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Acceptability and Barriers of Self-Collected Cervicovaginal Samples for HPV DNA Testing in Northeast India

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ABSTRACT

Background: Cervical cancer remains a major public health challenge in India, with screening coverage below 2%. HPV DNA testing is the gold standard for early detection, but barriers to clinician-based sampling limit participation. Self-collected cervicovaginal samples may offer a culturally acceptable alternative, particularly in underserved regions.

Aim: To evaluate the acceptability of self-collected cervicovaginal samples for HPV DNA testing and to identify barriers and facilitators influencing women's participation in Northeast India.

Methods: A prospective cross-sectional study was conducted among 140 women aged 25–65 years attending tertiary care and outreach facilities. Participants performed self-sampling using sterile kits with illustrated instructions. Structured questionnaires assessed comfort, perceptions, and barriers. Statistical analyses included chi-square tests and logistic regression to identify predictors of acceptability.

Results: Only 33.3% of participants reported feeling comfortable with self-sampling, while 66.7% expressed discomfort. Major barriers included fear of incorrect technique (31%), lack of confidence in handling kits (24%), embarrassment (94.6%), and fear of cancer diagnosis (83.3%). Awareness was limited—only 39.3% had prior knowledge of cervical cancer screening, and just 13.3% knew it was preventable. Education level and prior awareness of HPV were significant predictors of acceptability. Facilitators included privacy, convenience, and instructions in local languages.

Conclusion: Self-collected HPV DNA testing shows promise but remains under-accepted in Northeast India due to psychological and cultural barriers. Strengthening awareness campaigns, counselling, and community health worker involvement is essential to improve confidence and uptake. Integration of self-sampling into national programs could expand screening coverage and reduce disparities.

Keywords: HPV DNA testing, cervical cancer screening, self-sampling, Northeast India, acceptability barriers, public health implementation

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INTRODUCTION

Cervical cancer is a major global health problem, ranking as the fourth most common cancer among women worldwide. Each year, more than 660,000 new cases are diagnosed, and over 350,000 women die from the disease, with the majority of deaths occurring in low- and middle-income countries.[1] In India, cervical cancer is the second most common cancer among women, accounting for nearly 127,526 new cases annually and 79,906 deaths in 2022, contributing significantly to cancer-related mortality.[2] Despite the availability of effective preventive strategies, including vaccination against high-risk human papillomavirus (HPV) and organised screening programs, uptake remains alarmingly low. National screening coverage in India is estimated at less than 2%, far below the World Health Organization (WHO) target of 70% by 2030.[3]

Cervical Cancer Burden in India

The disproportionate burden of cervical cancer in India is shaped by socio-demographic and health system factors. Rural and tribal populations, particularly in the Northeast, face barriers such as limited healthcare infrastructure, cultural stigma, and lack of awareness.[4] These challenges contribute to delayed diagnosis, advanced disease presentation, and poor survival outcomes. The Northeast region of India is characterised by unique socio-cultural diversity and geographical isolation, which further complicates access to preventive and diagnostic services. Addressing these disparities requires innovative approaches that are culturally acceptable, cost-effective, and scalable.

HPV DNA Testing and Self-Sampling

Persistent infection with high-risk HPV types is the primary cause of cervical cancer. HPV DNA testing has emerged as a highly sensitive method for detecting precancerous lesions, outperforming cytology in sensitivity and reproducibility.[5] Traditionally, samples are collected by clinicians during pelvic examinations. While effective, this approach is hindered by embarrassment, fear of pain, lack of female providers, and logistical constraints such as travel distance and time away from work.[6] Self-collected cervicovaginal samples present a promising alternative, offering women privacy, convenience, and empowerment. Studies in India and globally have demonstrated that acceptance of self-sampling was 80–99% once women received adequate health education.[7,8] Moreover, self-sampling has the potential to reach under-screened populations, particularly in rural and tribal areas where healthcare access is limited.

Evidence from Indian Settings

Recent prospective studies across urban, rural, and tribal settings in India have shown that self-sampling is both feasible and acceptable. Participation rates improve significantly when community health workers are involved in awareness campaigns and when screening is integrated into existing health services.[9] Importantly, referral compliance among screen-positive women varies by setting, with higher rates in urban areas than in rural and tribal regions, reflecting disparities in healthcare access.[10] These findings suggest that while self-sampling can overcome individual barriers, systemic challenges such as laboratory capacity, referral pathways, and treatment availability must be addressed for successful implementation.

Relevance to Northeast India

The Northeast region of India presents unique challenges for cervical cancer prevention. Women in this region often face limited access to tertiary care facilities, compounded by economic constraints and cultural taboos surrounding gynaecological examinations.[11] Introducing HPV self-sampling in such settings could significantly enhance participation, particularly among women reluctant to undergo clinician-collected sampling. Moreover, leveraging community health workers and mobile health technologies could

facilitate awareness, sample collection, and follow-up care. Implementation research focusing on Northeast India can provide critical insights into how self-sampling strategies can be adapted to resource-limited settings, thereby informing policy decisions and strengthening health systems.

Aim of the Research

While the clinical validity of self-sampling is well established, its integration into national screening programs requires careful evaluation of acceptability, feasibility, and scalability. Implementation research is essential to identify context-specific barriers and facilitators, particularly in underserved regions such as Northeast India. Such evidence will be crucial for informing national policy, guiding resource allocation, and ultimately reducing the burden of cervical cancer. By focusing on acceptability and feasibility, this study aims to contribute to the growing body of evidence supporting HPV self-sampling as a viable strategy for scaling up cervical cancer prevention in India. The study aimed to evaluate the acceptability of self-collected cervicovaginal samples for HPV DNA testing and to identify barriers and facilitators influencing women's participation in Northeast India.

MATERIALS AND METHODS

Study Design and Setting

This prospective cross-sectional study was conducted at Agartala Government Medical College and GBP Hospital. The study specifically evaluated the acceptability and feasibility of self-collected cervicovaginal samples for HPV DNA testing. The region was chosen due to its high burden of cervical cancer, limited healthcare infrastructure, and sociocultural barriers to conventional screening.

Study Population

Women aged 25–65 years attending gynaecology outpatient departments, community health camps, and outreach programs were invited to participate. Eligibility criteria included:

- No prior history of cervical cancer or hysterectomy
- Not currently pregnant
- Willingness to provide informed consent

Women with active genital infections, recent cervical procedures, or those unwilling to participate were excluded.

Sample Size and Recruitment

A total of 140 participants were recruited using consecutive sampling until the required sample size was achieved. The calculation was based on expected differences in acceptability, with a 95% confidence level and 80% power.

Self-Sampling Procedure

After obtaining written informed consent, participants were provided with sterile self-collection kits and illustrated instructions. They performed self-sampling in a private setting, with trained female health workers available to assist if required. Each specimen was labelled, coded, and transported under cold chain conditions to the molecular diagnostics laboratory.

Laboratory Analysis

HPV DNA was analysed using the fully automated Cobas HPV Test (Cobas 4800 System, Roche Molecular Systems, USA). The assay employs magnetic particle adsorption for DNA extraction and purification, followed by PCR amplification targeting specific regions of the HPV genome and the β-globin gene. Detection is based on cycle threshold (Ct) values across three channels—HPV16, HPV18, and a pooled group of 12 other high-risk types (HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)—with an overall HPV result generated according to predefined Ct cut-off thresholds.

Acceptability and Barrier Assessment

Following sample collection, participants completed a structured questionnaire assessing:

- Comfort and ease of procedure
- Perceived privacy and autonomy
- Barriers to participation (psychological, cultural, or logistical)
- Awareness and perceptions of cervical cancer screening

Researchers conducted interviews in local languages to ensure clarity and minimise bias.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee of AGMC (Ref. No. F.4 (6-13)/AGMC/Medical Education/IEC Approval/2022/24336). Written informed consent was obtained from all participants. Confidentiality was maintained by anonymising data and restricting access to study investigators only.

Data Management and Statistical Analysis

All collected data were entered into a secure database and analysed using SPSS version 26. Descriptive statistics were used to summarise sociodemographic characteristics and responses regarding the acceptability of self-sampling. Frequencies and percentages were calculated to present the distribution of HPV DNA detection results and participant perceptions.

RESULTS

Participant Characteristics

The study included 140 participants with varied socio-demographic backgrounds. In terms of age, the majority were between 30–59 years (82.1%, 115/140), while smaller proportions were under 30 years (11.4%, 16/140) and over 60 years (6.4%, 9/140). Regarding residence, more than half of the participants were from rural areas (57.9%, 81/140), whereas 42.1% (59/140) lived in urban settings. By caste distribution, the largest group belonged to the General category (57.1%, 80/140), followed by Scheduled Tribes (22.1%, 31/140), Scheduled Castes (17.1%, 24/140), and a small proportion from Other Backwards Classes (3.6%, 5/140). In terms of education, 39.3% (55/140) had completed primary schooling, 21.4% (30/140) secondary, 20.0% (28/140) higher secondary, and 19.3% (27/140) were graduates or above. With respect to occupation, the majority were homemakers (80.7%, 113/140), while 17.9% (25/140) were employed, and 1.4% (2/140) were students (Figure 1).

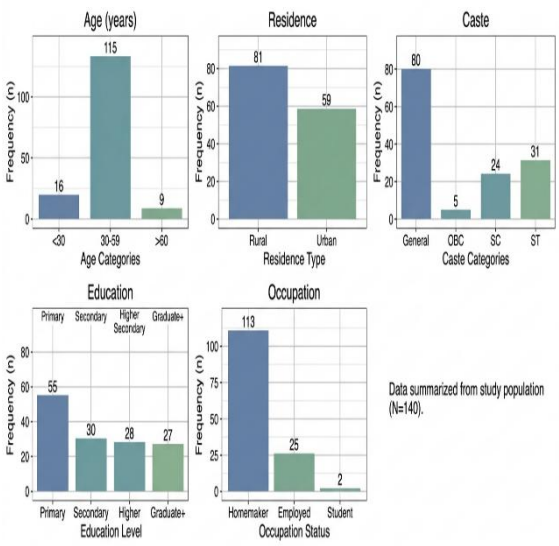

Figure 1: Demographic characteristics of the study population (N=140)

Distribution of HPV DNA Detection by Self-Collected Samples

Among the 140 self-collected cervicovaginal samples analysed, 19 (13.6%) tested positive for HPV DNA, while 121 (86.4%) tested negative. This distribution highlights that self-sampling can successfully identify women carrying high-risk HPV, though the overall positivity rate in this cohort was relatively low (Figure 2).

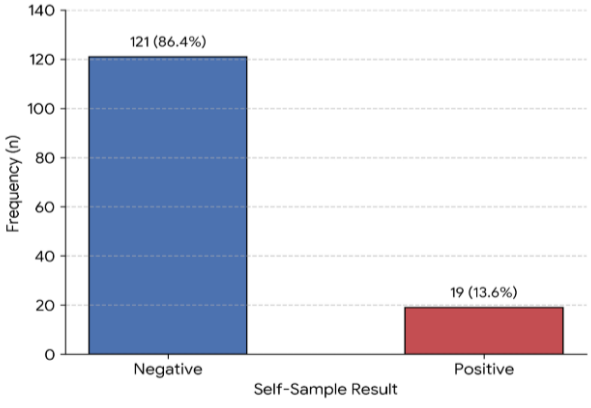

Figure 2: Distribution of HPV DNA Detection by Self-Collected Samples (N=140)

Acceptability of Sampling Methods

In the present study, the acceptability of self-sampling was limited: only 33.3% of participants reported feeling comfortable with this method, while the majority (66.7%) expressed discomfort (Figure 3). This indicates that although self-sampling has the potential to overcome barriers such as embarrassment and logistical challenges, its acceptance among women in this population remains relatively low.

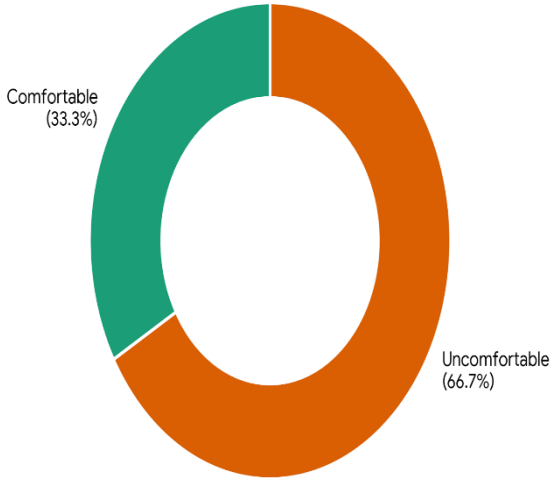

Figure 3: Acceptability of self-sampling methods

Barriers and Facilitators to Cervical Cancer Screening

Based on the data presented, the findings reveal that awareness and perception toward cervical cancer screening remain limited among the participants. Only 39.3% of women had any idea about screening for cervical cancer, indicating a substantial gap in knowledge. Psychological barriers were predominant—94.6% felt embarrassed to attend screening programs, 98.7% were scared of the procedure, and 83.3% feared being diagnosed with cancer after screening. These emotional factors strongly discourage participation. Financial concerns were less significant, as only 37.3% perceived screening as costly. Social support also appeared inadequate, with just 32% receiving encouragement from husbands or family members. Comfort with self-sampling was low (33.3%), suggesting hesitation toward alternative screening methods. Furthermore, only 13.3% knew that cervical cancer is preventable, and a mere 9.3% considered screening important even in the absence of symptoms (Figure 4).

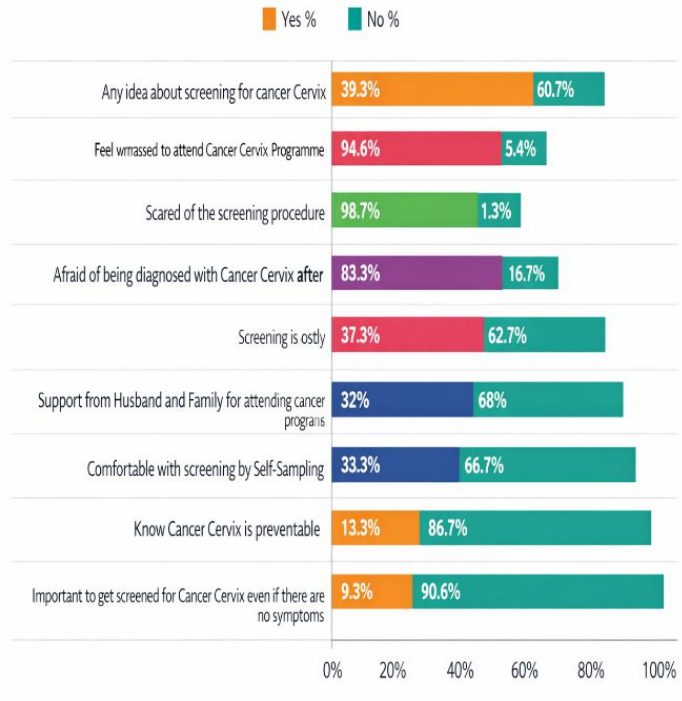

Figure 4: Barriers to cervical cancer screening

Facilitators included privacy, ease of use, and availability of instructions in local languages.

DISCUSSION

HPV self-sampling has gained global recognition as a promising strategy to overcome barriers in cervical cancer screening, particularly in low- and middle-income countries (LMICs) such as India, where coverage remains below 2%.[12] Unlike clinician-collected samples, self-sampling empowers women to collect cervicovaginal specimens privately, reducing embarrassment, logistical challenges, and dependence on healthcare providers. Evidence from Indian studies shows that once women receive structured health education, acceptance of self-sampling exceeds 90–98%, highlighting

its feasibility and cultural acceptability across diverse settings.[13,7]

Reliability and Accuracy

Meta-analyses confirm that PCR-based HPV assays on self-collected samples achieve sensitivity comparable to clinician-collected specimens and surpass cytology in detecting cervical intraepithelial neoplasia grade 2 or worse.[14] A recent systematic review further demonstrated that self-sampling maintains high specificity when validated devices and standardised protocols are used, making it a safe alternative for large-scale screening.[15] These findings validate self-sampling as a reliable screening modality, supporting its inclusion in national programs.

Barriers to Uptake

Despite its promise, barriers persist. Indian women often express fear of incorrect technique, lack of confidence in handling kits, and anxiety about positive results. Cultural stigma surrounding reproductive health and limited awareness of cervical cancer prevention exacerbate reluctance, particularly in rural and tribal communities.[16] LMIC reviews emphasise that systemic challenges—such as inadequate laboratory infrastructure, weak referral pathways, and limited treatment facilities—remain critical obstacles to scaling self-sampling.[17] Addressing these barriers requires culturally sensitive education and involvement of female community health workers.

Facilitators and Equity

Facilitators include privacy, convenience, and instructions in local languages. Community health worker involvement significantly improves participation and referral compliance, especially in rural and tribal settings.[12] Innovative delivery methods, such as community-based distribution and digital health technologies, have shown promise in increasing uptake while reducing costs by up to 48%.[18] Self-sampling also addresses equity gaps by reaching underserved populations who are less likely to access clinician-based screening.

Policy and Global Context

The WHO now recommends HPV self-sampling as an additional option within national screening programs, aiming to achieve 70% coverage by 2030.[19] The American Cancer Society has similarly updated its guidelines to include self-collection for primary HPV testing, reinforcing its global acceptance.[20] In India, integration of self-sampling into the National Programme for Prevention of Non-Communicable Diseases could substantially expand coverage, reduce disparities, and align with WHO's elimination targets.

Future Directions

Future research should focus on optimising self-sampling devices, ensuring linkage to follow-up care, and validating biomarkers to enhance accuracy. Implementation strategies must be tailored to local contexts, leveraging community engagement and digital platforms to overcome cultural and infrastructural barriers. Longitudinal studies are needed to assess the cost-effectiveness and sustainability of repeated self-sampling rounds.

Study Limitations

This study has several limitations. The geographic scope was restricted to selected regions, limiting generalisability. Acceptability was assessed using self-reported measures, which may be subject to social desirability bias. The cross-sectional design did not capture long-term adherence to repeated self-sampling. Infrastructure gaps in laboratory capacity and referral pathways were not fully addressed, affecting scalability. Reliance on a single device and assay may limit applicability across technologies. Finally, cultural stigma and limited awareness remain barriers, particularly in underserved populations, and integration into national programs was not evaluated.

CONCLUSION

HPV self-sampling represents a feasible, acceptable, and scalable strategy to overcome barriers in cervical cancer screening. By addressing psychological concerns, strengthening laboratory networks, and integrating community-based interventions, self-sampling can significantly improve screening uptake in India and globally. Policymakers should prioritise its inclusion in national programs to accelerate progress toward cervical cancer elimination.

Declaration by Authors

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- **Conflict of Interest:** The authors confirm that there are no conflicts of interest associated with this publication.
- **Data Availability Statement:** The datasets supporting the conclusions of this study are accessible from the corresponding author upon reasonable request.

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