REVIEW

Editorial Process: Submission:10/06/2025 Acceptance:05/01/2026 Published:05/19/2026

AOGIN India Policy Statement on the Use of HPV Vaccination for Cervical Cancer Elimination

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Abstract

Objective: Nearly one-fifth of the worldwide burden of cancer-related deaths among Indian women is attributable to cervical cancer. The World Health Organization (WHO) mandates that 90% of adolescent girls receive the HPV vaccine by age 15 to achieve cervical cancer elimination. Integrating the HPV vaccine into the Universal Immunization Program is necessary to accomplish this in India. **Method:** To provide clarity on HPV vaccination dosage, schedules, and delivery methods, AOGIN India has developed this policy statement based on the most recent evidence from both India and around the world, including data from single-dose efficacy trials. **Result:** To facilitate the rapid and efficient expansion of vaccination, this document offers evidence-based recommendations for health care professionals, policymakers, and program managers. **Conclusion:** AOGIN India is the national chapter of the Asia Oceania Research Organization in Genital Infection & Neoplasia, working to promote education, training, community-based interventions, and research for cervical cancer prevention. This policy statement aims to reduce disparities in access to HPV vaccination and accelerate India's progress toward the WHO's 90-70-90 elimination targets by translating scientific evidence into context-specific guidelines.

Keywords: HPV vaccination- policy statement- AOGIN India

Asian Pac J Cancer Prev, **27 (5)**, 1603-1607

Introduction

Cervical cancer remains a leading cause of cancer-related deaths among women globally, with 604,000 new cases and 342,000 deaths annually. Nearly 90% of this burden falls on low- and middle-income countries (LMICs) [1]. India accounts for approximately one-fifth of the global cervical cancer burden, with an estimated 127,526 new cases and 79,906 deaths in 2022 [2]. It is the second most common cancer among Indian women and a leading cause of death in women aged 15–44 years [3].

In response to this persistent burden, the World Health Organization (WHO) issued a call for the global elimination of cervical cancer through a 3-pillar approach, setting a target of vaccinating 90% of girls by the age of 15 years by 2030 [4].

AOGIN India's unique multidisciplinary structure allows it to combine scientific evidence, clinical and implementation expertise. This policy statement therefore offers greater clarity and India-specific applicability by providing actionable recommendations tailored to India's heterogeneous health system and emerging immunisation landscape.

HPV vaccination in the adolescent age group

Adolescent girls aged 9–14 years are the primary target group for HPV vaccination due to their high immunogenic response, minimal prior exposure to HPV, and ease of programmatic reach [5]. HPV is typically acquired after sexual debut, which occurs at a median age of 17.2 years; vaccinating before this ensures maximum protection [6]. Immunological studies show that vaccination in this age group produce 2–3 times higher antibody titers than older individuals, enabling robust, long-lasting immunity [7]. The WHO recommends vaccinating this cohort as a global standard, through a school- or community-based approach. With school enrolment rates above 85% in India, school-based vaccination is logistically feasible and highly cost-effective [8]. Community-based campaigns have the advantage of offering an opt-in approach and ensuring parental consent. Modelling studies predict that vaccinating 90% of girls aged 9–14 could reduce

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cervical cancer incidence by up to 90%, making early adolescent vaccination both a scientific and public health imperative [9].

HPV vaccines currently available in India are Gardasil® (MSD Pharmaceuticals) against HPV types 6, 11, 16, and 18; Gardasil®-9 (MSD Pharmaceuticals) against HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58 and Cervavac® (Serum Institute of India Pvt. Ltd) against HPV types 6, 11, 16, and 18. The immune response from Cervavac has been shown to be non-inferior to that produced by Gardasil, and based on this data, Cervavac is licensed by the Drug Controller General of India [10]. The bivalent vaccine Cervarix™ (GSK) is currently not available in India. HPV vaccination in India is given mainly in the private sector, where parents bring their daughters and very occasionally their sons to health facilities for HPV vaccination, allowing eligible individuals and families to choose from available vaccines based on availability and affordability.

The inclusion of HPV vaccination in the national universal immunisation programme in India has been recommended by the National Technical advisory Group on Immunisation (NTAGI) since 2022 and it is expected to be rolled out soon. Meanwhile, certain states have initiated vaccination through their own budgets: Sikkim was the first to implement a state-wide HPV immunisation program for adolescent girls with high coverage rates reported [11]. Bihar initiated the program in 2024 and Tamil Nadu plans to launch it in a few months.

Dosage recommendations

HPV vaccination initially started as a 3-dose vaccine but was later changed to a 2-dose recommendation for younger girls following WHO recommendations. Since 2022, WHO has included the option of a single dose recommendation for not only the primary target age group of 9–14 years but also for girls up to the age of 20 years. This is at variance at present with the manufacturer's recommendations, which are based on their trials conducted for licensure.

Manufacturer's recommendations for Gardasil (Quadrivalent) for girls/women aged 9–45 years are as follows:

- 9–14 years: 2 doses six months apart.
- 15–45 years: 3 doses at 0, 2, and 6 months.

For Gardasil 9 and Cervavac

- 9–14 years: 2 doses six months apart.
- 15–26 years: 3 doses at 0, 2, and 6 months.

Both Cervavac and Gardasil 9 are licensed for vaccinating boys as well in a similar dosage schedule.

Vaccine efficacy

HPV vaccine efficacy has been firmly established through several large randomized trials involving over 70,000 participants [12]. These vaccines demonstrated high efficacy against surrogate endpoints such as HPV infection, anogenital warts, and cervical intraepithelial neoplasia (CIN), and more recently, against invasive cervical cancer [13, 14]. The quadrivalent and nonavalent vaccines offer 97% protection against HPV 6/11-related warts in HPV-naïve women, while both bivalent and quadrivalent vaccines provide 94% protection against persistent HPV infection. Cross-protection is also observed, with the bivalent vaccine offering protection against HPV 31, 33, and 45 at rates of 77%, 43%, and 79%, respectively [15]. A Cochrane review by Arbyn et al. reported 99% protection against HPV 16 and 18-associated CIN2+ and CIN3, and 90% protection against adenocarcinoma in situ in HPV-naïve populations [16]. Long-term follow-up data from Finland and Sweden confirm reductions in cervical cancer incidence [17].

Real-world impact has been documented globally, including significant declines in HPV prevalence, cytological abnormalities, and high-grade CIN, even in countries with suboptimal vaccine coverage [18-20].

Vaccine safety

The safety profile of HPV vaccines is well-documented and supported by extensive data from both pre-licensure and post-marketing surveillance. Over 270 million doses have been administered worldwide with no serious safety concerns identified. The most common adverse events include mild local reactions such as pain, redness, or swelling at the injection site, and transient fever. The WHO and other global regulatory bodies have thoroughly reviewed the Vaccine Adverse Event Reporting System (VAERS) and found no link between HPV vaccination and autoimmune conditions, Guillain–Barré syndrome, premature ovarian insufficiency, or any new chronic illnesses [21]. Fainting episodes, while rare, have led to the recommendation that adolescents be seated during vaccination and observed for at least 10 minutes post-injection. The vaccines are contraindicated in individuals with known hypersensitivity to any vaccine component; for example, Gardasil should not be given to those allergic to yeast, and Cervarix should be avoided in individuals with latex allergy. No adverse outcomes have been reported in cases of inadvertent administration during pregnancy, though the remaining schedule should be completed postpartum. HPV vaccination is also safe in breastfeeding mothers.

Efficacy of single dose HPV vaccine

The first proof of concept for a single dose recommendation came from The Costa Rica HPV Vaccine Trial (CVT), where it was seen that participants who had received only a single dose or two doses of the bivalent vaccine demonstrated sustained protection against HPV 16/18 for over 10 years [22]. This served as proof of concept for the IARC India trial, which originally aimed to investigate the efficacy of two versus three doses of the quadrivalent vaccine Gardasil. The premature cessation of recruitment in this trial resulted in large and almost equal numbers of girls in the single dose, two dose and three dose arms. Continued follow-up of these participants along with unvaccinated cohorts found that a single dose of the quadrivalent vaccine offered durable protection for up to 10 years, with efficacy comparable to two or three doses in preventing persistent HPV infection [23]. A comprehensive monograph in the Journal of the National

Cancer Institute concluded that single-dose schedules are not only efficacious and durable but also programmatically and economically advantageous, especially in LMICs [24].

The IARC India trial has further served as proof of concept for various randomized trials on single dose efficacy including the KENSHE trial in Kenya which has demonstrated that a single dose of either the bivalent or nonavalent vaccine provided up to 98% efficacy against persistent HPV 16/18 infection over three years. The DORIS and the Costa Rica ESCUDDO trials also support single dose HPV vaccination [25, 26].

Based on evidence from clinical trials to date, the WHO now recommends the option of a single-dose schedule for girls/young women aged 9 to 20 years and two-dose schedule at least six months apart for women aged 21 years and older. The option of one or two doses for girls aged 9–20 years as it appears on the WHO website, often leads to a lack of clarity amongst health care professionals. Essentially it offers an option for countries to continue with a two-dose regimen based on previous recommendations of the WHO, while awaiting the final results of the randomized trials. Presently, 75 countries have adopted a single-dose HPV vaccine strategy in their national immunisation schedules. These not only include LMICs like Nigeria, which introduced the single-dose HPV vaccine into its routine immunization program in 2023, and Rwanda, which has achieved a coverage rate of 90% through school-based campaigns and community outreach programs, but also many developed countries including Australia, Canada and the United Kingdom.

The previously licensed bivalent, quadrivalent and nonavalent vaccines have all been approved for single dose schedules by WHO. An ongoing immunobridging study (CTRI/2024/08/072040) is evaluating the single-dose efficacy of Cervavac in comparison to Gardasil, to demonstrate antibody stability at two years; the results are expected in 2027 [27].

Public Health Perspective

While an individualized approach to HPV vaccination supports early protection, broader public health impact requires structured delivery strategies. For India, the NTAGI has recommended a single-dose schedule with one-time multi-age cohort (MAC) campaign for girls aged 9–14, followed by routine vaccination at age of 9 years [28].

Given supply constraints, costs, and implementation challenges, three strategies using Cervavac have been proposed as pragmatic solutions based on currently available evidence. Adopting an extended interval strategy, where one dose is administered initially and a second dose is deferred by 3–5 years, to be administered if required later seems to be a pragmatic alternative. This strategy maximizes coverage in the short term, allowing catch-up or dose adjustment once data on single-dose efficacy of Cervavac becomes available in 2027. Findings from the Quebec extended-interval study indicate that lengthening the gap between two doses (up to 3–5 years) does not compromise immunogenicity or effectiveness [24].

Rolling out HPV vaccination In India

Successful HPV vaccine rollout in India requires systematic preparedness across supply chain, training, and communication systems. Vaccine hesitancy persists not only in communities but also among healthcare providers. Clear and transparent messaging would be imperative to ensure that the importance of HPV vaccination is understood by the community and would go a long way in preventing vaccine hesitancy [29]. Training of healthcare workers—including those currently undergoing Indian Medical Association-supported multi-specialty training—must ensure consistent counselling messages, proper administration practices, and proactively debunking myths about HPV vaccination. Media engagement will be necessary to ensure that accurate scientific information reaches the public and counteracts misinformation. India's COVID-19 vaccination campaign demonstrated the nation's capacity to manage complex national immunisation logistics, providing a strong precedent for HPV rollout.

Improving HPV vaccination uptake in India requires practical, community-driven, and system-integrated strategies. Both school-based and community-based vaccination are valid approaches for routine delivery in the 9–14year age group, but their success hinges on proactive involvement of community health workers, teachers, and local leaders who are essential to build trust, address stigma, and facilitate uptake. Gaps often exist between planning and implementation—underscoring the need for localized strategies that account for logistical challenges, including ensuring that hard-to-reach populations have access to the vaccine, cultural sensitivities, and follow-up systems. Digital platforms like U-WIN should be fully leveraged for tracking, reminders, and data transparency [30]. Ensuring equitable access—particularly in remote, tribal, and underserved regions—must remain central to programme design.

A single-dose strategy substantially reduces logistical complexity and enables wider coverage for the same cost. Globally, evidence shows that completion rates decline significantly between first and subsequent doses, underscoring the real-world advantage of single-dose regimens. While gender-neutral vaccination strategies are followed in countries like Australia and the UK, for India, the most cost-effective strategy would be first to vaccinate adolescent girls. Economic and budgetary considerations will determine whether India adopts a single-age cohort or a multi-age cohort (MAC) approach initially. Many states in India have already opted for single-age cohorts, while a national strategy may introduce a MAC first to rapidly expand herd protection. A national single-dose schedule would enhance coverage and improve cost-efficiency by reducing overall programme expenditure.

Modelling studies—including Irene Man's analyses [31]—consistently show that the optimal phased pathway for India would be: (1) vaccinate adolescent girls, (2) implement an initial MAC to accelerate population-level immunity, and (3) consider gender-neutral or male catch-up vaccination only once high and equitable female coverage is achieved. This phased strategy balances gender equity goals and long-term disease prevention.

Emerging research highlights that India is at a decisive moment, and delays in operationalising HPV vaccination could erode the benefits of strong scientific evidence. It is imperative that India moves swiftly from planning to implementation to realise population-level impact [32].

In conclusions, HPV vaccines are safe and efficacious. There is ample evidence at present to support feasibility, efficacy and safety of single-dose HPV vaccination in the 9–20-year-olds. It offers a transformative opportunity for India to protect millions of girls, reduce inequities in cervical cancer prevention, and make measurable progress toward elimination targets [33]. Delaying action could mean millions of missed opportunities. The question is not whether to adopt HPV vaccination as a national program, but how quickly we can do so.

Author Contribution Statement

Latha Balasubramani, Bhagyalaxmi Nayak, Nisha Singh, Seema Singhal, Vinotha Thomas, and Neerja Bhatla drafted, reviewed, and approved this policy statement on behalf of the Executive Committee of AOGIN India.

Acknowledgements

Funding and Conflict of Interest

The authors declare no external funding was received for this work and state no conflicts of interest that could influence the policy statement.

Institutional and Ethical Status

This document is an official policy statement of AOGIN India and a synthesis of existing published evidence; therefore, it is not a student thesis and did not require formal ethical committee approval or clinical trial registration.

Data Availability

As this is a policy statement, it generates no new primary data. All supporting evidence is available through the cited public domain references.

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