

Short Communication

Comparison of HPV vaccination strategies for pilot implementation in North India

Abdul Basith K. M., Nivedita Chakravarti, Tarundeep Singh*

Department of Community Medicine and School of Public Health, PGIMER, Chandigarh, India

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*Correspondence:

Dr. Tarundeep Singh,

E-mail: tarundeep.singh@gmail.com

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ABSTRACT

Cervical cancer remains a leading cause of cancer mortality among women in India. India's 2024 interim budget prioritization of HPV vaccination for girls aged 9-14 years provided a pivotal opportunity for state-led pilots to inform national policy. This paper compares three vaccination strategies (Single-dose Gardasil; Two-dose Cervavac; and Single-dose Cervavac) within the planning for a school-based HPV vaccination pilot targeting 6,300 girls in North India. A comparative analysis of programmatic feasibility, estimated financial cost, and scientific evidence was undertaken. Strategy 1 (single-dose Gardasil) and Strategy 2 (two-dose Cervavac) had comparable financial outlays (~23 million INR), but Strategy 2 imposes a 64% higher human resource burden (2,120 vs. 1,288 man-hours). While Strategy 1 is supported by the strongest longitudinal efficacy data, Strategy 2 aligns with the national interest of indigenous vaccine with minimal cost per dose. We recommend an approach that leverages single-dose Gardasil vaccination until further trial data on single-dose Cervavac is available, to optimize the coverage and improve programmatic efficiency.

Keywords: Cervical cancer, Cervavac, Gardasil, HPV vaccination, India, Single-dose schedule

INTRODUCTION

Cervical cancer remains a significant public health challenge in India, accounting for an estimated 127,526 new cases and 79,906 deaths in 2022.¹ This burden persists despite cervical cancer being a disease with both primary (vaccination) and secondary (screening) prevention potential. The World Health Organization (WHO) has set an ambitious 90-70-90 target for global elimination of cervical cancer, including 90% Human Papilloma Virus (HPV) vaccination coverage for girls by age 15.²

India's interim budget announcement in 2024 marked a pivotal policy opportunity to address this gap by encouraging state-led HPV vaccination for girls aged 9-14 years.³ As individual Indian states prepare for pilot implementation using school-based platforms, decision-makers face a critical choice between competing

vaccination strategies. The core dilemma involves balancing emerging evidence supporting a single-dose HPV vaccination schedule for an established vaccine (Gardasil) against the National priority of implementing an indigenous vaccine (Cervavac), while accounting for cost-effectiveness and the programmatic challenges associated with multi-dose vaccination. This paper therefore compares three strategies for school-based HPV vaccination pilot planned in a Constituency in a North Indian state, aiming to inform an evidence-based and operationally sound policy decision for cervical cancer prevention in India.

METHODS

Study design, setting and period

This was a comparative programmatic and cost analysis undertaken to inform planning for an HPV vaccination

pilot in a Constituency in a North Indian state. The target population for the pilot planning comprised an estimated 6,300 girls aged 9-14 years, including approximately 6,000 school-going girls across 169 schools and 300 out-of-school girls. The planning and the comparative analyses were undertaken between July to August, 2025.

Vaccination strategies compared

Three strategies were compared.

Strategy 1

Single-dose Gardasil (quadrivalent HPV vaccine; Merck Sharp & Dohme LLC, US).

Strategy 2

Two-dose Cervavac (quadrivalent HPV vaccine; Serum Institute of India), administered at 0 and 6 months.

Strategy 3

Single-dose Cervavac (quadrivalent HPV vaccine; Serum Institute of India).

Data sources and comparison parameters

The analysis used operational data, resource mapping, microplanning details, and cost component assumptions derived from official sources. This was supplemented by recommendations from WHO Strategic Advisory Group of Experts on Immunization (SAGE), India's National Technical Advisory Group on Immunization (NTAGI), WHO position paper on HPV vaccines, and the national Operational Guidelines for HPV vaccine introduction, along with evidence from single-dose efficacy trials, Cervavac licensure trial data, and cost effectiveness modelling studies in the Indian context.⁴⁻⁷ Key comparison parameters included programmatic feasibility, programmatic cost, and the strength of supporting evidence. The programmatic costs, including logistics, human resource, operational cost and, vaccine

procurement prices were estimated based on stakeholder consultations and prevailing market information for pilot programme procurement (approximately Rs. 3,400 per dose for Gardasil and Rs. 1,700 per dose for Cervavac). Ethical approval was not required, as the analysis was based on publicly available guidelines, operational planning documents, and published literature.

RESULTS

The three strategies presented a distinct trade-off with respect to the programmatic requirements, financial cost, and the strength of the supporting evidence, as summarized in Table 1.

Programmatic requirements

Strategy 1 (single-dose Gardasil) requires only a single school visit per vaccination cohort, giving it the lowest programmatic burden of the three options, despite having the highest per-dose vaccine procurement cost. Strategy 2 (two-dose Cervavac) is administered at 0 and 6 months and therefore requires two school visits per cohort. Although its per-dose procurement cost was lower than Gardasil's, this strategy required greater cold-chain capacity and carried the highest overall logistics and human-resource burden of the three options. The Strategy 3 (single-dose Cervavac) shares strategy 1's similar programmatic burden as strategy 1 due to single school visit, and at the lower per-dose price of Cervavac.

Comparative programmatic and financial costs

Comparative estimates of programmatic and financial costs of the three strategies are presented in table 2. Strategy 1 incurred the highest vaccine procurement cost but lower logistics and human resource (HR) expenditure. Strategy 2 required double the number of vaccine doses, resulting in higher logistics and HR expenditure, including a 64% higher total HR requirement than Strategy 1 or Strategy 3 (2,120 vs. 1,288 man-hours). Strategy 3 had the lowest total estimated cost of the three strategies, but currently lacks supporting evidences for programmatic adoption.

Table 1: Comparative analysis of three HPV vaccination strategies for a pilot in a North Indian state (target: 6,300 girls).

Parameter	Single-dose Gardasil (MSD, USA)	Two-dose Cervavac (SII, India)	Single-dose Cervavac (SII, India)
Efficacy and immunogenicity	A single dose of HPV vaccine provided similar protection, 95.4% (95% CI 85.0-99.9) against persistent infection from HPV 16 and 18 (the genotypes responsible for nearly 70% of cervical cancers) ⁸	Immune-equivalence with a single dose of Gardasil ¹⁰	ICMR is currently conducting an immuno-bridging study comparing one dose of Cervavac and one dose of Gardasil; results are expected only in 2027 ¹³
Procurement and logistic cost	Rs. 3,400 per dose Single dose vaccine vial.	Rs. 1,700 per dose 2-dose vial available (reduces operational cost)	Rs. 1,700 per dose Single-dose vaccine vial needed (not supported by evidence)

Continued.

Parameter	Single-dose Gardasil (MSD, USA)	Two-dose Cervavac (SII, India)	Single-dose Cervavac (SII, India)
WHO/ NTAGI advisory status in India	WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommended single-dose schedules. ⁴ NTAGI recommendations are not available.	18 th meeting of NTAGI on 26th July 2023, recommended consideration of the indigenously developed HPV vaccine for introduction in the UIP as a two-dose regimen. ⁵	Trial results awaited before programmatic reforms ¹³
Advantage	Avoids the logistic complexities of tracking the girls to administer the second dose.	Lesser per-dose procurement cost and indigenous vaccine product. Indigenous vaccine Feasibility of a two-dose schedule demonstrated in India (Sikkim's statewide campaign in 2018 achieved high coverage among girls aged 9–14 years using two-dose Gardasil) ¹²	Lowest cost of vaccine and fewer resources needed. Indigenous vaccine. Avoids the logistic complexities of tracking the girls to administer the second dose.
Challenge	Vaccine hesitancy Awareness generation across general population as well as service providers Inter-departmental collaboration High cost per-vaccine dose	Vaccine hesitancy Awareness generation across general population as well as service providers Inter-departmental collaboration Complexities of tracking the girls to administer the second dose	Lack of product-specific single-dose evidence
Total estimated cost and HR requirement*	Rs. 2,30,38,194; 1,288 man-hours	Rs. 2,32,07,526; 2,120 man-hours	Rs. 1,17,90,994; 1,288 man-hours

*Full itemized cost and human-resource breakdown in Table 2.

Table 2: Estimated programmatic and financial cost comparison for a pilot in a North Indian state (target: 6,300 girls).

Parameter	Strategy 1: Gardasil (1 dose)	Strategy 2: Cervavac (2 dose)	Strategy 3: Cervavac (1 dose)
Vaccine procurement (in INR)			
Vaccine price (per dose)	3,400	1,700	1,700
Doses required (6,300 girls, 5% vaccine wastage factor)	6,615	13,230	6,615
Subtotal: Vaccine cost	2,24,91,000	2,24,91,000	1,12,45,500
Logistics (non-HR) (in INR)			
Consumables (syringes, hub cutters, indelible markers, bio-medical waste bags)	27,989	55,478	27,989
Kits (AEFI/Anaphylaxis)	7,500	15,000	7,500
IEC (One-time + Per-visit)	1,25,150	1,94,300	1,25,150
Cold Chain (One-time ILR cost)	50000	50,000	50000
Subtotal: Logistics cost	2,10,639	3,14,778	2,10,639
Human resources (HR)			
Total man-hours			
Training (One-time, all staff)	456	456	456
Delivery (4 staff, 4 hrs)	672	1344	672
Supervision	160	320	160
Subtotal: Total HR Man-Hours	1,288	2,120	1,288
Total HR cost (incentives-in INR)			

Continued.

Parameter	Strategy 1: Gardasil (1 dose)	Strategy 2: Cervavac (2 dose)	Strategy 3: Cervavac (1 dose)
Training (ASHA incentives+venue)	15,150	15,150	15,150
Delivery (ASHA incentive/session)	6,300	12,600	6,300
Subtotal: Total HR Cost (in INR)	21,450	27,750	21,450
Total estimated cost	Rs. 2,30,38,194	Rs. 2,32,07,526	Rs. 1,17,90,994
Total estimated hour	1,288 man-hours	2,120 man-hours	1,288 man-hours

DISCUSSION

The comparative findings above must be interpreted against the existing evidence base and current national policy. Strategy 1 (single-dose Gardasil) is supported by the strongest available evidence, including a 10 years follow-up data from India showing approximately 95% efficacy (95% CI: 85.0–99.9) against persistent HPV 16/18 infection with a single dose, comparable to two- and three-dose regimens.⁸ This finding are in line with the 2022 WHO SAGE recommendation for an alternative single-dose schedule and has been shown to be highly cost-effective in Indian modelling studies.^{4,9} But, this strategy have a higher per-dose procurement cost and this also relies on non-indigenous vaccine product. This must be weighed against national policy priorities favouring indigenous vaccine manufacture.³

Strategy 2 (two-dose Cervavac) uses an indigenously developed vaccine and aligns with the current NTAGI recommendation for introduction of an HPV vaccine into the Universal Immunization Programme. The efficacy of this strategy is also based on a two-dose non-inferiority trial.^{5,10} However, two-dose schedules might increase the risk of dropout between doses, which can reduce overall effectiveness and increase the cost per fully immunized girl. This also inflates the programmatic and cold-chain burden than single-dose schedules.¹¹ A statewide two-dose HPV vaccination campaign in Sikkim achieved over 95% second-dose coverage, demonstrating that high two-dose coverage is achievable within the Indian programmatic context.¹² However, replicating this outcome in a new pilot setting would, require a similarly high level of intersectoral coordination, sustained follow-up, and political and administrative commitment.

Strategy 3 (single-dose Cervavac) represents an emerging rather than a policy-ready option for HPV vaccination piloting. As discussed, the two-dose schedule of Cervavac has established non-inferiority to Gardasil.¹⁰ But, WHO's single-dose recommendation for HPV vaccination does not automatically extend to newly licensed vaccines in the absence of product-specific data.^{4,6} The Indian council of medical research (ICMR) is currently conducting an immune-bridging study comparing single-dose Cervavac with single-dose Gardasil, with results expected in 2027.¹³ Programmatic adoption of single-dose Cervavac would be premature until this evidence becomes available, even though it offers the lowest theoretical cost

and would avoid the logistical burden of multi-dose delivery.

Taking all these considerations, highlight a substantive trade-off for the pilot between Strategy 1 and Strategy 2, reflecting a broader tension between adopting the schedule with the strongest global efficacy evidence versus adhering to the national product recommendation for an indigenously manufactured vaccine. This analysis has certain limitations. It relies on cost estimates derived from operational planning documents and standard programmatic assumptions rather than actual expenditure data, and it does not model long-term programmatic impact or potential waning of vaccine-induced immunity. The findings reflect a specific pilot context in North India and may not be directly generalizable to other states or settings with different school-enrolment patterns, cold-chain infrastructure, or health-workforce availability.

CONCLUSION

Within the context of a pilot in Indian setting, Strategy 1 (single-dose Gardasil) appears to be the most evidence-based and operationally efficient choice for initial implementation in the constituency. This approach maximizes the likelihood of achieving high, equitable vaccination coverage with minimal operational burden. However, acknowledging the national importance of Cervavac and its potential long-term cost advantages, the single-dose Cervavac strategy and the associated policy decision may be revisited as further evidence becomes available from the ongoing ICMR trial.

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