Empowering India's fight against cervical cancer: Harnessing routine HPV immunisation

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ABSTRACT

Cervical cancer, driven by human papillomavirus (HPV) infection, presents a significant health challenge in India, marked by high morbidity and mortality rates among women. This systemic review synthesises the latest research on HPV epidemiology in India, evaluates the effectiveness of existing vaccination programmes and compares India's strategies with those of countries that have successfully mitigated cervical cancer burden. Despite available vaccines targeting high-risk HPV types, vaccine coverage remains suboptimal due to challenges, such as accessibility, vaccine hesitancy and socioeconomic barriers. Comparative analysis suggests that school-based and community engagement strategies could enhance vaccination efforts. Addressing India's cervical cancer burden requires a multifaceted approach that includes expanding HPV vaccination coverage, implementing public awareness campaigns and adopting best practices from global successes. Economic analyses affirm the cost-effectiveness of such strategies, highlighting the potential for significant public health and financial benefits.

Keywords: Cervical cancer, HPV vaccine, low and middle income countries, cost-effectiveness

Introduction

Cervical cancer burden remains a significant global public health concern, with cervical cancer being the leading cause of cancer-related deaths among women in the country which is largely preventable.^[1] Cervical cancer's occurrence and distribution can be effectively analysed through the epidemiological triad, comprising the agent, host and environment. The primary agent is the human papillomavirus (HPV), particularly high-risk types, such as HPV-16 and HPV-18, which are responsible for most cervical cancer cases.[1]

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Aim

This systematic review aimed to assess the impact and effectiveness of routine HPV immunization programs in India for combating cervical cancer with a comparative perspective on similar initiatives in developed countries.

Methodology

Eligibility criteria

Studies included in this review focus on HPV immunization and cervical cancer prevention in India, particularly routine immunization and associated public health outcomes. We included studies if they: Analyzed routine HPV vaccination implementation in Indian and Western contexts. Assessed outcomes related to cervical cancer incidence or prevention. Were published in English. Involved population-based studies, randomized controlled trials, cohort studies, and systematic

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reviews from 2000 to the present. Included immunization barriers, strategies, and health policy aspects of HPV in India.

Data sources

Searches were conducted in databases including PubMed, Embase, Scopus, and Cochrane Library, supplemented by Google Scholar and government or organizational websites (e.g., WHO, Indian Ministry of Health).

Search strategy

Keywords and phrases were used with Boolean operators such as: "HPV immunization" OR "HPV vaccination" AND "India" "Cervical cancer prevention" AND "routine immunization" AND "India" "HPV vaccine coverage" AND "India".

Study selection process

All search results were imported into a reference manager software (Zotero) to facilitate screening. Initial screening was based on titles and abstracts to remove irrelevant studies. Full texts of potentially eligible studies were independently reviewed by two authors to confirm inclusion [Figure 1].

Data extraction

A structured data extraction form was used to capture details such as study characteristics, sample size, HPV vaccine coverage, intervention strategies, outcomes, and recommendations.

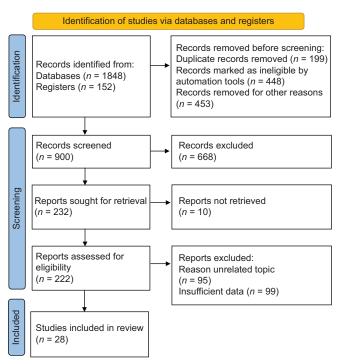


Figure 1: PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only

Quality assessment

The quality of studies was assessed using the Cochrane Risk of Bias tool for RCTs and the Newcastle-Ottawa Scale for observational studies.

Data synthesis

Narrative synthesis was used to summarize and interpret the findings. Where possible, quantitative data on HPV vaccination outcomes were collated and analyzed.

Results and Discussion

HPV, belonging to the Papillomaviridae family, consists of small, non-enveloped DNA viruses. Its classification relies on DNA sequence, predominantly utilising the L1 open reading frame of the genome. Among over 100 serotypes identified, approximately 15-20 are oncogenic, with an interval of 15-20 years between oncogenic HPV infection and invasive cervical cancer (ICC) onset. Genital HPVs are further categorised into high-risk, probable high-risk and low-risk types based on their association with cervical cancer. Globally, HPV-16 and HPV-18, accounting for over 70% of cervical cancer cases, predominantly HPV-16 (50–60%) and HPV-18 (10–12%), are prevalent. Similarly, HPV-16 and HPV-18 are the most detected genotypes in Indian women. [2] Non-oncogenic HPV serotypes, such as 6 and 11, cause over 90% of benign genital infections, such as genital warts. At the same time, oncogenic types are linked to various cancers, including anal, vulvar, vaginal, penile and oropharyngeal. HPVs infect the basal epithelium and are classified as cutaneous and mucosal types. Cervical HPV infection results in a spectrum of cervical lesions ranging from normal to high-grade precancerous stages (CIN-1, CIN-2, CIN-3/carcinoma in situ), eventually progressing to ICC. HPV infection detection usually involves measuring HPV DNA in cervical cells, with HPV-16/18 frequency escalating with lesion severity. [3] Host factors significantly influence susceptibility, with socio-demographic variables, such as lower socioeconomic status and limited education reducing access to preventive measures, such as screening and vaccination. Behavioural factors, including early sexual activity, multiple sexual partners, long-term use of oral contraceptives and smoking, further increase the risk. Environmental factors play a crucial role as well; limited access to healthcare services in low- and middle-income countries exacerbates the burden of cervical cancer. Additionally, cultural attitudes towards women's health and sexual behaviour, along with misconceptions and stigma about HPV and its vaccine, hinder participation in preventive programmes.^[4] In middle-aged women (35-50 years), HPV prevalence exhibited notable variation across different geographical regions: Africa reported approximately 20%, Asia/Australia around 15%, Central and South America about 20%, North America near 20%, Southern Europe/Middle East roughly 15% and Northern Europe approximately 15%. Studies showed inconsistent trends in HPV prevalence among older women, with most indicating a decline or stabilisation in older ages, while some reported an increase. Similar age-related trends in HPV-16 and/or HPV-18 prevalence

were observed among the 12 populations with available data.^[5] According to the Indian Council of Medical Research (ICMR), it is estimated that there were over 96,000 new cases of cervical cancer and approximately 60,000 deaths in India in 2020 alone. Additionally, the World Health Organization (WHO) reports that India accounts for around one-fourth of the global burden of cervical cancer deaths due to HPV infection [Figure 2].^[1]

HPV infection poses a significant health challenge, particularly due to its strong association with cervical cancer. India carries a substantial burden of HPV infection, with epidemiological studies indicating high prevalence rates across various age groups and geographical regions. India's HPV prevalence varies greatly by area. Indian women are at risk for 2.5% lifetime risk and 1.4% cumulative mortality risk from cervical cancer. The general population's female cervical HPV infection rate is estimated to be 6.6% at any one time. HPV serotypes 16 and 18 are assumed to be the cause of 76.7% of cervical cancer cases in India. [2] Age-standardised incidence rate for cervical cancer in India is 18.0% and the mortality rate is 11.4%. [6]

Several factors contribute to the widespread transmission of HPV in India, including inadequate awareness about sexually transmitted infections, limited access to healthcare services, socio-cultural factors influencing sexual behaviour and challenges in implementing vaccination and screening programmes. The prevalence of high-risk HPV types, notably HPV-16 and HPV-18, further amplifies the risk of cervical cancer among Indian women.^[7–9] The prevalence of high-risk HPV strains, particularly HPV-16 and HPV-18, which are responsible for most occurrences of cervical cancer, highlights the urgent need for focused immunisation campaigns, although in the ground level, implementation of HPV vaccination is not easy at all.^[9]

The implementation of HPV vaccination programmes faces several challenges, including socio-cultural barriers, misinformation, logistical issues and financial constraints. In many regions, there is a lack of awareness and understanding about the HPV vaccine

and its benefits, leading to hesitancy and resistance among parents and communities. Misinformation and myths about the vaccine's safety and efficacy further exacerbate these issues. Logistically, reaching remote and rural populations with limited healthcare infrastructure poses a significant hurdle. Additionally, while the introduction of affordable vaccines, such as CERVAVAC, has mitigated some financial challenges, funding for widespread vaccination programmes remains a critical concern.^[10,11]

Addressing these challenges requires a multifaceted approach. Public health campaigns that educate and raise awareness about the benefits and safety of the HPV vaccine can help counter misinformation and increase acceptance. Additionally, insight from behavioural studies or community engagement efforts would be helpful. Collaboration with community leaders and influencers can also play a crucial role in changing perceptions and encouraging vaccination. Improving healthcare infrastructure and ensuring efficient distribution channels are vital for reaching underserved populations. Moreover, securing sustained funding and integrating the HPV vaccine into national immunisation programmes can ensure long-term success and wider coverage. [12–14]

Regional analysis shows differences in infection rates; due to limited access to screening and immunisation services, infection prevalence is higher in rural areas. The utilisation of epidemiological data is crucial in customising public health interventions to the unique requirements of heterogeneous communities throughout India. [15–17] For rural and underserved populations, where access to health care is limited, health system may entail the use of mobile vaccination units, collaborating with local non-governmental organizations (NGOs) and utilising digital health technologies.

Preventive methods

Preventive methods are crucial in reducing the burden of HPV infection and its associated diseases. Vaccination against HPV is one of the most effective preventive strategies, with vaccines

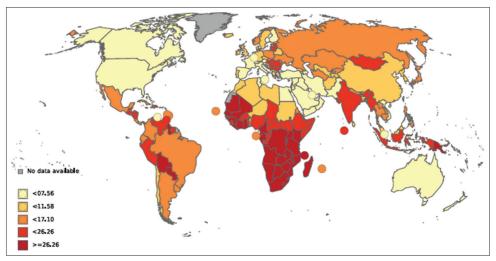


Figure 2: Cervical Cancer Incidence (WHO)

available to protect against several high-risk HPV types, including HPV-16 and HPV-18, which are responsible for the majority of cervical cancer cases worldwide. Vaccination is recommended for both males and females, ideally before sexual debut, to maximise its effectiveness in preventing HPV infection. Additionally, regular screening for cervical cancer, such as Pap smear tests or HPV DNA testing, enables early detection of precancerous lesions, allowing for prompt treatment and prevention of cervical cancer development. Health education and promotion campaigns to raise awareness about HPV transmission, the importance of vaccination and the significance of regular screenings also contribute to preventive efforts. Moreover, practising safe sexual behaviours, such as condom use and limiting sexual partners, can reduce the risk of HPV transmission. Comprehensive preventive measures, including vaccination, screening, health education and promotion of safe sexual practices, are essential for effectively combating HPV-related diseases and improving public health outcomes.[18,19]

One economic research demonstrates the cost-effectiveness of HPV vaccination as a cervical cancer prevention strategy using data from India. Immunisation campaigns, especially those with the nonvalent HPV vaccine, show up as highly economical approaches from the viewpoints of society and medicine. In particular, the nonvalent vaccine's incremental cost per disability-adjusted life year (DALY) avoided was USD 362.78, demonstrating its economic viability compared to not receiving any vaccination. This research supports the efforts of the Ministry of Health and Family Welfare to lessen the burden of cervical cancer by highlighting the potential for significant annual savings and health benefits.[20] India has the potential to greatly improve public health outcomes by implementing HPV vaccination, especially through Universal Immunization Programme (UIP) at negotiated costs. This provides strong evidence in favour of the vaccine's wider adoption. [21]

The cost of the newly developed HPV vaccine, CERVAVAC, in India is significantly lower than previously available vaccines. CERVAVAC, developed by the Serum Institute of India (SII) and priced between Rs 200 and 400 per dose, is a more affordable option compared to foreign vaccines, such as Gardasil and Cervarix, which cost around Rs 2,000 to Rs 3,500 per dose. India has made substantial progress in manufacturing enough supply to meet the demand for HPV vaccines. The SII, known for its large-scale production capabilities, is key in this regard. This ensures that the supply of CERVAVAC is sufficient to cater to the target population, which includes adolescents and young adults. Despite the availability of affordable vaccines and sufficient supply, challenges remain in distributing the vaccines effectively to the target population. Efforts are needed to improve awareness and implement robust vaccination programmes. School-based vaccination initiatives and collaborations with private healthcare facilities and NGOs are essential to enhance vaccine coverage and reach the intended demographic.[22]

Efficacy of HPV vaccine

The bivalent and quadrivalent HPV vaccines serve as preventive measures rather than treatments, offering no confirmed protection against initially detected vaccine types. However, individuals previously positive for any vaccine HPV type develop immunity against others. Efficacy rates of 99–100% were noted against conditions associated with vaccine types. Five-year follow-up studies indicated continued protection and a robust response to boosters. Immunogenicity studies in females aged 9-15 years revealed antibody levels comparable to those aged 16-26 years. HPV-16 antibody levels declined after the third dose but stabilised within 24 months, remaining higher in vaccinated individuals than those receiving the placebo. No established minimum protective antibody level has been determined. A thorough analysis showed efficacy against vaccine HPV diseases at 95.8%, with complete efficacy against vaccine-related cervical intraepithelial neoplasia or external genital lesions. Ongoing long-term follow-up studies persist. Immunogenicity studies in children aged 9-15 years showed similar responses to those aged 16-26 years, with higher antibody levels in younger patients at 18 months post-vaccination. [20,23,24]

Cost-effectiveness of HPV vaccine

Cost-effectiveness analysis (CEA) is a widely recognised approach used to compare different health interventions' costs and health outcomes, although it demands substantial resources. To expand upon existing knowledge, scholars are devising techniques to transfer CEA findings across various contexts. Previous methodologies often fail to utilise all available data and neglect to quantify disparities across settings. In this study, we conducted a meta-regression analysis on published CEAs concerning HPV vaccination. The systemic review aimed to assess the impact of various factors at the country, intervention and methodological levels and to forecast incremental cost-effectiveness ratios (ICERs) for HPV vaccination across 195 countries.^[24]

The study concluded that on a global scale, the introduction of the HPV vaccine and the attainment of high HPV vaccine coverage are pivotal measures in alleviating the burden of cervical cancer. Drawing upon comprehensive data, the study findings advocate for implementing and broadening HPV vaccination programmes, particularly in numerous countries eligible for subsidised vaccines through initiatives, such as Gavi, the Vaccine Alliance and the Pan American Health Organization. The vaccine cost emerges as a significant factor, and their developed models can efficiently forecast ICERs and associated uncertainty intervals (UI) as vaccine subsidies extend to additional nations or if there are alterations in vaccine pricing. [24] Prospective approaches for India might be found in a comparative study with nations, such as Australia and Rwanda, which have significantly decreased the incidence of cervical cancer and HPV. Robust public health campaigns, extensive immunisation programmes and cervical screening initiatives were executed in both nations. We can learn a lot from Rwanda's accomplishment of high vaccine coverage

Component	Description	Benchmarks for success	Key performance indicators (KPIs)
Establishing baseline data	Initial assessment of HPV prevalence, cervical cancer incidence, vaccination rates and awareness levels. Gather detailed demographic information.	Baseline data established within the first year.	Initial HPV prevalence rates, cervical cancer incidence rates, vaccination rates, public awareness levels.
Setting clear objectives	Define goals for vaccination coverage, reduction in HPV prevalence and reduction in cervical cancer incidence.	90% vaccination coverage within 5 years. – 50% reduction in HPV infection rates within 10 years. – 30% reduction in cervical cancer incidence within 15 years.	Vaccination coverage rates, HPV infection rates, cervical cancer incidence rates.
Data collection and management	Implement surveillance systems, utilise electronic health records and conduct regular surveys.	Continuous data collection and management systems in place by the end of the second year.	Number of surveillance systems operational, percentage of digital health records maintained, frequency of surveys conducted.
Evaluation and feedback mechanisms	Annual reports, mid-term reviews and community feedback mechanisms.	Annual reports published. – Comprehensive mid-term evaluations every 5 years. – Regular community feedback sessions.	Number of reports published, completion of mid-term reviews, frequency of community feedback sessions.
Capacity building and training	Regular training for healthcare providers and community health initiatives.	Healthcare worker training sessions conducted annually. – Community health worker initiatives launched within the first 3 years.	Number of training sessions held, number of community health worker initiatives launched.
Policy and funding	Secure sustained funding and policy support for HPV vaccination integration into national immunisation schedules.	Long-term financial commitments secured. – Policy integration achieved within the first 5 years.	Amount of funding secured, policy adoption and integration status.
Research and development	Conduct operational research and long-term impact studies to optimise vaccine delivery strategies and evaluate programme effectiveness.	Initial research projects launched within the first 3 years. – Impact studies conducted every 5 years.	Number of research projects initiated, number of impact studies completed.
Short-term benchmarks (1–5 years)	Achieve 70% vaccination coverage, establish a reliable supply chain and initiate public awareness campaigns.	70% vaccination coverage among target age group, reliable vaccine supply chain, public awareness campaigns operational.	Vaccination coverage rates, supply chain efficiency, public awareness levels.
Medium-term benchmarks (5–10 years)	Increase coverage to 90%, reduce HPV prevalence and integrate vaccination with routine healthcare services.	90% vaccination coverage, significant reduction in HPV prevalence, integration with routine healthcare services.	Vaccination coverage rates, HPV infection rates, integration status.
Long-term benchmarks (10–15 years)	Achieve substantial reduction in cervical cancer incidence, maintain high vaccination coverage and establish a robust, sustainable monitoring system.	Substantial reduction in cervical cancer incidence, sustained high vaccination coverage, robust monitoring and evaluation system.	Cervical cancer incidence rates, vaccination coverage rates, effectiveness of monitoring system.

through community engagement and Australia's successful school-based immunisation programme. ^[25] The efficacy of HPV vaccination campaigns may be increased by tailoring these tactics to India's socio-cultural and healthcare context.

Initiatives from the government of India

Under the leadership of our honourable prime minister, Sri Narendra Modi Ji, the central government has communicated with all states and union territories to raise awareness regarding cervical cancer prevention and emphasise the significance of the HPV vaccine among female students nationwide. In a collaborative letter, it was underscored that globally, cervical cancer ranks as the fourth most prevalent cancer in women. Within India, cervical cancer stands as the second most common cancer among women, with India bearing the largest share of the global burden of cervical cancer. Highlighting cervical cancer as a preventable and treatable ailment, provided it is detected early and managed effectively, the letter notes its association with the HPV and

underscores the potential of the HPV vaccine in averting the majority of cervical cancer cases if administered before exposure to the virus. Vaccination stands as a key component of the WHO's Global Strategy for the elimination of cervical cancer. The letter further mentions the National Technical Advisory Group for Immunization (NTAGI) recommendation to include the HPV vaccine in the UIP, proposing a one-time catch-up vaccination for adolescent girls aged 9-14 years, followed by routine vaccination at 9 years. The vaccination drive would primarily operate through schools (using a grade-based approach from 5th to 10th grade), leveraging high rates of female school enrolment. Vaccination services would be extended at health facilities to ensure coverage for girls unable to attend school on the designated campaign day. In contrast, out-of-school girls would be targeted through community outreach and mobile teams, specifically focusing on the age group of 9-14 years. The U-WIN App would facilitate registration, recording and reporting vaccination statistics.^[26] The letter requests that states/union territories issue directives at suitable administrative levels to undertake the following initiatives to ensure the success of the campaign:

- Arranging HPV vaccination centres within school premises for administering the vaccine.
- Instructing the District Education Officer to collaborate with the District Immunization Officer and participate in the efforts of the District Task Force on Immunization (DTFI) under the supervision of the District Magistrate.
- Coordinating with both Government and Private School Management Boards within the district.
- Assigning a designated contact person in each school to oversee vaccination activities, compile the number of girls aged 9–14 years and upload this information in bulk to the U-WIN platform.
- Utilising special parents-teachers meetings (PTAs) as a platform for school teachers to raise awareness among parents.
- Assisting in compiling an updated list of all school types (as per UDISE+) in each block for precise planning and utilising geographic information system (GIS) mapping of schools to district immunisation officers to formulate micro-plans to ensure comprehensive coverage during the vaccination campaign.
- Collaborating with the health team to strategise the vaccination campaign across the state, avoiding months of examinations and holidays.

In January 2023, the Indian Ministry of Health and Family Welfare contacted seven state governments, spanning from Himachal Pradesh to Tamil Nadu, urging them to prepare for the rollout of the HPV vaccine for girls aged 9–14 years. These efforts represent the initial phase of India's planned HPV vaccine distribution. Once these states complete vaccination for this age group, HPV immunisation will become a part of their routine vaccination schedules. Subsequent phases will extend to additional states and union territories in 2024 and 2025. Ultimately, it is projected that 68 million Indian girls will receive the HPV vaccine, with a further 11.2 million 9-year-old girls targeted annually for routine HPV vaccination after that which need to be monitored and evaluated. [27,28] In Table 1, a framework is proposed for the long-term monitoring and evaluation of HPV vaccination programmes.

Conclusion

HPV vaccination provides primary prevention by targeting specific serotypes with limited cross-protection against cervical carcinoma. Developing a cost-effective second-generation HPV vaccine is crucial for tackling region-specific challenges in developing nations. Meanwhile, routine cervical cancer screening, using cost-effective methods, such as Pap smears and HPV DNA tests, remains vital for secondary prevention. Importantly, the vaccine does not contain a live virus, eliminating the risk of HPV infection. Combining HPV vaccination with regular cervical screening emerges as the most effective strategy for preventing cervical cancer.

Future research avenues

Future research avenues for HPV vaccines encompass several key areas to optimise vaccine effectiveness, accessibility and safety. Firstly, ongoing studies are needed to assess the long-term efficacy and durability of current HPV vaccines, particularly in diverse populations and age groups. This includes evaluating the need for booster doses and assessing the potential impact of waning immunity over time. Additionally, research on developing next-generation HPV vaccines with broader coverage against additional high-risk HPV types and improved cross-protection is essential. Further investigation into the immunogenicity and efficacy of HPV vaccines in special populations, such as immunocompromised individuals and those with coexisting medical conditions, is warranted. Moreover, efforts to enhance vaccine delivery strategies, including novel formulations, alternative administration routes and approaches to improve vaccine acceptance and uptake, are important for maximising vaccine impact. Lastly, ongoing surveillance and monitoring of vaccine safety and adverse events are critical to ensure continued confidence and trust in HPV vaccination programmes globally. Collaborative interdisciplinary research efforts, involving vaccine developers, epidemiologists, immunologists and public health experts, will be essential for advancing these research agendas and addressing remaining challenges in HPV vaccine development and implementation.

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Conflicts of interest

There are no conflicts of interest.

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