.

The following themes emerged from recent analyses evaluating single-dose HPV vaccination:

- Compared to no vaccination, single-dose HPV vaccination yields substantial health benefits and is good value for money.[11]
- The impact and cost-effectiveness of adding a second dose are driven by the duration of single-dose vaccine protection and the ability to possibly achieve higher coverage with a single dose versus multiple doses.[12,13,14]
  The second dose is not cost-effective in many settings if one dose can give at least 20 years of protection. [12]
- Most health benefits associated with two-dose vaccination are achieved with one-dose vaccination, even with lower efficacy or duration of protection.[14]
- Alternative uses of the second dose, such as vaccinating young adult women or boys with a single dose, have been shown to have greater impact and cost-effectiveness than giving a second dose.[15]
- Immediate implementation of a single-dose schedule leads to greater health benefits than postpoining its adoption.[15]
- If vaccine supply is constrained, single-dose or extended interval strategies have greater health impact and are more efficient than two-dose strategies.[16,17]

Policy recommendations

Given the strong evidence base showing that a single dose of HPV vaccine provides similar protection against HPV infection as a multi-dose regimen, the World Health Organization (WHO) issued in December 2022 an updated recommendation[3] that includes a single-dose regimen:

- One- or two-dose HPV vaccine for the primary target of girls aged 9–14 years old.
- One- or two-dose schedule for young women aged 15–20 years old.
- One- or two-dose schedule for boys/men aged 9–20 years old.
- Two doses with a 6-month interval for women aged over 21 years old.
- Immunocompromised individuals, including those with HIV, should receive three doses if feasible, and if not, at least two doses.

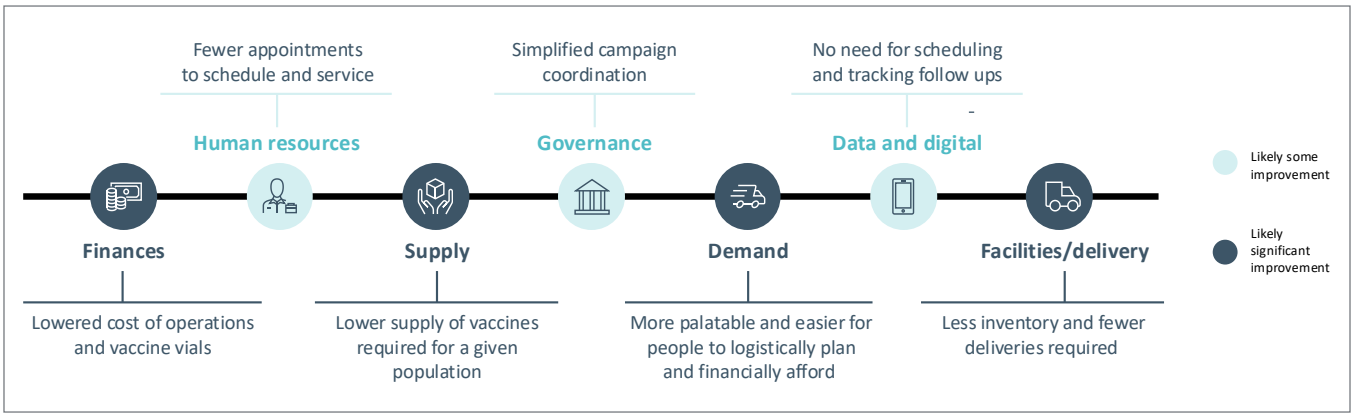
As of March 2026, **more than half of countries** with national HPV vaccination programs **have adopted a single-dose HPV vaccine schedule**.

WHO urges countries to introduce HPV vaccination for the primary target group of girls aged 9–14 and, where feasible and affordable, prioritize catch-up in older cohorts and missed girls through multi-age cohort vaccination up to the age of 18.[3]

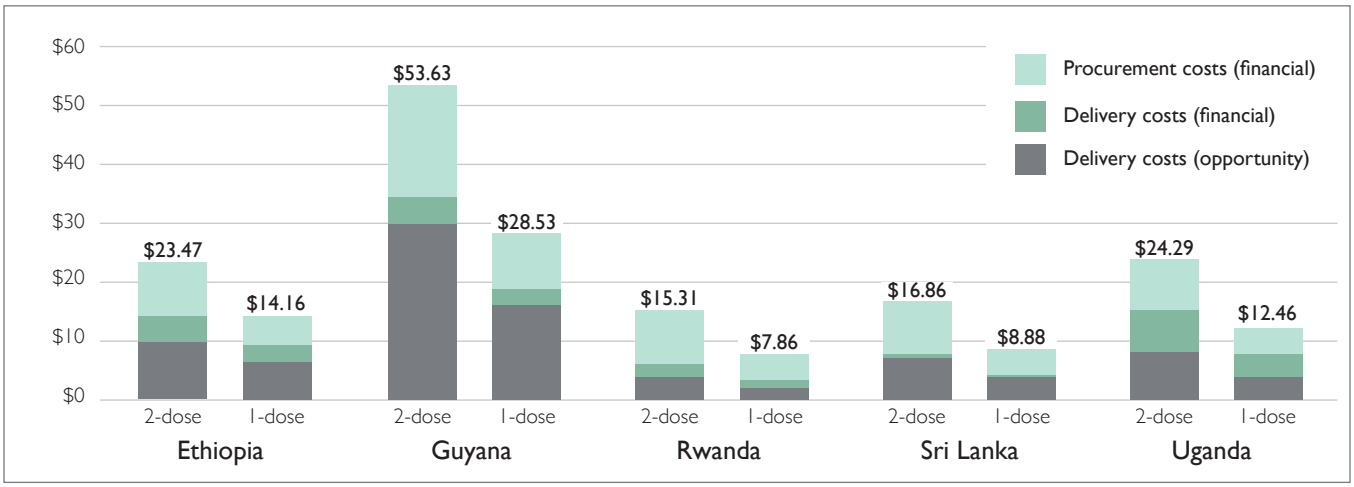
The Pan American Health Organization (PAHO) Technical Advisory Group and the WHO AFRO Regional Immunization Technical Advisory Group accepted the global recommendation in 2023 and 2024, respectively. Gavi, the Vaccine Alliance, supports single-dose schedules, including switch grants for countries already implementing multi-dose schedules.

Program implementation opportunities

A qualitative study based on key informant interviews from Burkina Faso, Ethiopia, and Solomon Islands, found that a single-dose scheduled afforded operational advantages, such as reduced losses to follow-up, lower vaccine and human resource costs, and more efficient delivery.[18] Modeling suggests that prioritizing multi-age catchup (MAC) campaigns in older girls (followed by young women and then by gender-neutral vaccination) is the most efficient way to repurpose additional HPV vaccine doses freed up by a single-dose schedule and reduce cervical cancer.[19] A single-dose schedule could encourage countries to introduce HPV vaccines that have delayed doing so because of financial, logistical, or other barriers.



A single-dose regimen addresses several obstacles by reducing the quantity of doses to be procured and subsequently distributed, stored, tracked, and administered.



Modeled cost savings with a single-dose regimen in five countries ranged from 40% to 49% per fully vaccinated adolescent. Depending on the country context, there were differences in whether these savings could be largely for financial (direct monetary outlays) or opportunity costs (costs of using existing resources).[21]

Topics for future research

Evidence on the health and economic impacts of reduced-dose HPV vaccination in HIV-positive individuals, including on level and duration of protection, requires additional studies. Until more data are available, WHO recommends a multi-dose HPV vaccination regimen for this population. The potential impact of HIV acquisition following HPV vaccination (in all dose regimens) also requires further research. With limited data available on boys, additional research will help programs weigh the potential public health impact of gender-neutral programs.

Several ongoing clinical trials continue to collect data on efficacy of a single dose of HPV vaccine in older and younger populations, as well as in boys, by comparing findings to multi-dose regimens and by immunobridging to other studies. Information on additional clinical measures, such as effectiveness against the development of cancer and precancerous lesions, will eventually be available. Although current evidence suggests that duration of protection is long-lived, longer-term cohort follow-up will continue to provide valuable insights about duration of protection and durability of the immune response and inform mathematical modeling.

The Single-Dose HPV Vaccine Evaluation Consortium will continue to evaluate emerging evidence pertaining to single-dose HPV vaccination, including effectiveness and data in additional populations (i.e., people living with HIV and boys) as it becomes available.

References

1 Global Cancer Observatory. Cervix uteri. Accessed January 15, 2025. https://gco.iarc.who.int/media/globocan/factsheets/cancers/23-cervix-uteri-fact-sheet.pdf

2 WHO HPV Vaccine Programme Schedule. Accessed November 26, 2025. https://app.powerbi.com/view?r=eyJrIjoiNDIxZTFkZGUtMDQ1Ny00M-DZkLThiZDktYWFlYTdkOGU2NDcwIiwidCI6ImY2MTBjMGI3LWJkMjQtNGIzOS04MTBiLTNkYzI4MGFmYjU5MCIsImMiOjh9

3 Human papillomavirus vaccines: WHO position paper (2022 update). *Weekly Epidemiological Record*. 2022;97:645–672. http://apps.who.int/iris/bitstream/handle/10665/365350/WER9750-eng-fre.pdf

4 Barnabas RV, Brown ER, Onono MA, et al. Durability of single-dose HPV vaccination in young Kenyan women: Randomized controlled trial 3-year results. *Nature Medicine*. 2023;29(12):3224–3232.

5 Changalucha J, Maxwell C, Mutani P, et al. Durability of single-dose HPV vaccine immune responses up to 5 years post-vaccination in girls participating in the DoRIS trial in Tanzania. Abstract #6857 presented at: EUROGIN 2024; March 13–16, 2024; Stockholm.

6 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.

7 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;23(1):e16]. *Lancet Oncology*. 2021;22(11):1518–1529.

8 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.

9 Porras, C, Romero B, Kemp T, et al. HPV16/18 antibodies 16-years after single dose of bivalent HPV vaccination: Costa Rica HPV vaccine trial. *JNCI Monographs*. 2024;2024(67):329–336.

10 Baisley K, Kemp TJ, Kreimer AR, et al. Comparing one dose of HPV vaccine in girls aged 9-14 years in Tanzania (DoRIS) with one dose of HPV vaccine in historical cohorts: An immunobridging analysis of a randomised controlled trial. *Lancet Global Health*. 2022;10(10):e1485–e1493.

11 Zeng Y, Moscicki A-B, Woo H, et al. HPV16/18 antibody responses after a single dose of nonavalent HPV vaccine. *Pediatrics*. 2023;152(1):e2022060301.

12 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 Medicine*. 2023;21(1):313.

13 Burger EA, Campos NG, Sy S, Regan C, Kim JJ. Health and economic benefits of single-dose HPV vaccination in a Gavi-eligible country. *Vaccine*. 2018;36(32):4823–4829.

14 Bénard É, Drolet M, Laprise JF, et al. Potential population-level effectiveness of one-dose HPV vaccination in low-in¬come and middle-income countries: a mathematical modelling analysis. *Lancet Public Health*. 2023;8(10):e788–e799.

15 Burger EA, Laprise JF, Sy S, et al. Now or later: Health impacts of delaying single-dose HPV vaccine implementation in a high-burden setting. *International Journal of Cancer*. 2022;151(10):1804–1809.

16 Bénard É, Drolet M, Laprise JF, et al. Potential benefit of extended dose schedules of human papillomavirus vaccination in the context of scarce resources and COVID-19 disruptions in low-income and middle-income countries: A mathematical modelling analysis. *Lancet Global Health*. 2023;11(1):e48–e58.

17 Prem K, Cernuschi T, Malvolti S, Brisson M, Jit M. Optimal human papillomavirus vaccination strategies in the context of vaccine supply constraints in 100 countries. EClinicalMedicine. 2024;74:102735.

18 Insights from Seven Low- and Middle-Income Countries on Reaching Out-of-School Girls with HPV Vaccination. PATH, on behalf of the HAPPI Consortium. Accessed November 2025. https://www.path.org/our-impact/resources/project-brief-insights-from-seven-low-and-middle-income-countries-on-reaching-out-of-school-girls-with-hpv-vaccination/.

19 Bernard E, Drolet M, Gingras G, et al. Prioritizing HPV vaccination strategies in 67 lo w- and middle-income countries (LMICs) based on efficiency at preventing cervical cancer: a modeling study. Abstract presented at: 36th International Papillomavirus Conference; November 12–15, 2024; Edinburgh, UK.

20 PAHO Technical Advisory Group recommends countries of the Americas to use single-dose HPV vaccine schedule. News release. Pan American Health Organization; Sept 3, 2023. https://www.paho.org/en/news/5-9-2023-paho-technical-advisory-group-recommends-countries-americas-use-single-dose-hpv

21 Africa immunization advisory group urges single-dose HPV vaccine adoption to advance vaccination efforts. News release. World Health Organization Regional Office for Africa; March 1, 2024. https://www.afro.who.int/news/africa-immunization-advisory-group-urges-single-dose-hpv-vaccine-adoption-advance-vaccination.

22 Gavi, the Vaccine Alliance. Human papillomavirus vaccine support. Accessed April 23, 2025. https://www.gavi.org/types-support/vaccine-support/human-papillomavirus

23 Bernard E, Drolet M, Gingras G, et al. Prioritizing HPV vaccination strategies in 67 low- and middle-income countries (LMICs) based on efficiency at preventing cervical cancer: a modeling study. Abstract presented at: 36th International Papillomavirus Conference; November 12–15, 2024; Edinburgh, UK.

24 Slavkovsky R, Mvundura M, Debellut F, Naddumba T. Evaluating potential program cost savings with a single-dose HPV vaccination schedule: A modeling study. *JNCI Monographs*. 2024;2024(67):371–378.

Single-Dose HPV Vaccine
EVALUATION CONSORTIUM

The Single-Dose HPV Vaccine Evaluation Consortium, coordinated by PATH, includes Harvard University, London School of Hygiene & Tropical Medicine, Université Laval, University of British Columbia, US Centers for Disease Control and Prevention, US National Cancer Institute, Wits Reproductive Health and HIV Institute, and the Kirby Institute at University of South Wales.

In addition to the Consortium members, representatives from the following institutions serve as advisors: World Health Organization; International Agency for Research on Cancer; Medical Research Council Unit The Gambia at the London School of Hygiene & Tropical Medicine; Instituto Nacional de Salud Pública de Mexico; Institut National de Santé Publique du Quebec; Victorian Cytology Service, Australia; University of Washington, United States; and International Vaccine Institute, South Korea.

For information about the Single-Dose HPV Vaccine Evaluation Consortium and access to the full review of current evidence, visit path.org/singledosehpv. Inquiries about this project can be directed to: Evan Simpson, PATH, 437 N 34th Street, Seattle, WA 98103, US, esimpson@path.org.

February 2026