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Review Article

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HPV vaccines in China: A narrative review

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ABSTRACT

Cervical cancer is the fourth most common malignancy among women worldwide, with persistent high-risk HPV infection as its necessary cause. The World Health Organization (WHO) has set the "90-70-90" targets for 2030 to accelerate cervical cancer elimination. Given China's large population, progress in vaccine accessibility, coverage, and long-term protection will have a major impact on global control efforts. Despite advances in vaccine development, approval, and policy innovation, challenges remain, including uneven coverage, limited long-term follow-up, low male vaccination uptake, and financial sustainability. This review synthesizes evidence on vaccine development, clinical evaluation landscape, policy practice, and HPV vaccination coverage in China to identify key barriers to implementation and outline strategic directions for achieving sustainable high coverage. It aims to inform the design of a unified national immunization program in China and provide lessons for cervical cancer prevention in other low- and middle-income countries.

KEYWORDS: Human papillomavirus (HPV); Cervical cancer prevention; Health policy; One Health

1. Introduction

Cervical cancer is the fourth most common cancer in women globally with around 350 000 deaths in 2022[1]. Persistent infection with oncogenic HPV plays a central role in cervical carcinogenesis[2]. Human papillomavirus (HPV) is a small double-stranded DNA virus that infects cutaneous and mucosal epithelial cells[3]. It falls into two categories: high-risk (HR-HPV) and low-risk (LR-HPV). HR-HPV contributes to a broad spectrum of anogenital malignancies and is responsible for more than 90% of cervical cancer and anal cancers and approximately 70% of vaginal and vulvar cancers[4], while LR-HPV mainly causes benign conditions including anogenital warts. Most HPV infections resolve naturally, yet exposure is almost universal. About 80% of sexually active individuals will acquire at least one type during their lifetime[5]. Although infection is common, most cases are cleared naturally by the immune system. Epidemiological studies indicate that about 70% of infections resolve within one year and up to 90% within two years, while roughly 10% persist rather than clearing[6]. The WHO reports that there were around 660 000 new cases in 2022, and approximately 700 000 new cases are projected for 2030 without additional interventions[1,7]. Cervical cancer thus represents the most burdensome HPV-associated malignancy and a major global public-health challenge, calling for comprehensive prevention through vaccination, screening, and timely treatment. HPV-related diseases are classified into the following categories: 1) Head and neck squamous cell carcinoma, which includes oropharyngeal cancer; 2) Anogenital cancers, encompassing cervical cancer, vaginal cancer, vulvar cancer, penile cancer, and anal cancer; 3) Benign lesions, such as condyloma acuminatum (genital warts); and 4) Other associated conditions, notably male infertility[8–10]. HPV-associated diseases stratified by sex. Male-

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specific diseases include penile cancer and male infertility. Female-specific diseases include cervical, vaginal, and vulvar cancers. Diseases common to both sexes include head and neck squamous cell carcinoma, oropharyngeal cancer, anal cancer, and anogenital warts.

The development of cervical cancer has been linked to multiple independent risk factors. These include persistent infection with HR-HPV, as well as non-viral factors such as long-term smoking[11], multiparity[12], impaired immune function[13], and prolonged use of oral contraceptives[14]. The One Health approach, which recognizes the interconnectedness of human health, social determinants, and health systems, advocates for coordinated actions across healthcare, education, and policy sectors[15]. From this perspective, HPV vaccination is not merely a biomedical intervention but a societal measure requiring multisectoral collaboration to ensure equitable access and high coverage. Through such collaboration, prevention can be shifted upstream and progress toward cervical cancer elimination can be accelerated. Prophylactic HPV vaccines have been recognized as the cornerstone of primary prevention. Their broad coverage has been associated with substantial reductions in both incidence and mortality of cervical cancer, thereby providing the foundation for elimination. In 2020, the World Health Organization (WHO) launched the Global Strategy to Accelerate the Elimination of Cervical Cancer[16], which set the "90-70-90" targets for 2030: 90% of girls fully vaccinated with HPV vaccine by age 15, 70% of women screened with a high-performance test at ages 35 and 45, and 90% of women diagnosed with precancer or cancer receiving appropriate treatment.

Within this global framework, China has occupied a distinctive position. The size of its population means that national achievements will have a major influence on global progress. At the same time, rapid advances in domestic vaccine development and policy innovation in China have created opportunities to contribute new models and experiences to other countries. Given China's unique vaccine innovation capacity, evolving regulatory landscape, and growing public health demand, a comprehensive review is warranted to contextualize these developments within the global elimination strategy. This article reviews the current status of HPV vaccination and vaccine evaluation in China, assesses achievements and limitations, and discusses future challenges and opportunities, with the aim of providing insights for cervical cancer elimination both nationally and globally.

2. Licensed and pipeline HPV vaccines in China

As of 2025, a total of six HPV vaccines have been approved in China, including bivalent, quadrivalent, and nine-valent products. The imported vaccines, Cervarix, Gardasil, and Gardasil9, are all produced using insect cell expression systems, which are well established and highly immunogenic, but remain limited by higher costs and production capacity[17]. The domestic vaccines, Cecolin, Walrinvax, and Cecolin9, are based on *Escherichia coli* or *Pichia pastoris* expression platforms, offering advantages such as lower production costs and scalability, with some products already approved for export. Overall, domestic vaccines have demonstrated favorable immunogenicity and safety profiles[18], and show potential advantages in accessibility and supply capacity. The key characteristics, target populations, and dosing schedules of these vaccines are summarized in Table 1.

2.1. Development of higher–valency vaccines

Multivalent vaccine development is gaining momentum. Although bivalent, quadrivalent, and nonavalent vaccines cover the major high-risk types globally, infections with HPV52 and HPV58 occur more frequently in China than in some other settings[19,20], and HPV59 remain prevalent in certain regions[21]. To address these local patterns, 11-, 14-, and 15-valent candidates are being advanced by Chinese research institutes and companies[22,23]. For example, an 11-valent candidate that includes HPV59 has entered clinical testing, aligning more closely with domestic epidemiology.

Cost-effectiveness remains central to decisions about developing and adopting multivalent vaccines. Bivalent vaccines have shown

Table 1. Overview of HPV vaccines approved in China.

Attribute	Cervarix	Gardasil	Gardasil9	Cecolin	Walrinvax	Cecolin9
Manufacturer	GlaxoSmithKline (GSK)	Merck & Co.	Merck & Co.	Xiamen Innovax (Wantai)	Walvax Biotechnology	Xiamen Innovax (Wantai)
HPV types covered	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58	16, 18	16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58
Regulatory approval	WHO/NMPA	WHO/NMPA	WHO/NMPA	WHO/NMPA	NMPA	NMPA
Expression system	Baculovirus–insect cell	*Saccharomyces cerevisiae*	*Saccharomyces cerevisiae*	*Escherichia coli*	*Pichia pastoris*	*Escherichia coli*
Indication / dosing	Females 9–45 yrs; 3-dose	Females 9–45 yrs; 3-dose	Females 9–45 yrs; Males 16–26 yrs; 3-dose	Females 9–14 yrs: 2-dose; 15–45 yrs: 3-dose	Females 9–14 yrs; 15–45 yrs; 3-dose	Females 9–17 yrs: 2-dose; 18–45 yrs: 3-dose

NMPA: National Medical Products Administration; WHO: World Health Organization.

high efficacy, but cost-effectiveness depends on disease burden, pricing, and coverage. Under some epidemiological and economic conditions, nonavalent vaccination has been found to be more cost-effective than bivalent or quadrivalent schedules[24,25]. As valency increases, however, antigen interactions and immunological complexity also rise. Whether these factors affect the durability and consistency of immune responses will need to be clarified through long-term follow-up.

2.2. Therapeutic HPV Vaccines

Beyond prophylactic vaccines, therapeutic vaccine development has emerged as a new direction. Unlike preventive vaccines that rely on neutralizing antibodies to block viral entry, therapeutic vaccines are designed to activate cellular immunity, particularly by inducing cytotoxic T lymphocytes ($CD8^+$ T cells)[26], to eliminate persistent infections and precancerous lesions. Common candidates include DNA[27], mRNA[28], protein-based vaccines[29], as well as viral vector and dendritic cell vaccines[30]. Although these platforms differ in design, their central strategy is the delivery of tumor-associated HPV antigens such as E6 and E7 to antigen-presenting cells. Through major histocompatibility complex class I or II pathways, cellular immune responses are then triggered to clear infected cells.

Therapeutic vaccines developed on these platforms have shown promise. Nucleic acid vaccines can stably express antigens and are relatively easy to manufacture. Viral vector and dendritic cell-based vaccines, by directly targeting antigen-presenting cells and enhancing antigen presentation, are considered more immunogenic. Several E6/E7-targeted candidates have demonstrated encouraging results in preclinical models and early-phase clinical trials[31]. Nevertheless, important challenges remain. Although E6 and E7 have become the predominant targets, other antigens such as E5 have not yet produced sufficient immune responses for clinical application[32]. Certain adjuvants, such as CpG oligodeoxynucleotides, can strengthen immune responses but have yielded inconsistent results in animal studies[33]. Balancing immunogenicity with safety and reproducibility will be essential for successful clinical translation.

Despite still being in the research and validation stage, therapeutic vaccines signal a shift in HPV control—from exclusive reliance on primary prevention toward secondary and even tertiary interventions after disease onset. If barriers such as immune evasion, inefficient antigen delivery, and tumor-induced immunosuppression can be overcome, advances in China are expected not only to enrich the global portfolio of therapeutic strategies but also to provide new options for cervical cancer and other HPV-related malignancies.

3. Current landscape of HPV vaccine evaluation in China

Multiple clinical studies have been conducted in China to evaluate HPV vaccines, with a primary focus on short-term immunogenicity and safety. Findings indicate that domestic vaccines perform comparably to imported products in terms of immune response and have favorable safety profiles[34,35]. However, compared with mature international cohorts that provide long-term (>10 years) effectiveness data[36–38], Chinese studies remain largely trial-oriented, with typical Phase II–III studies enrolling 300–800 participants and having follow-up periods of only two to three years[39]. Evidence on long-term protection, particularly beyond ten years, is still lacking.

Another major limitation lies in the representativeness of study populations and regions. Most available data are derived from economically developed coastal provinces, while evidence from central, western, and rural areas remains scarce. This imbalance limits the generalizability of study findings and constrains equitable policy implementation. In addition, most studies target women of eligible age, with little data on men or immunocompromised populations. Given the role of men in HPV transmission and disease burden, these gaps reduce the accuracy of public-health impact assessments and delay the development of gender-neutral vaccination strategies.

At the policy level, China has begun to strengthen the standardization of vaccine evaluation and coverage. The National Health Commission has mandated the establishment of systems for monitoring vaccine effectiveness and immunization coverage in the Regulations on Immunization Practice[40]. In 2025, the Chinese Clinical Application Guidelines for Prophylactic HPV Vaccines (2025 edition) issued standardized recommendations on target populations and evaluation criteria, offering a regulatory basis for vaccine effectiveness studies[41]. Key milestones in the development of vaccine regulation, HPV vaccine approvals, and representative provincial initiatives are summarized in Figure 1, highlighting the parallel evolution of national policy frameworks and local implementation efforts.

More recently, the concept of real-world evidence has been introduced, and several provinces have launched government-supported vaccination programs that generate large-scale administrative records and real-world data. Efforts are underway in China to link the National Immunization Information System with cancer registry data, although nationwide integration has not yet been fully achieved. If sustained, these initiatives could strengthen the scientific rigor and policy relevance of HPV vaccine evaluation in China, and provide robust evidence for optimizing vaccination strategies under the National Immunization Program.

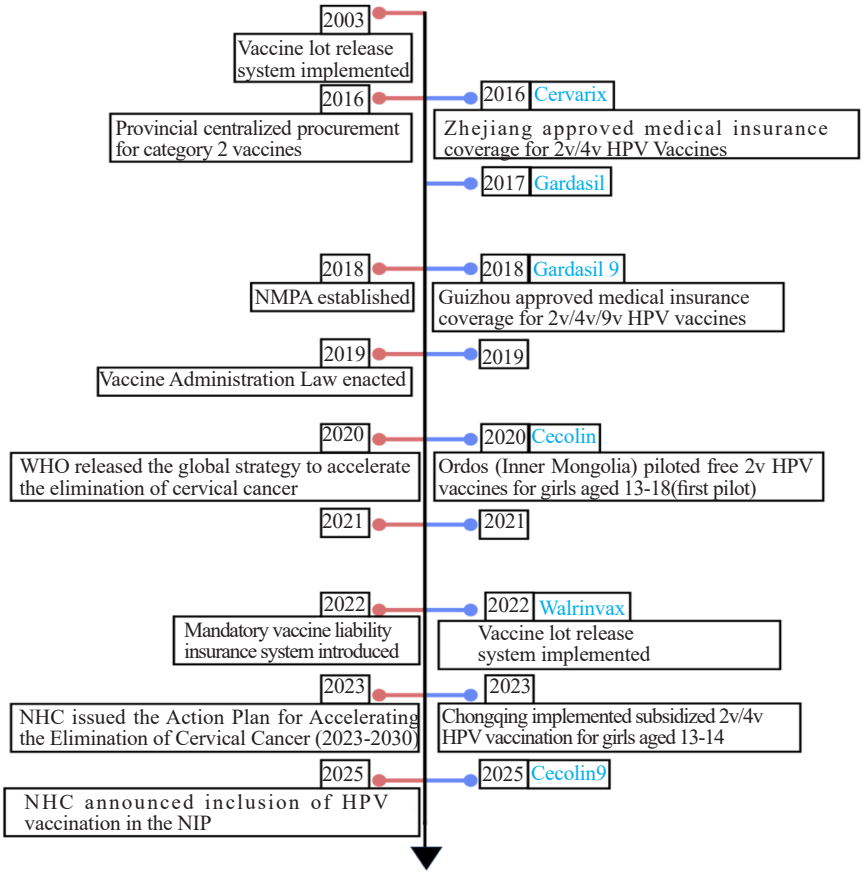

Figure 1. Timeline of HPV vaccine policy and implementation in China[42–45]. The left side (red markers) shows national-level milestones in vaccine regulation and HPV-related policy, including the establishment of the National Medical Products Administration (NMPA), enactment of the Vaccine Administration Law, and release of the national Action Plan for Accelerating the Elimination of Cervical Cancer (2023–2030). The right side (blue markers) indicates the market introduction of bivalent, quadrivalent, and nine-valent HPV vaccines (imported and domestic) and representative provincial initiatives, categorized as insurance coverage, government subsidies, and free vaccination programs. Together, these parallel timelines illustrate the progressive alignment of regulatory frameworks and local implementation, which has expanded access and coverage leading up to the inclusion of HPV vaccination in the National Immunization Program in 2025.

4. Challenges and strategies

Despite substantial progress in HPV vaccine development and cervical cancer prevention initiatives, significant disparities remain in vaccine uptake, screening coverage, and program implementation across China. These gaps arise from a complex interplay of sociocultural, economic, infrastructural, and policy factors. Understanding these challenges is essential for identifying targeted and feasible strategies to improve equity and effectiveness in HPV prevention. The following sections summarize the major barriers currently facing HPV vaccination and cervical cancer screening in China and outline potential strategies to address them.

4.1. Vaccine hesitancy

Vaccine hesitancy is a key factor influencing HPV vaccine uptake[46]. Adolescent females, especially those in secondary school, are regarded as the optimal age group for vaccination[16,39]. However, the decisions are often strongly shaped by their guardians. Concerns about vaccine safety remain one of the major causes of hesitancy[47]. Although serious safety incidents related to the HPV vaccine are uncommon in mainland China, past incidents involving other vaccines have undermined public confidence in vaccine safety[48], and related anxiety has often been exacerbated by social media[49]. Studies have shown that female guardians, urban households, and groups with higher education or income levels usually have a clearer understanding of the necessity, importance, and safety of the HPV vaccine[50]. They are also less likely to be influenced by misinformation. By contrast, some women in rural or less developed areas have limited awareness of HPV infection risks, knowledge of cervical cancer prevention, and the differences between vaccines of different valencies. This lack of knowledge reduces their willingness to vaccinate[51].

Economic factors also influence vaccine choice. In wealthier regions, imported nonavalent vaccines are generally preferred,

despite their higher price and limited supply, as they are perceived to provide the most comprehensive protection[52]. Domestically produced bivalent vaccines, although cheaper and more widely available, are often undervalued due to low awareness and limited public trust. The influence of social media and online platforms further reinforces these perceptions[51]. It is important to emphasize that while HPV vaccines differ in the number of viral types covered, extensive evidence has confirmed that any HPV vaccine significantly lowers the risk of cervical cancer and precancerous lesions[34,53,54]. Strengthening health education and raising public awareness are therefore crucial[47], would improve overall vaccination coverage.

4.2. Gaps in screening

Although most HPV infections resolve within a few years without clinical consequences, persistent infection can lead to high-grade precancerous lesions, such as cervical intraepithelial neoplasia grades 2 and 3, and may eventually progress to cervical cancer. Approximately 30% of cervical intraepithelial neoplasia 3 lesions progress to invasive cancer over a 30-year period[55,56]. The typically slow progression provides multiple opportunities for detection and treatment, thereby interrupting the natural history of the disease. Cervical cancer screening remains a critical intervention for achieving this goal. Despite these preventive opportunities, both the incidence and mortality of cervical cancer have shown a steady increase in China in recent years.

Free screening programs were introduced in rural areas in 2009 and expanded to cover 10 million women annually by 2012[57], and have since been extended to all counties and districts across 31 provinces. The program targets women aged 35-64 years and adopts an organized screening model, providing cytology every three years or high-risk HPV testing every five years depending on local laboratory capacity[58], yet overall coverage has remained inadequate. Recent data (Figure 2) show that in 2023-2024, screening rates among women aged 35-64 continued to display a pronounced urban-rural disparity[59]. Although the expansion of the “two cancers” screening program has gradually increased coverage in some regions, further progress has been hindered by limited public awareness, reluctance to undergo screening and follow-up colposcopy, and underutilization of alternative screening methods[60]. These shortcomings have concentrated risks in vulnerable populations and diminished the effectiveness of current programs. Notably, no comparable population-based screening pathway exists for HPV-related diseases among men, despite their documented role in HPV transmission and their risk of developing anal, penile, and oropharyngeal cancers[61].

Globally, HPV DNA testing has become the preferred screening method[62]. In contrast, primary healthcare facilities in China still rely mainly on VIA/VILI[63,64], a technological lag that risks leaving screening behind vaccine rollout. AI-based tools have recently been proposed to support cytology and imaging-based screening[65], offering potential improvements in accuracy and reductions in labour costs, although large-scale adoption and standardisation remain unrealised. Importantly, evidence indicates that screening every three to five years in rural areas is highly cost-effective[66,67],

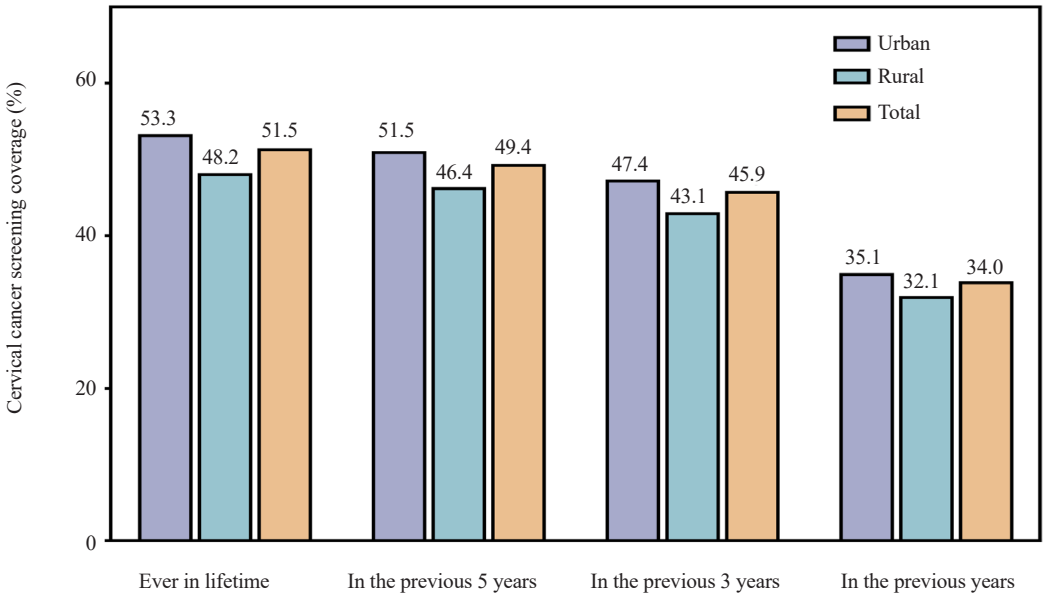

Figure 2. Cervical cancer screening coverage among women aged 35–64 years in China, 2023–2024[60]. Coverage rates are presented separately for urban and rural populations, together with the national average.

underscoring the feasibility of broader expansion even under resource constraints.

4.3. Low HPV vaccination coverage among males

Insufficient vaccination among males has emerged as a potential weakness in cervical cancer prevention programs. Evidence indicates that approximately one-third of men aged 15 years or older worldwide have been infected with at least one type of HPV, and about one-fifth have been infected with at least one high-risk type[68]. Because early vaccine promotion and policy design primarily targeted women, public awareness of the need for male vaccination has remained limited[69]. In 2022, the WHO updated its HPV vaccine position paper, for the first time recommending the inclusion of males in the global vaccination strategy[70]. In China, the 9-valent vaccine was approved in 2025 for use in males aged 9-26 years[71]. These developments indicate that HPV prevention in men has received increasing attention. However, in China, vaccination coverage among males remains low, constrained by limited public awareness and financial barriers. Internationally, Australia has incorporated males into their national immunization programs in 2013, providing routine vaccination for boys aged 12-13 years along with a catch-up program for those aged 14-15 years[72]. Evidence from national studies have shown marked reductions in genital warts among heterosexual men during the vaccination period, with an 81.8% decline in those under 21 years (P<0.001) and a 51.1% decline in men aged 21-30 years (P<0.001)[73]. These experiences provide valuable reference points for the potential expansion of male vaccination in China.

Among males, high-risk groups face particularly significant challenges. Men who have sex with men (MSM) are reported to have higher HPV infection rates than heterosexual men, with HPV infection levels approximately three to four times greater in MSM (30% *vs.* 8%)[74], accompanied by elevated risks of anal and oropharyngeal cancers[75]. Individuals with compromised immune function, such as those living with HIV, are also more likely to experience persistent infection and precancerous lesions[74,75]. Targeted education and policy support for these populations remain limited, resulting in insufficient protection.Before 2025, HPV vaccines in China were not licensed for male indications, thus precluding direct vaccination for MSM populations. Furthermore, due to the nature of HPV transmission within MSM communities, indirect protection from female vaccination was not a significant factor for this group. Modeling studies in China have further suggested that HPV vaccination could substantially reduce the incidence and mortality of HPV-related diseases among MSM and may be cost-effective under certain conditions. In particular, quadrivalent vaccines were most effective for preventing anogenital warts, whereas nine-valent vaccines provided the greatest benefit for anal cancer prevention in MSM aged 27–45 years[76].

Male HPV vaccination not only helps to reduce the disease burden at the individual level but may also contribute to broader public health gains through the strengthening of herd immunity along with additional indirect protection for women. Similar gender-neutral vaccination strategies adopted in parts of Europe have further demonstrated, under conditions of high coverage, their effectiveness in accelerating the establishment of herd immunity[77].

4.4. Cold–chain transportation

Cold-chain storage refers to maintaining vaccines at controlled temperatures throughout transport and storage to preserve their potency. When these temperature requirements are not met, vaccines may lose effectiveness or become unsuitable for use. China's vaccine cold-chain infrastructure has expanded rapidly in recent years. According to data from the National Immunization Information System, the total number of vaccine cold-chain devices in China reached 269 132 by 2023[78], with an average of 1.91 units per 10 000 people. However, substantial disparities remain in storage capacity across administrative levels. Provincial Centers for Disease Control and Prevention reported an average cold storage volume of 568.56 cubic meters (m^3), while primary vaccination clinics had only 2.44 m^3 on average, representing a 233-fold difference. Overall capacity is regarded as broadly adequate; however, the limited volume at the terminal level leaves little buffer for biologics such as HPV vaccines, which require stringent temperature control. This imbalance increases the risk of vaccine degradation and wastage, reducing accessibility and public trust.

Given these constraints, maintaining the integrity of HPV vaccines is particularly challenging. They should be stored at 2℃–8℃ but are often subject to temperature excursions during transport and handling[79]. Evidence suggests that short-term exposure to moderately elevated temperatures does not always compromise potency, but prolonged or repeated overheating can affect virus-like particle conformation and reduce immunogenicity[80,81]. Freezing near 0 ℃ poses a well-documented risk because aluminum adjuvants can undergo flocculation, impair antigen dispersion, and cause irreversible potency loss that cannot be detected visually[82]. In many resource-limited settings, the absence of continuous temperature monitoring allows overheating or freezing episodes to go unnoticed, potentially resulting in compromised vaccines reaching recipients. These challenges highlight the importance of more reliable monitoring systems and robust cold-chain management[83]. Compared with high-income countries, real-time monitoring coverage and terminal equipment reliability remain limited, creating an opportunity to strengthen infrastructure through

smart monitoring and coordinated resource-sharing platforms.

4.5. Local policy responses in China

Policy initiatives have provided tangible momentum for expanding HPV vaccination. With declining vaccine prices and growing fiscal engagement at the provincial level, an increasing number of jurisdictions have introduced free or subsidized vaccination schemes. By 2025, 17 provinces had implemented such policies[84], and pooled procurement in some regions has effectively reduced household costs. According to the National Health Commission, national coverage among eligible women has reached approximately 40%[85]. Nevertheless, structural challenges remain. Fiscal sustainability is a major constraint: wealthier provinces can maintain free vaccination programs, whereas less-developed regions struggle to ensure continuity, widening regional disparities[17,86]. Inconsistencies in target age groups, funding mechanisms, and program design across provinces further fragment the vaccination landscape and hinder nationwide coordination.

International experience highlights the benefits of unified procurement and nationwide immunization programs. Australia and the United Kingdom have achieved and maintained over 80% coverage through school-based[87], publicly funded vaccination and centralized procurement, leading to measurable reductions in HPV prevalence and precancerous cervical lesions[88]. Malaysia, a middle-income country, scaled up rapidly to exceed 85% coverage within five years through government-led pooled procurement and nationwide rollout[89]. These examples demonstrate that national coordination can reduce costs, harmonize coverage, and narrow regional inequities. In sum, while local pilots have generated valuable experience and demonstrated feasibility, China's long-term goal of equitable HPV vaccine access will depend on integrating provincial initiatives into a unified national immunization framework that ensures stable financing, coordinated procurement, and consistent eligibility criteria.

5. Conclusions and perspectives

China's role in the global effort to eliminate cervical cancer involves both challenges and opportunities. Its large population and high disease burden mean that progress in China will directly influence global outcomes. Advances in vaccine development and evolving policy practices provide a foundation for evidence-based approaches that can inform other countries. Future policy should rely on robust cost-effectiveness analyses to allocate resources efficiently, introduce reimbursement and subsidy mechanisms to reduce household costs, and strengthen public acceptance of vaccination. Including HPV vaccines in the national immunization program is critical for achieving sustainable and equitable coverage and for improving coordination between screening, vaccination, and treatment.

Incorporating the One Health perspective highlights that cervical cancer prevention is not only a women's health issue but also an essential component of population health and socioeconomic development. Policy design should encourage collaboration across healthcare providers, schools, and community organizations to ensure integrated service delivery. Drawing on international experience such as school-based vaccination programs, while tailoring implementation to China's health system, can produce models that are feasible for other low- and middle-income countries. As domestic production capacity expands, China can advance toward universal vaccine access and share affordable products and implementation strategies with other countries, contributing to global cervical cancer prevention. In summary, progress in HPV vaccination in China should combine scientific evidence with practical implementation, improve accessibility and equity, and generate models that can support the global One Health agenda.

Conflict of interest statement

The authors claim there is no conflict of interest.

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Data availability statement

The data supporting the findings of this study are available from the corresponding author upon request.

Authors' contributions

Zhao LX, Mao WY, and Lu JY conceived and designed the study. Zhao LX and Mao WY prepared the original draft and contributed to visualization. Lu JY was responsible for writing—review and editing. All authors have read and agreed to the published version of the manuscript.

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