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EDITORIAL

Progress toward cervical cancer elimination: global disparities and China's contributions

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Introduction

Progress toward the global elimination of cervical cancer as a public health concern remains slow and highly uneven across countries. High-income nations such as Australia and Finland—both of which have achieved high human papillomavirus (HPV) vaccination coverage and implemented quality-assured cervical cancer screening programs—have successfully decreased the incidence rates to below 8 cases per 100,000 women[1]. These countries are on track to reach the elimination threshold of fewer than 4 cases per 100,000 women within the next few years, as defined by the World Health Organization (WHO).

In stark contrast, many sub-Saharan African countries continue to report incidence rates exceeding 25 per 100,000 women, with little evidence of decline[1]. The disparity is even more striking when considering mortality rates, which range from fewer than 2 deaths per 100,000 women in many European countries to more than 50 per 100,000 in Malawi, thus highlighting profound global health inequities.

Most low- and middle-income countries, which collectively bear the highest burden of cervical cancer, are not on track to meet the 3 key targets set by the WHO for elimination[2]:

1. **90%** of adolescent girls fully vaccinated against HPV by age 15
2. **70%** of eligible women screened with a high-performance test at least twice in their lifetime
3. **90%** of women with precancerous lesions or invasive cancer appropriately treated.

Over the past 3 decades, researchers in China—working in close collaboration with domestic industrial partners—have developed and evaluated several innovations that could accelerate progress toward cervical cancer elimination, both within China and globally. These innovations span all 3 strategic pillars of vaccination, screening, and treatment. Herein, we describe the key studies in China that have generated valuable evidence to inform national and international guidelines in HPV vaccination, cervical cancer screening, and management of cervical precancers.

Increasing the availability of affordable HPV vaccines

Despite a notable increase in global HPV vaccine coverage among girls under 15 years of age, from 16% in 2021 to 31% in 2024, coverage remains well below the WHO elimination target of 90%[3]. The barriers are multifactorial. Even in high-income and upper-middle-income countries, coverage is threatened by vaccine hesitancy, weak implementation strategies, and inadequate communication efforts.

However, a more critical challenge is that 49 countries, predominantly low- and lower-middle-income nations with the highest burden of cervical cancer, have yet to introduce HPV vaccination into their national immunization programs. The primary obstacles include high vaccine cost and insufficient global vaccine supply. Some countries have needed to withhold vaccination scale-up after regional introduction, because of irregular vaccine supply.

The recent WHO prequalification of several Chinese-manufactured HPV vaccines represents a major advancement with potential to diversify global supply chains, lower costs,

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and facilitate broader vaccine access in resource-limited settings. To date, the WHO has prequalified 5 HPV vaccines, including 2 from China: Cecolin® (Innovax, Xiamen) and Walrinvax™ (Zerun Biotech, Yuxi)[4]. Both are bivalent vaccines targeting HPV types 16 and 18, and have undergone rigorous safety and efficacy evaluation.

Cecolin®, produced with a high-yield *E. coli*–based expression system, has demonstrated 100% efficacy (95% CI: 67.2–100.0) against high-grade lower genital tract lesions (including CIN 2/3 and adenocarcinoma *in situ* associated with HPV 16/18) at 66 months of follow-up[5]. Walrinvax™, developed with a yeast-based production platform, has been evaluated in a phase III randomized controlled trial among women 18–30 years of age and has shown 78.6% efficacy (95% CI: 23.3–96.1) against HPV16/18-related CIN 2+ after 48 months[6]. The efficacy of the vaccine has been demonstrated in 9- to 14-year-old Chinese girls in an immunobridging study[7].

Building on this success, Innovax has recently received regulatory approval for Cecolin-9, a nonavalent HPV vaccine—only the second such vaccine globally available after Gardasil-9. In a randomized controlled trial conducted in China among women 18–26 years of age, Cecolin-9 demonstrated non-inferior immunogenicity to Gardasil-9 across all 9 targeted HPV types[8]. Non-inferiority was established on the basis of the predefined criterion that the lower bound of the 95% confidence interval for the geometric mean concentration ratio between Cecolin-9 and Gardasil-9 be ≥ 0.5.

In a notable policy development, both Cecolin and Walrinvax have been prequalified by the WHO for single-dose use, after the WHO's endorsement of one-dose HPV vaccination schedules for primary prevention in girls 9–20 years of age.

These advancements reflect substantial progress in making high-quality, affordable HPV vaccines more accessible and offer a critical opportunity to accelerate global efforts toward cervical cancer elimination. A modeling-based cost-effectiveness study by Chinese researchers has projected that nationwide introduction of routine HPV vaccination with the bivalent vaccine by 2023 could decrease cervical cancer incidence by 56.5% by the year 2100, even under the status quo of opportunistic screening[9]. The estimated decrease could substantially increase, to nearly 80%, if the bivalent vaccine were replaced by the nonavalent vaccine. A vaccine with higher valency targeting 14 HPV types is undergoing a phase III trial in China (registration No. CTR20232472) and is likely to increase the range of protection against cervical cancer.

As expanded HPV immunization programs are gradually rolled out at the provincial and city levels in China, with joint efforts among industry, regulatory authorities, and the academic community, China is set to markedly decrease vaccine cost.

Transforming cervical cancer screening with HPV testing and self-collection

The global landscape of cervical cancer screening has considerably evolved after the WHO's strong recommendation to use HPV nucleic acid testing (DNA or mRNA) as the primary screening modality[10]. This shift was grounded in extensive evidence from multiple systematic reviews and meta-analyses, which have consistently shown high concordance between self-collected and provider-collected samples in the detection of high-risk HPV with PCR-based DNA assays[11].

The use of self-collected vaginal samples for HPV testing has been transformative in both high- and low-income settings, because of its high acceptability and logistical simplicity, and the ability for women to collect samples at home, without a need for clinician involvement.

A landmark study in this field, the Shanxi Province Cervical Cancer Screening Study (SPOCCS) from rural China, was among the earliest to rigorously evaluate HPV detection methods, including self-collection[12]. As early as 2001, the SPOCCS reported a 95% sensitivity and 85% specificity of the HPV detection test (Hybrid Capture II; Digene Corp, USA) for detecting CIN 2+ lesions in physician-collected samples. Although self-collected samples had a lower sensitivity (83%), they still offered a promising alternative. As evidence accumulates, signal amplification tests such as Hybrid Capture II are currently well-established to have lower sensitivity in self-collected samples than PCR-based tests.

The longitudinal data from the SPOCCS cohort, followed for 3 additional screening rounds every 5 years (with CIN 2+ lesions censored at detection), provided critical insights when they were published in 2018[13]. The cumulative incidence of CIN 2+ among women whose physician-collected samples tested positive for HPV was 27.4% (95% CI: 22.7%–32.1%) in the second screening round, 34.3% (95% CI: 29.2%–39.4%) in the third screening round, and 35.5% (95% CI: 30.4%–40.6%) in the fourth screening round. These findings underscore the importance of continued follow-up of women with HPV positivity.

Importantly, the study demonstrated a high negative predictive value of HPV testing, even with self-collected samples. Among women with HPV-negative findings on self-collected samples, the risk of developing CIN 2+ was remarkably low: 1.1% at 5 years, 3.0% at 10 years, and 4.7% at 15 years.

Moreover, the risk of CIN 2+ among women with HPV-negative findings in physician-collected samples did not differ from those with HPV-negative findings for co-testing (HPV plus cytology), thus reinforcing the limited additional value of co-testing as a screening strategy.

China has conducted several high-quality studies evaluating the performance of PCR-based HPV detection tests, with a focus on self-collected samples—an approach increasingly endorsed because of its feasibility and scalability.

One study conducted across Inner Mongolia and Shanxi Province, involving 9,526 women, has demonstrated very high sensitivity of a domestically developed PCR-based assay, Sansure High-Risk HPV Test (Sansure, Changsha, China). The test's sensitivity of 96.7% in detecting CIN 2+ and 91.4% in detecting CIN 3+ underscored its diagnostic robustness[14].

Similarly, a large multicenter population-based trial enrolling 10,885 women 30–59 years of age from 15 sites in 7 provinces, it has reported equivalent sensitivity with the Cobas 4,800 test (Roche) on self-collected and clinician-collected samples in detecting CIN 3+ lesions (95.07% in both sample types)[15].

In a landmark randomized controlled trial conducted in 60,732 women 35–64 years of age, 3 screening modalities were compared: HPV testing (including both PCR-based and signal amplification-based assays); liquid-based cytology (ThinPrep, Hologic); and visual inspection with acetic acid (VIA), followed by visual inspection with Lugol's iodine (VILI) for VIA-positive women. At baseline, HPV-based screening, compared with cytology, detected twice as many CIN 2+ cases and 2.7% more CIN 3+ lesions. After 24 months, a follow-up screening round indicated significant decreases in the detection of CIN 2+ (RR 0.5) and CIN 3+ (RR 0.2) in the HPV screening arm, thus highlighting the preventive effects of early detection and management of CIN 2+ lesions in the first round. Similar trends to those in the VIA/VILI group were observed.

A recently published study from China has reported high sensitivity (86.7%) of a PCR-based HPV detection test on first-void urine samples in detecting CIN 2+[16]. HPV testing on urine samples has potential to make the test more acceptable and accessible to women.

Data from China has demonstrated the superior cross-sectional and longitudinal sensitivity of HPV detection tests versus cervical cytology or VIA. This evidence is instrumental in shaping global and regional policy recommendations, in influencing WHO guidelines and the International Agency for Research on Cancer (IARC) evidence synthesis[17], the European Commission's screening guidance, and several national screening programs. In the context of scaling up HPV detection-based screening in China, mobilizing funding to set up test facilities and purchase test kits for a target population of millions poses a major challenge. A suitable triaging test is also required for the management of the HPV-positive women (discussed below), to avoid overloading colposcopy and treatment services. Program managers' hard negotiation with national test manufacturers might help decrease the cost.

Triaging of HPV-positive women: evidence from China

Effective triage of HPV-positive women is critical to balance the benefits of early treatment against the risks of overtreatment. Several high-quality studies from China have explored various triaging strategies using molecular markers, genotyping, and cytology-based approaches.

One such study conducted in Inner Mongolia and Shanxi Province enrolled 9,526 women 30–65 years of age and reported an HPV positivity rate of 19.2% with the Sansure PCR-based high-risk HPV test. That study evaluated the "screen-and-treat" strategy recommended by the WHO for resource-limited settings. Although this approach offers simplicity, it was associated with a high overtreatment rate of 90.5% in the study, defined as treatment of women without histologically confirmed CIN lesions[18].

The study demonstrated that triaging with HPV 16/18 genotyping (treating only those positive for HPV 16/18) led to treating only the 18.6% of HPV-positive women, thus decreasing the overtreatment rate by 69.3%. A more refined strategy, treating only HPV 16/18-positive women with colposcopic abnormalities, decreased the overtreatment rate to 15.2%.

The same study also assessed host gene methylation testing (GynTect®, Oncgnostics GmbH, Germany), which detects methylation of 6 genes: *ZNF671*, *ASTN1*, *ITGA4*, *RXFP3*, *SOX17*, and *DLX1*[19]. When used alone, the methylation panel had a sensitivity of 83.0% and a specificity of 69.9% for detecting CIN 2+ lesions. When combined with HPV 16/18 genotyping, the sensitivity substantially increased, to 95.6%, although the specificity decreased to 58.3%.

Longitudinal follow-up over 3 years further underscored the clinical value of these triage strategies. Among all HPV-positive women, the cumulative incidence of CIN 2+ was 6.8%. Strikingly, 33.7% of women who were positive for both HPV 16/18 and methylation at baseline developed CIN 2+ during follow-up, although they had no detectable lesions at enrollment.

In addition, other large studies from China have demonstrated the superior triage performance of combining partial HPV genotyping with $p16^{INK4a}$ immunocytochemistry, thus further supporting the utility of multimodal triage strategies[20].

Treatment of cervical precancers: evidence supporting thermal ablation from China

In response to the limitations of cryotherapy for treating cervical precancerous lesions, particularly in resource-constrained settings, the WHO has recommended thermal ablation as an alternative ablative treatment[21]. However, because the recommendation was initially made in 2019 and was based on low-certainty evidence, high-quality data remain needed.

A prospective study conducted in China and published in 2020 notably strengthened the evidence base for thermal ablation[22]. The study enrolled 170 HPV-positive women with colposcopically suspected low- or high-grade lesions who met the eligibility criteria for thermal ablation. All participants underwent cervical biopsies before treatment, although the results were reviewed after treatment.

Among those treated with thermal ablation, 69 had histologically confirmed CIN 1, 37 had CIN 2, and 13 had CIN 3. An additional 48 women with confirmed CIN 2 or CIN 3 were managed with large loop excision of the transformation zone.

Women treated with thermal ablation were followed up at 6, 12, and 18 months with both HPV testing and liquid-based cytology. Women with a positive result for either test underwent colposcopy-directed biopsy.

Women were considered cured if both HPV and liquid-based cytology yielded negative results, or histopathology confirmed no CIN, at the last visit. The cure rate for women with CIN 1 at baseline was 90.3% (95% CI: 80.5–95.5), whereas that for women with CIN 2+ lesions was 76.2% (95% CI: 61.5–86.5). HPV clearance in women without histological CIN was 83.0%. The negative predictive value of a negative HPV test during follow-up for CIN 2+ was 98.7% (95% CI: 95.3–99.6).

This study provides robust, real-world evidence supporting the use of thermal ablation for cervical precancers in HPV-based screening programs, particularly in low-resource settings. The high cure rates and negative predictive value reinforce its potential as a frontline treatment option capable of replacing more expensive and complex excisional procedures.

Artificial intelligence-based solutions in cervical cancer screening: advances from China

Artificial intelligence (AI) has substantial promise for improving objectivity, accuracy, and turnaround time, and decreasing dependency on trained health professionals in cervical cancer screening. Recognizing this potential, researchers in China have made substantial investigations in AI technologies tailored to cytology-based screening.

China's technological edge in this domain is bolstered by access to large, high-quality datasets, such as the Cx22 dataset, which contains expertly annotated cervical cytology images[23]. These datasets enable the training and validation of robust AI models for clinical application.

The AI-assisted workflow includes acquisition of digital images from stained cytology slides, region of interest identification, segmentation to isolate relevant cellular features (e.g., nuclei), and image classification based on the severity of abnormalities. This approach can markedly decrease cytologists' workload and increase throughput in screening programs.

Zhang et al.[24] have developed a deep neural network named Global Context UNet (GC-UNet) for nuclear segmentation in cytology slides. The model's high real-world accuracy (99.5%) makes it a powerful tool for diagnostic automation. Bao et al.[25] have trained a supervised deep learning algorithm on 188,542 digital cytological images. Their model has demonstrated equivalent sensitivity to skilled cytologists but higher specificity, particularly in interpreting slides from HPV-positive women (relative specificity: 1.26; 95% CI: 1.20–1.32). Many additional technologies are in the development pipeline[26].

AI is being used to interpret cervical images (collected by either a colposcope or other devices, such as mobile phones) to identify the type of transformation zone and detect any precancer or cancer. The use of the Colposcopic Artificial Intelligence Auxiliary Diagnostic System (CAIADS) to detect abnormalities on the basis of digital colposcopy images has

been evaluated in a colposcopy clinic of Xinjiang Medical University in Xinjiang, China[27]. The sensitivity of the model in detecting CIN 2+ lesions (80%) was comparable to that achieved through expert interpretation. Moreover, the algorithm was found to be particularly useful in training junior colposcopists, thus helping meet a major requirement for increasing capacity.

AI-based solutions offer a scalable, cost-effective, and accurate method for cervical cancer screening and management. Advancements from China are paving the way to the incorporation of AI-assisted screening algorithms into routine clinical practice, particularly in high-volume or resource-constrained settings.

Conclusions

The substantial contributions of Chinese scientists are playing a critical role in accelerating progress toward cervical cancer elimination within the country. A major milestone was the launch of free HPV vaccination for schoolgirls 9–14 years of age in Inner Mongolia in August 2020, and plans are in place for gradual expansion across other provinces. In 2022, HPV testing was officially integrated into China's National Cervical and Breast Cancer Screening Program, and was accompanied by a policy decision to include screening costs under health insurance coverage[28].

Despite these advancements, the task of scaling up HPV screening remains formidable, given that more than 500 million women are eligible countrywide. Achieving effective scale-up will require pragmatic policies and strategic planning, with a focus on prioritizing screening among women 30–49 years of age, in line with WHO recommendations. Ensuring programmatic efficiency, including the establishment of robust quality assurance mechanisms and regular monitoring, will be essential to translate decades of scientific progress into meaningful public health impact.

Conflict of interest statement

No potential conflicts of interest are disclosed.

Disclaimer

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