RESEARCH ARTICLE

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Evaluating The Feasibility and Acceptability of Cervical Cancer Screening in an Urban Slum Community by HPV Self-Sampling With the Aid of Telecounselling: Lessons Learnt

Nilanchali Singh[1]*, Shivangi Mangal[1], Pranay Tanwar[2], Seema Singhal[1], Akanksha Yadav[1], Sandeep Mathur[3]

Abstract

Introduction: HPV testing is the most sensitive method of secondary cervical cancer prevention and the preferred method recommended by the World Health Organization. To increase cervical cancer screening, self-sampling has been introduced, which has shown significant results in improving access and simplifying screening for large and remote populations in low- and middle-income countries. This study aims to evaluate the feasibility and acceptability of HPV self-sampling in an urban slum community using tele-counselling, which is a niche population for HPV positivity and HPV-related diseases. **Methods:** This study is a community-based, prospective, single-arm design. Women were counselled telephonically about the methods of self-sampling, and HPV self-sampling kits were couriered to them. The collected kits were returned via courier and tested at the study site. In the case of a positive test result, the individual was linked to treatment at the study center. Test positives were offered either a 'see and treat' approach or colposcopy triage. **Results:** In the community, 982 women were enrolled in the study, but only 600 (61%) women consented to screening by HPV self-sampling. Ninety-six (15.6%) out of 600 women tested positive for Hr-HPV. Age, educational status, locality, occupation, menopausal status, and smoking status were similar in both screen-negative and screen-positive groups. Among the 600 women, 570 (95%) found it easy to take a self-sample, and 588 (98%) were satisfied with the overall experience. CIN I was found in 6 (6.4%), and CIN II was found in 4 (4.3%) cases. LEEP was performed in patients diagnosed with CIN II. **Conclusions:** HPV self-sampling is an acceptable method of cervical cancer screening, with an acceptance rate of 61% among urban slum women. It demonstrates that HPV self-sampling is feasible when supported by tele-counselling.

Keywords: HPV self-sampling- screening- community- Tele-counselling- Tele-oncology

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Introduction

Cervical cancer is the fourth most common female cancer worldwide and second most common cancer in India [1]. Despite the efforts made by the World health organization, cervical cancer show increase in incidence and mortality in Low and Middle income countries (LMICs) [2].

HPV infection is more prevalent in areas characterized by sexual promiscuity, low socioeconomic status, and crowded living conditions [3]. Urban slums are especially vulnerable due to poor hygiene, early marriage, promiscuous behaviour, multi-parity, and lack of awareness about cervical cancer. Low education levels are positively associated with HPV infection [4]. In one study from Karnataka, only 26% of women in slums had knowledge of cervical cancer, and just 3.8% were aware of HPV vaccination [5]. These communities should be prioritized for cervical cancer education and active screening to reduce infection rates.

World Health Organisation now endorses HPV self-sampling as an evidence-based screening method [6]. Studies report increased screening uptake with self-sampling [7], with higher participation rates compared to clinician-collected samples among under-screened women (30.8% vs 6.5%) [8]. Other studies observed participation rates of 80–94% with self-sampling [9]. One large study found self-sampling comparable to physician collection and cytology [10]. A rapid, affordable HPV self-test is feasible for primary screening in low-resource settings. Self-sampling is widely accepted due to its privacy, ease, comfort, and cost-effectiveness. Mailing HPV self-

*[1]Department of Obstetrics & Gynaecology, All India Institute of Medical Sciences, New Delhi, India. [2]Department of Laboratory Oncology, Dr BRAIRCH, All India Institute of Medical Sciences, New Delhi, India. [3]Department of Pathology, All India Institute of Medical Sciences, New Delhi, India. *For Correspondence: nilanchalisingh@gmail.com*

sampling kits has also improved participation in hard-to-reach groups [11].

In a study by the authors, training Accredited Social Health Activists led to 58.2% test uptake, with 99% of women finding it easy to use and 99.6% satisfied with ASHA counselling [12].

Despite its advantages, HPV self-sampling faces challenges in low- and middle-income countries due to limited infrastructure, budget constraints, and low test acceptability. Screening efforts encounter barriers at multiple levels beneficiary, healthcare provider, and system-based. Among beneficiaries, misconceptions, fear, low motivation, lack of confidence in sample collection, poor sample quality, privacy concerns, and refusal of screening or follow-up treatment are significant obstacles. This study aimed to assess the feasibility and acceptability of HPV self-sampling among women in urban slum communities.

Materials and Methods

The study is a community-based, prospective, single-arm study. This study was conducted in an urban slum population to evaluate the acceptability of the HPV-DNA self-sampling, which is an essential component of assessment of the feasibility of running a cervical cancer screening programme in remote areas. Accredited social health (ASHA) workers are an important part of the primary health care in India and work at the village and slum level. We decided to include ASHA workers in the study to recruit women in community as they could easily have access of the address, phone numbers and demographic details of the women in their respective localities. One ASHA worker is appointed for a population of 1000 people. ASHAs were engaged to facilitate outreach in slum communities, utilizing their trusted relationships with local women to effectively promote participation in cervical cancer screening. ASHAs are in contact with both central institute and the community. They were first trained to counsel women on HPV self-sampling, they were provided with video infographics, trained to take feedback from women and to assess their baseline knowledge on cervical cancer (Figure 1). They were an essential part that helped covering a large sample of women in the urban slums and helped in closing the gap between central hospital and slums. These workers contacted women. Thereafter, the research workers involved in the study trained and counselled women on telephone about HPV self-sampling kits and process. The research workers involved in the study counselled and sent them video infographics, had video calls and provided the training required to collect HPV samples by themselves. Women between the ages of 35-45 years were targeted as per recommendations by the WHO. The demographic, baselines details of the women were collected. HPV positive women underwent colposcopy triage (They were brought to hospital by ASHA workers) and the women who had a histopathology reports positive for cervical

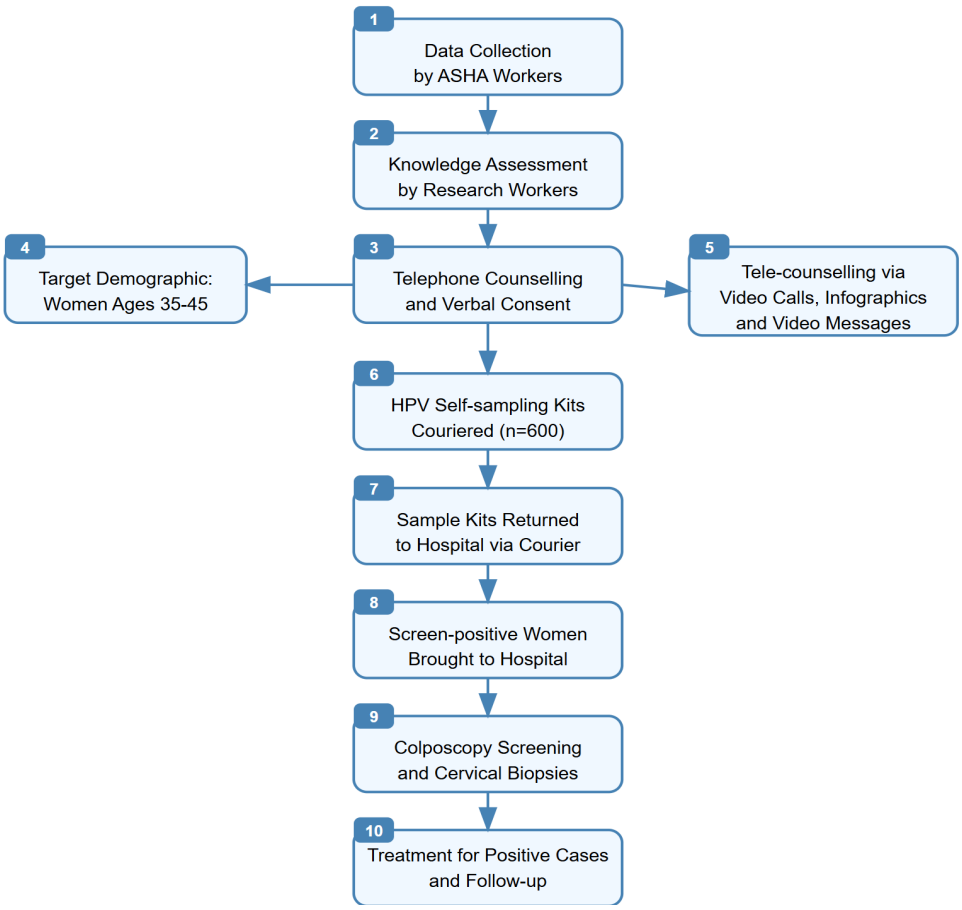

Figure 1. Flowchart of Steps Taken for HPV Self-Sampling

pre-invasive lesions were provided the required treatment at our hospital.

Sample size calculation

Presuming about 12.0% prevalence in self-collected sample and by allowing 6% confidence interval width (expected prevalence between 9 and 15%), the adequate sample size with 95% confidence level was 450 [10]. By anticipating about 10% dropout rate or sampling inadequacy, the total sample size required was 500. A total of 982 women were approached for screening with the help of ASHAs, out of which 600 women gave consent for the study and were willing to participate and follow up.

Tele-counselling

Women who were pregnant, had a diagnosis of cervical dysplasia, had undergone cervical surgery or hysterectomy, or had been screened for cervical cancer in the past three years were excluded from the study. Eligible women were contacted by telephone (Figure 2) by research workers and their details were procured with the help of local Acrredited social health acitivist (ASHA) workers. Their socio-economic and other demographic details were obtained telephonically. A small survey of their knowledge was conducted on telephone by creating and validating a brief questionnaire (Supplementary Table 1). E-pamphlets and video conferencing were used for counselling. The researchers explained them about cervical cancer screening and the need for screening among women of reproductive age group. The video infographics about the same were sent to them in both languages, English and Hindi using WhatsApp social media for the ease of understanding of the process of self-sampling. They were informed about the self-sampling procedure, including how to collect their own samples, pack them securely in the provided leak-proof containers, keep them at room temperature, and contact the research staff immediately after completing the sampling for getting the samples couriered to the study site. The average number of calls made to one woman was three before they would send their sample. They were also explained about the rationale behind using HPV DNA as the method of cervical cancer screening. Women could approach their ASHAs or the research workers by telephone for feedback or in case of facing difficulties at the time of collection or in understanding the procedure.

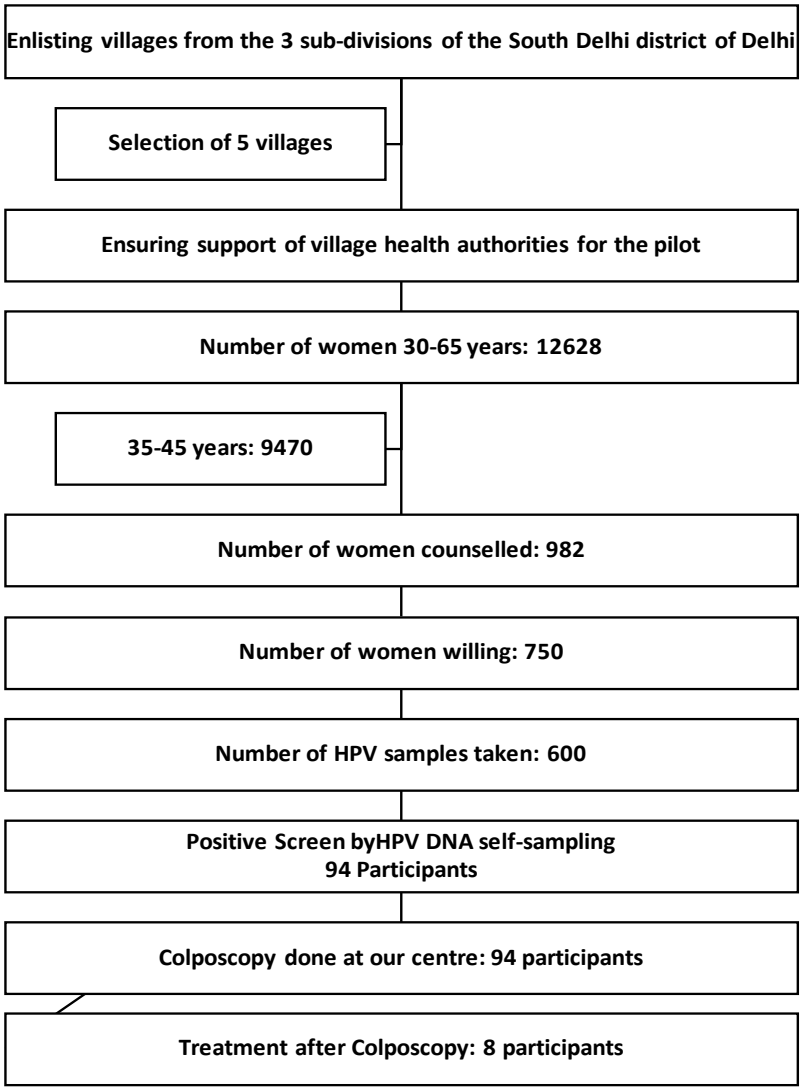

Figure 2. Consort Diagram

Sample collection and transport

Verbal consent was taken telephonically. After women understood the procedure and felt confident, they were couriered HPV self-sampling kits and sampled kits were received back via courier along with the written informed consent forms that had been sent with the kits. The Digene® HC2 DNA Collection Device kit was used for the self-collection purpose and is specifically designed for the collection and transport of cervical specimens for high-risk HPV DNA testing. It included a cervical brush along with a tube containing transport medium. It ensures reliable specimen integrity during transportation and is compatible with the Hybrid Capture 2 (HC2) assay system. Collection can be done alone in private or in any location. The clients in this study were promoted to perform it in a private setting at their own comfort and ease. They were asked to insert the brush vaginally and safely put the brush back into the kit. The courier services were hired by investigators which delivered and collected samples from nearby primary health center. Samples were kept at room temperature (20-25°C) during transport and storage. The samples were tested at the study site.

Sample testing

The researchers used the Hybrid capture-2 test. Among the molecular HPV tests available, the second-generation molecular Hybrid capture 2 test (HC2, Digene Corp, Gaithersburg, MD, USA) [13] is an extensively validated test across different settings and identifies women at risk of developing cervical cancer [14]. The test has probes for all 13 recognized oncogenic HPV types, reported worldwide [15]. The high-risk types identified by the HPV Hybrid Capture 2 test are: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. Types 16 and 18 are responsible for about 70% of all cases of cervical cancer.

Follow up of screen positive cases

In case of positive test result, the individual was linked for treatment and follow-up at study site. At follow-up, Colposcopy was done for the HR-HPV positive patients and a Swede score was calculated. In women with high swede scores suggesting a pre-invasive lesion, colposcopy directed biopsy was taken and sent for histopathology, for the diagnosis of pre-invasive or invasive lesions. Test positives were offered both 'see and treat' and colposcopy triage. Women living with HIV were only offered Screen-triage-treat. If the lesion was amenable for Loop electrosurgical excisional procedure (LEEP), it was performed in patients diagnosed to have cervical intraepithelial neoplasia.

Results

Six hundred women (61%) were screened in the community by HPV self-sampling out of the 982 women who were offered screening. The average age of patients recruited in the study was 37.66±0.84 years. Out of 600 women, 127 (21%) women were illiterate and 445 (74%) women were homemakers and without any personal income source. The average population (64%) belonged to the lower socioeconomic class according to the Modified Kuppuswami Scale. A brief survey of knowledge was conducted among 465 women (total 600 women who underwent HPV DNA screening). Out of 460 women, 440 (95.6%) women were aware of cervical cancer as a disease, before this study and 284 (62%) women were aware of all the symptoms of cervical cancer. About 284 (62%) women were aware of the various possible risk factors for cervical cancer and 110 (24%) women were aware that prolonged HPV infection can cause cervical cancer. Nine (2%) women knew that low immunity can lead to early development of cervical cancer.

Out of the participants, 570 women (95%) found HPV self-sampling easy to perform, while the remaining reported mild discomfort during the process. A total of 588 women (98%) expressed satisfaction with the overall experience and considered self-sampling to be a feasible screening method. Additionally, 338 women (73%) indicated that they would like their relatives to undergo HPV testing as well. Among the non-participants, 382 women (39%) cited "feeling uncomfortable" as the primary reason for declining to be screened. The stated reasons were that, they could not understand the procedure well while being counselled on the telephone or they did not find the insertion of the brush safe.

High-risk HPV was detected in 94 women (15.6%) who underwent screening. Table 1 shows the characteristic of women who screened positive and screened negative for Hr-HPV. The age, educational status, locality, occupation, menopausal status, smoking status were similar in both the groups. However, symptomatic women had an association with Hr-HPV positivity. Among the women who tested positive for high-risk HPV, 45 (48%) were symptomatic. Vaginal discharge and irregular vaginal bleeding are the symptoms which were present commonly in Hr-HPV infection (p=0.032). Among the HPV negative women, 94 (18.6%) had vaginal discharge, ten (1.9%) women had heavy menstrual bleeding, 8 (1.5%) women had irregular vaginal bleeding. These women had not reported to any healthcare facility for these symptoms.

Colposcopy was done in all screen positive. Out of all, 91 (96.8%) women had satisfactory colposcopy. None of the women gave consent for 'see and treat' and thus 'screen-triage-treat' was done. Out of total of 94 Hr-HPV positive patients, 10 patients after traige with colposcopy directed biopsy were diagnosed with pre-invasive lesion. Among the pre-invasive lesions, CIN I was found in 6 (6.4%) and CIN II was found in 4 (4.3%) cases of HPV positive. LEEP was performed in all four patients who had CIN II and the patients are under follow-up. Table 2 shows management and follow-up of screen positive women.

Various reasons for not accepting the cervical cancer screening were found among women who refused screening. The common ones were existing misconceptions in the society in 20% of women, 32% women had lack of awareness about the disease, non-prioritization of personal health in 14% of women and 44% women did not realize the need for screening when they were asymptomatic.

Table 1. Characteristics of Clients who Screen Negative and Screen Positive with HPV Self-Sampling

Characteristic	Screen Negative, N = 506	Screen Positive, N = 94
Age in years, Median (IQR)	37 (31 – 42)	37 (32 – 43)
Husband's Age, Median (IQR)	41 (36 – 47)	42 (36 – 49)
Education, n (%)		
Illiterate	93 (18.38)	34 (36.2)
VIIIth/ Xth Standard	189 (37.4)	32 (34)
XIIth Standard	117 (23.1)	12 (12.8)
Graduate	76 (15)	12 (12.8)
Postgraduate	31 (6.1)	4 (4.3)
Village, n (%)		
Begumpur	104 (20.6)	21 (22.3)
Chhatar Pur	163 (32.2)	34 (36.2)
Chirag Delhi	89 (17.6)	18 (19.15)
Gautam Nagar	84 (16.6)	9 (9.6)
Hauz Khaz	66 (13)	12 (12.8)
Occupation, n (%)		
Homemaker	415 (82)	30 (31.9)
Unorganized Sector	47 (9.3)	23 (24.5)
Organized Sector	21 (4.2)	19 (20.2)
Self-Employed/ Business	17 (3.4)	14 (14.9)
Other	6 (1.2)	8 (8.5)
Menopausal Status, n (%)		
Pre-menopausal	410 (81)	58 (61.7)
Post-menopausal	96 (19)	36 (38.3)
Current Symptoms (if any), n (%)		
Asymptomatic	394 (77.9)	46 (48.9)
Vaginal Discharge	94 (18.6)	29 (30.8)
Heavy menstrual bleeding	10 (1.9)	4 (4.3)
Irregular vaginal bleeding	8 (1.5)	15 (15.9)
Smoker, n (%)	20 (3.9)	8 (8.5)
History of prior screening, n (%)	51 (10.1)	16 (17)
Difficulty of self-sampling, n (%)		
Easy to self-sample	484 (95.7)	87 (92.6)
Difficult to self-sample	22 (4.3)	8 (8.5)
Overall Experience with Self-Sampling(%)		
Good	496 (98.0)	92 (97.9)
Bad	10 (1.9)	2 (2.12)

Table 2. Follow-up of Screen Positive Women

Follow up of screen positive women	
Characteristic	N = 94
Age in years, Median (IQR)	38 (34 – 44)
HPV Screen positive	94/600 (15.6)
Symptomatic, n (%)	48 (51.1)
Family History of Malignancy, n (%)	3 (3.2)
Colposcopy, n (%)	
Satisfactory	91 (96.8)
Not satisfactory	3 (3.2)
Histopathology Examination Report, n (%)	
CIN 2	4 (4.3)
CIN 1	6 (6.4)
Squamous Metaplasia	10 (10.6)
Chronic Cervicitis	6 (6.4)
Treatment offered 'See and treat', n (%)	4 (4.3)
Willing for 'See and treat', n (%)	0 (0)
LEEP performed	4 (4.3)

Discussion

Prevalence of HPV infection and cervical cancer is high in women belonging to lower socioeconomic strata and living in crowded areas of slums [16]. Therefore, screening for cervical cancer in these areas is important, but due to scarcity of resources, unawareness of the disease and fear of losing man-wage hours, these women are often reluctant to visit healthcare centers. Poor screening rates due to lack of awareness about the disease in slums has been reported in various studies from India in states of Karnataka and Mumbai [17, 18]. It has been studied using various HPV testing kits already that there is a fair agreement of HPV positivity rates between self-collected and clinical-collected samples [19]. The current study is the first study which was conducted in the urban slums of Delhi, India to evaluate the feasibility of training slum women for HPV self-sampling using tele-counselling and to assess the acceptability of the test. The goal was to screen these at risk women and treat them for cervical cancer pre-invasive or invasive lesions.

Self-sampling for HPV is a convenient, cost-effective way to increase screening rates, particularly among women who are hard to reach [11]. Studies have shown that the accuracy of HPV self-sampling is comparable to clinical samples [7, 8]. According to a meta-analysis, high-risk HPV polymerase chain reaction-based tests are similarly accurate when performed on self-collected samples versus clinician-collected ones [16]. The findings suggest that offering self-sampling kits is generally more effective in reaching under-screened women than simply sending invitations [16]. Research by Gravitt et al. [17] demonstrated that HPV DNA screening through self-sampling by women in their own homes in village settings showed sufficient accuracy for primary screening in developing regions, with sensitivity and specificity for detecting CIN2+ comparable to, or better than, Pap smears and VIA. Another study by Ma'som et al. [18], involving 839 multiethnic participants from urban Malaysia, also found self-sampling to be an acceptable alternative to Pap smears.

In India, telemedicine, or remote healthcare delivery, is a relatively new approach for clinicians. With more people using mobile phones and the internet, it's now possible to share health information in innovative ways. A study done in city of Mysore in southern India demonstrated that by using mobile health applications, we can counsel women and also assess for their knowledge and awareness about cervical cancer and its screening. The study also observed a 5% increase in the uptake of PAP smears after counselling [20]. A Meta-analysis done in low and

middle income countries also reported that there is an increase in the cervical cancer screening uptake when mobile technologies, particularly telephone reminders or messages are used [21]. Applications are used to provide infographics to clients, send mails and reminders for testing and follow ups. They are an essential tool for training of women for HPV self-sampling to decrease the need for hospital visits and need for onsite visit by healthcare workers. This study used tele-counselling and video messages for training women for HR-HPV self-sampling and the approach demonstrates how mobile technology can be integrated into health education and diagnostics, especially in areas with limited access to traditional medical resources. So women require encouragement that can be achieved by comprehensive usage of tele-counselling services to break barriers such as lack of awareness and communication with the health professional [22].

In this study, the acceptance rate of cervical cancer was 61%. This is low in comparison to previous studies that have reported acceptance rates of up to 80% in Latin America [23]. Self-sampling in women by sending invitations have high acceptability [24]. 39% women refused HPV self-sampling. The reasons which came out were that women felt incompetent in conducting tests themselves, few were unable to understand the test on teleconsultation.

Among those who underwent screening, 95% women found self-sampling easy and 98% had an overall good experience of counselling, video counselling sessions, taking self-samples and sending them back. It saved their time, provided them the privacy and kept the tests confidential. 73% women wanted to test their relatives as well showing that women understood the importance of screening. A study by Luisa Narvaez et al, concluded using non-standardized questionnaires that women considered self-sampling more comfortable, easier, and less painful than conventional cytology. The procedure was associated with less embarrassment and a greater sense of privacy [23].

The study was feasible to conduct as it was able to enroll women who did not initially know about cervical cancer or its screening. The implementation of study i.e. via phone calls and video conferencing was easy and can be replicated in other population groups as well. This method can be integrated into the national screening programme if they come into play and can be expanded to thousands of women. The overall cost of testing is also reduced by decreasing the patient visit and hence decreasing the hospital burden. Counselling and explaining the role of HPV DNA helped in successfully screening women in slum areas. Among the screened patients, many women were hesitant in reporting physical symptoms like vaginal discharge and menstrual irregularities. They did not report to any healthcare facility for these symptoms. Hence, reinforcing cancer symptoms to women is necessary while conducting a screening programme.

The study shows that women belonging to low and middle income countries and lower socioeconomic backgrounds such as slums, accept a test reasonably if counselled well and are willing to participate if adequately trained. Indian women shy away from personal health, sexual health and other intimate issues. Talking about these matters is considered a taboo in some underprivileged sections of society. Urban slums are niche of health and hygiene issues and this area was targeted in our study. Hence, community awareness and spread of knowledge is very important. These were some lessons learnt while conducting the community screening.

Strengths and Limitations of the study

This is one of the first study to be conducted in the urban slum population in India, which is a hard to reach population due to constraints of wage hours, infrastructure of screening services and other monetary resources. Urban slum population is high risk group due to crowding, lack of hygienic infrastructure and lack of awareness. This study targeted these areas and was able to treat the screen positive women who might have been missed without an active screening intervention. Telephonic outreach services, using video infographics, tele-counselling and usage of WhatsApp, helped in reducing the manpower and monetary resources required to conduct the study and helped in overcoming the barriers of counselling women belonging to low educational background.

However, this study could not evaluate the variables having a role in refusal of screening by the women, in terms of their demographic factors, educational, occupational factors and socio-economic status. This is because data of these women refusing screening could not be collected. The researchers could not survey all the screened women for their knowledge due to difficulty in surveying the disinterested women telephonically. There is no comparison with any other population groups or any other method of cervical cancer screening in terms of privacy, cost, comfort of testing and patient's follow up. We could not screen these women with other methods like cytology or Liquid based cytology as it would have required a clinician or paramedical staff to collect these samples and the purpose of the study was to assess for feasibility of self-sampling by women of urban slums.

Conclusion: HPV self-sampling is feasible and acceptable method of cervical cancer screening among women in urban slum community. WHO recommends HPV testing as the preferred method of cervical cancer screening. HPV self-sampling by using tele-counselling services, can show promising improvement in cervical cancer screening coverage in Indian scenario, wherein, it overcomes some of the taboos prevalent in society.

Author Contribution Statement

Dr. Nilanchali Singh: Conceiving and Designing the Study, Conducting the Research, Drafting the Manuscript, Coordinating with Co-authors, Handling Revisions, Submitting the Manuscript, Accountability. Shivangi Mangal: Drafting the Manuscript, Handling Revisions, Submitting the Manuscript. Pranay Tanwar: Conceiving and Designing the Study, Conducting the Research. Seema Singhal: Conceiving and Designing the Study, Conducting the Research, Drafting the manuscript. Akanksha Yadav: Drafting the Manuscript, Handling Revisions, Submitting

the Manuscript Sandeep Mathur: Conceiving and Designing the Study, Conducting the Research

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Ethical clearance

Taken by the Institute Ethics Committee.

Conflicts of Interest

There are no conflicts of interest.

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