# Feasibility, Acceptability, and Efficacy of a Community Health Worker–Driven Approach to Screen Hard-to-Reach Periurban Women Using Self-Sampled HPV Detection Test in India

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**PURPOSE** Detection of high-risk human papillomavirus (HPV) in self-collected vaginal samples can significantly improve participation of hard-to-reach women; however, the implementation of such an approach in a real-life setting, especially in countries with limited resources, has certain challenges. Our study aimed to evaluate the feasibility, acceptability, and efficacy of implementing an HPV self-sampling–based approach to screen a so-cioeconomically disadvantaged, unscreened population with support from community health workers (CHWs) for community mobilization, counseling, and navigation. Different triaging options for HPV-positive women were also assessed.

**METHODS** Women age 30 to 65 years from low socioeconomic periurban areas who had never been screened before were motivated by CHWs to attend local community centers and provide self-collected vaginal samples for *care*HPV testing. Screen-positive women were informed and navigated by CHWs to attend colposcopy clinics where cervical biopsy and same-day ablative treatment were offered.

**RESULTS** Women readily accepted to provide self-collected samples after counseling by CHWs. Screen positivity was 6.4%, and CHWs successfully navigated 65% of HPV-positive women to colposcopy. Cervical intraepithelial neoplasia (CIN) 2+ detection rate was 9.7 per 1,000 women screened. The HPV test had a positive predictive value of 15.3% to detect CIN 2+ lesions. Triage using visual inspection with acetic acid significantly improved the positive predictive value (49.5% to detect CIN 2+), but missed a significant number of CIN 2+ lesions. Colposcopy sensitivity was also suboptimal. Of 51 women with lesions, 80% underwent ablative treatment and the majority accepted same-day treatment.

**CONCLUSION** CHW-driven self-sampling for HPV testing is feasible, well-accepted, and effective for screening unscreened hard-to-reach women. The screen-and-treat approach can ensure strong linkage between screening and treatment.

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#### INTRODUCTION

Cervical cancer is the second most common cancer in Indian women, resulting in more than 60,000 deaths in 2018.<sup>1</sup> To align with the recent call to action by WHO to eliminate cervical cancer, India should introduce screening of women with a highly sensitive test.<sup>2</sup> Detection of high-risk human papillomavirus (HPV) is the most sensitive screening test, with several advantages over other tests.<sup>3</sup> This is true even in the context of low- and middle-income countries.<sup>4</sup> Screening with such a highly sensitive test as HPV detection once or twice in a lifetime will have significantly more impact compared with repeated screening with moderately sensitive tests, such as cytology or visual inspection with acetic acid (VIA).<sup>5</sup> A randomized trial conducted in India has shown that a single round of HPV screening followed by appropriate

management is associated with a nearly 50% reduction in cervical cancer incidence and mortality.<sup>6</sup> A significant advantage of the HPV test, especially in limited-resourced settings, is that it empowers women to self-collect samples without experiencing the embarrassment of pelvic examination, thereby increasing the acceptability and accessibility of screening.<sup>7</sup> Selfsampled HPV testing significantly improves participation and is almost as accurate as clinician-sampled HPV tests.<sup>8</sup> HPV-based screening, like any other public health intervention, must be contextualized to the local setting. Our present study, conducted by the MNJ Institute of Oncology, aimed to evaluate the feasibility, acceptability, and efficacy of implementing an HPV self-sampling-based approach to screen a socioeconomically disadvantaged, unscreened population. We focused on the entire screening care

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#### CONTEXT

#### **Key Objectives**

How feasible and effective is human papillomavirus (HPV) self-sampling–based screening of socially disadvantaged women, especially if the motivation, counseling, and navigation is performed by community health workers (CHWs)?

#### Knowledge Generated

CHWs could motivate 4,643 socioeconomically disadvantaged unscreened women in India to participate in selfsampling–based HPV screening. CHWs successfully navigated 65% of 297 screen-positive women to colposcopy and treatment. Cervical intraepithelial neoplasia 2/3 were detected in 38 women, and 32 women (84.2%) were treated. Among the women who were offered ablative treatment, 91.2% accepted immediate ablation. Triaging of HPV-positive women with visual inspection with acetic acid was not effective. Compliance dropped with the number of visits.

#### Relevance

HPV self-sampling is feasible and well accepted by women. Given the low HPV positivity in the population and the challenges of ensuring compliance of screen-positive women, a simple screen-and-treat algorithm will be appropriate for India. CHWs can be gainfully used for community mobilization and patient navigation.

continuum, from community mobilization to appropriate management of women with positive screening tests. Our study also evaluated different triaging options for HPVpositive women.

#### **METHODS**

#### Study Setting

Our cross-sectional study was conducted in slum areas around the city of Hyderabad in central India (Fig 1). Residents of these slums are socioeconomically deprived and do not have access to the cervical cancer screening programs being implemented in some parts of the country. The majority of slum dwellers are migrants from the villages, and they live in temporary shelters and do not have their names listed in any of the population registers. This makes identifying and inviting age-eligible target women to screening challenging.

#### Selection and Recruitment of Women

Recruitment of approximately 5,000 eligible women between the ages of 30 and 65 years—target age recommended by the Indian national guidelines—was planned from thirteen area clusters. Meetings were held with local peer groups, such as women's self-help groups and political leaders, to ensure their support for the program.

Local female community health workers (CHWs) played a critical role in identifying eligible women through home visits and informing and motivating them to attend the group counseling sessions as well as in organizing such sessions in the locality. CHWs were selected from local Accredited Social Health Activist (ASHA) workers, primary school teachers, and local women's self-help group leaders. ASHAs are the designated CHWs working for the reproductive health programs of the Ministry of Health. CHWs, after being trained by the investigators, conducted group meetings

in the localities to educate the target women. Each CHW was paid a small honorarium of \$15 USD for mobilizing 100 women.

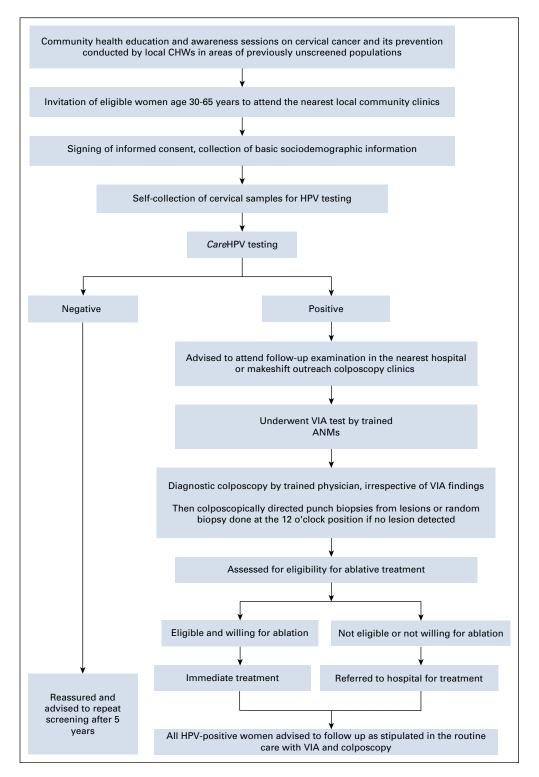
Eligible women were invited to local community centers also known as Anganwadi centers, which provide mother and child services—after group counseling for selfcollection of cervical samples. The average distance between a woman's residence and a community center was approximately 1 km. Married, nonpregnant women in the eligible age range with intact uterus, not screened earlier, and who were willing to give informed written consent were included in this study. Women with a diagnosis of cervical precancer or cancer were excluded.

#### Sample Collection and Transportation to the Laboratory

At the community center, a CHW explained to the women the process of self-collection of samples using a Digene soft conical brush (Qiagen, Gaithersburg, MD). The project employed and trained two auxiliary nurse midwives, who were also involved in counseling the women. Every woman collected the sample in the privacy of a room and immediately placed the brush in a labeled tube that contained the Digene transport medium. Samples were transported to the laboratory at MNJ Institute of Oncology after collection was over for the day. All community clinics were located within a 20-km distance from the hospital housing the laboratory.

#### **HPV Detection Assay**

Samples were analyzed using the WHO prequalified *care*HPV test (Qiagen). The *care*HPV test can analyze 90 samples at a time, and the running time for each batch is approximately 3 hours. The sample is positive if the relative light unit/cutoff value is 1.0 or greater, indicating the presence of any of the 14 most common high-risk HPV types in the sample. The laboratory delivered the results to CHWs, who communicated the same to women under their care. Women with positive results were advised to undergo



**FIG 1.** Flowchart of the cervical cancer screening program. ANM, auxiliary nurse midwife; CHW, community health worker; HPV, human papillomavirus; VIA, visual inspection with acetic acid.

additional examination. Test results were delivered to the women within 7 to 30 days of sample collection. Sample analysis was delayed at times as we had to wait until 90 samples were accumulated to be tested in a single batch.

#### Management of Screen-Positive Women

CHWs contacted the HPV-positive women, counseled them, and advised them to attend the colposcopy clinics for additional evaluation. Outreach colposcopy clinics were set up close to the community with a portable colposcope. Women who resided close to the MNJ Institute of Oncology were advised to attend the colposcopy clinic at the hospital. The women underwent VIA by either of the two trained auxiliary nurse midwives, which was followed by colposcopy by a trained clinician (irrespective of VIA outcomes).<sup>9</sup> The colposcopist was blinded to the VIA results. A colposcopy-guided cervical punch biopsy was obtained if any lesion was present. A random cervical biopsy was obtained from the 12 o'clock position in the absence of any visible lesion. Biopsy specimens were processed and interpreted at MNJ Institute of Oncology.

All women with cervical intraepithelial neoplasia (CIN) 1 or worse (CIN 1+) on colposcopy were advised to undergo treatment. Women with type I transformation zone of cervix, a lesion occupying fewer than three quadrants of ectocervix, and without any suspicion of malignancy were offered cryotherapy or thermal ablation immediately. Those women with lesions that were ineligible for ablation were referred to the MNJ Institute of Oncology for additional assessment and treatment. Women without any lesions visible on colposcopy but who had a diagnosis of CIN 2+ in the histopathology report that was available on a later date were also advised to undergo treatment.

#### **Ethical Issues**

The study protocol was approved by the Ethics Committee of the MNJ Institute of Oncology. All participating women provided written informed consent.

#### TABLE 1. Participant Characteristics

Characteristic	No. (%)
Participants assessed	4,643
Age, years	
30-34	1,693 (36.5)
35-39	1,036 (22.3)
40-44	766 (16.5)
45-49	511 (11.0)
50-54	298 (6.4)
55-59	187 (4.0)
60-64	152 (3.3)
Marital status	
Married	4,283 (92.2)
Widowed	328 (7.1)
Separated	32 (0.7)
Date of last menstruation, months	
< 12	3,649 (78.6)
≥ 12	980 (21.1)
No. of pregnancies	
0-1	542 (11.7)
2-3	3,327 (71.7)
≥ 4	774 (16.7)

#### **Statistical Considerations**

All statistical analyses were carried out using STATA 15.1 (StataCorp, College Station, TX). The presentation of sociodemographic and reproductive characteristics, process, and intermediate outcomes measures was done using proportions. The gold standard used for verification of final disease status to estimate test performance was the histopathology report. Some women with normal cervix on colposcopy refused biopsy. In such cases, the colposcopy report was considered to be the gold standard.

Process measures assessed were the following: HPV test positivity; colposcopy referral attendance among HPVpositive women, and women with high-grade CIN receiving treatment. Intermediate outcomes assessed were CIN detection rates, defined as the proportion of CIN detected among women screened, and the positive predictive value (PPV) of the HPV test, estimated as the proportion of women confirmed with CIN among HPV-positive women. In addition, the performance of the colposcopy with regard to the histopathology diagnosis was assessed.

### RESULTS

A total of 4,690 women provided self-collected specimens between March 2017 and August 2018. Of these, 47 with inadequate samples—liquid spilled out during either sample collection or transport—were excluded from the analysis. Mean age of the remaining 4,643 participants was 39.5 years, the majority (58%) of whom were between 30 and 39 years of age (Table 1).

Of the 4,643 women, 297 (6.4%) were screen positive (Table 2). Screen positivity among women age 30 to 59 years ranged between 5.6% and 6.8%, and was 9.9% for those age 60 to 64 years.

Of the 297 HPV-positive women, 104 (35.0%) did not comply with follow-up examinations despite repeated reminders from CHWs. For those who complied, 167 (86.5%) had cervical biopsies taken and the rest refused biopsy (Table 3). Among women who refused biopsy, only one woman had suspected low-grade lesions and the rest did not have any abnormalities detected on colposcopy (Table 3). Histopathology was inconclusive in 8 women and none of them had any high-grade lesion suspected on colposcopy.

CIN 1, CIN 2, CIN 3, and invasive cancers were detected in 36, 15, 23, and 8 HPV-positive women undergoing biopsy, respectively. Detection rates were 7.8 per 1,000 women screened for CIN 1, 8.2 per 1,000 women for CIN 2/3, and 1.7 per 1,000 women for invasive cancer (Table 2). The PPV of the HPV test to detect CIN 2 or worse disease (CIN 2+) was 15.2% and ranged between 13.3% in 60- to 64-year-old women and 21.2% in 50- to 59-year-old women.

We used colposcopy diagnosis to make treatment decisions. Among 66 women with abnormal colposcopy after excluding 2 cases without any histopathology—34

#### **TABLE 2.** Cervical Cancer Screening Process

Age Group, Years					
Screening Process	30-39	40-49	50-59	60-64	Total
Screening					
Women screened, No.	2,729	1,277	485	152	4,643
Women HPV positive	177 (6.5)	72 (5.6)	33 (6.8)	15 (9.9)	297 (6.4)
Compliance to disease confirmatory investigations					
HPV-positive women who complied					
With additional examinations	113 (63.8)	50 (69.4)	21 (63.6)	9 (60.0)	193 (65.0)
Disease confirmation	109 (96.5)	50 (100.0)	21 (100.0)	8 (88.9)	188 (97.4)
Colposcopy diagnosis	108 (95.6)	50 (100.0)	20 (95.2)	8 (88.9)	186 (96.4)
Histopathology diagnosis	95 (84.1)	42 (84.0)	16 (76.2)	6 (66.7)	159 (82.4)
CIN detection among HPV-positive women					
CIN 1 detection, No.	23	9	3	1	36
Rate per 1,000 women screened	8.4	7.0	6.2	6.6	7.8
CIN 2/3 detection, No.	22	7	7	2	38
Rate per 1,000 women screened	8.1	5.5	14.4	13.2	8.2
Invasive cancer detection, No.	3	5	0	0	8
Rate per 1,000 women screened	1.1	3.9	0.0	0.0	1.7
Positive predicative values for CIN 2 or worse detection	14.1	16.7	21.2	13.3	15.5

NOTE. Data presented as No. (%) unless otherwise indicated.

Abbreviations: CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus.

had CIN 2+ disease. Thus, the PPV of the colposcopy to detect CIN 2+ disease was 51.5%. Colposcopy sensitivity to detect CIN 2+ (with CIN 1 as the threshold of abnormal colposcopy) was 73.9% (34 of 46 women). Colposcopy was normal in 18 cases of CIN 1 and in 12 cases of CIN 2/3 (Table 3).

Table 4 lists the performance of VIA as a triage test among the 192 HPV-positive women undergoing VIA. Only 30% of these HPV-positive women had abnormalities detected on VIA. The PPV to detect CIN 2 or worse increased to 50.0% when VIA triage was considered; however, VIA triaging missed 16 (42.1%) of 38 CIN 2/3 lesions and one (12.5%) of 8 cancers—that is 37.0% (17 of 46) of all CIN 2+ lesions.

Ablative treatment was used to treat 58 women, of whom 53 (91.2%) accepted immediate treatment on the same day. Among the 58 women who were treated with ablation, 19 did not have any CIN on subsequent histopathology, leading to an overtreatment rate of 32.8% (Table 5). Of the 38 women who were diagnosed with CIN 2/3 lesions, 32 (84.2%) were treated (25 with thermal ablation, 2 with large-loop excision of the transformation zone, and 5 underwent hysterectomy; Table 5). Of the 8 women with invasive cancer, five had received radiation treatment, two

**TABLE 3.** Colposcopy Findings by Histopathology Done Among Human Papillomavirus–Positive Women

	Women	Biopsy, No. (%)		Histopathology, No. (%)				
Colposcopy Finding	Assessed on Colposcopy, No.	Not Taken	Taken	Normal	CIN 1	CIN 2/3	Invasive Cancer	Inadequate
Normal	118	20 (16.9)	98 (83.1)	62 (63.3)	17 (17.3)	12 (12.2)	0 (0.0)	7 (7.1)
Probable CIN 1	44	1 (2.3)	43 (97.7)	14 (32.6)	12 (27.9)	15 (34.9)	1 (2.3)	1 (2.3)
Probable CIN 2/3	20	0 (0.0)	20 (100.0)	2 (10.0)	4 (20.0)	11 (55.0)	3 (15.0)	0 (0.0)
Probable invasive cancer	4	0 (0.0)	4 (100.0)	0 (0.0)	0.0 (0.0)	0.0 (0.0)	4 (100.0)	0 (0.0)
Unsatisfactory	7	5 (71.4)	2 (28.6)	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	193	26 (13.5)	167 (86.5)	79 (47.3)	34 (20.4)	38 (22.8)	8 (4.8)	8 (4.8)
Abnormal colposcopy	68	1 (1.5)	67 (98.5)	16 (23.9)	16 (23.9)	26 (38.8)	8 (11.9)	1 (1.5)

NOTE. Of human papillomavirus-positive women, 112 did not receive colposcopy. Abbreviation: CIN, cervical intraepithelial neoplasia.

TABLE 4. Performance VIA Triage for HPV-Positive Women in the Detection of Cervical Neoplasia

	Age Group, Years					
VIA Triage	30-39	40-49	50-59	60-64	Total	
VIA triage of HPV positive women						
Women HPV positive, No.	177	72	33	15	297	
Women HPV positive with						
VIA triage done	111 (62.7)	51 (70.8)	21 (63.6)	9 (60.0)	192 (64.6)	
VIA triage positive	38 (34.2)	15 (29.4)	5 (23.8)	0 (0.0)	58 (30.2)	
CIN detection among HPV-positive women with VIA triage done and triage positive						
CIN 1 detection						
Among those with VIA triage done, No.	23	9	3	1	36	
Among those VIA triage positive	12 (52.2)	4 (44.4)	1 (33.3)	0 (0.0)	17 (47.2)	
CIN 2/3 detection						
Among those with VIA triage done, No.	22	7	7	2	38	
Among those VIA triage positive	15 (68.2)	3 (42.9)	4 (57.1)	0 (0.0)	22 (57.9)	
Invasive cancer detection						
Among those with VIA triage done, No.	3	5	0	0	8	
Among those VIA triage positive	3 (100.0)	4.0 (80.0)	0	0	7 (87.5)	
Positive predicative values for CIN 2 or worse detection, %	47.4	46.7	80.0		50.0	

NOTE. Data presented as No. (%) unless otherwise indicated.

Abbreviations: CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus; VIA, visual inspection with acetic acid.

underwent radical hysterectomy, and one had missing treatment information.

#### DISCUSSION

Our study describes a model of implementation of HPV detection on the basis of screening and associated challenges, especially among a socioeconomically disadvantaged periurban population. We demonstrated that CHWs who were selected from the target community could be successfully trained to identify and motivate a large number of previously unscreened hard-to-reach women. CHWs in India (ASHAs) have been successfully used to mobilize the community around sanitation, nutrition, and health issues. With one ASHA for approximately 1,000 people, there are now nearly one million ASHAs in the country, making this the largest CHW program in the world.<sup>10</sup> Our study shows that the ASHAs and other similar cadres of CHWs can be

a valuable workforce for mobilizing eligible women from the community, counseling them, delivering the screening test reports and recalling screen-positive women for additional assessment. CHWs were found to be so productive as a result of their proximity to the community, knowledge of the local population, and acceptance by families as providers of different health interventions.

Self-collection of samples is a great advantage of HPV detection–based screening. Self-sampling has been offered by CHWs in a variety of settings, including in the home, community centers, and health centers without any requirement of pelvic examination, thereby making it possible to screen hard-to-reach women. A pilot study in a rural heartland of India demonstrated HPV self-collection at home by CHWs to be a feasible method with good acceptance, low refusals, and high compliance to additional

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TABLE 5. Treatment Received by Human Papillomavirus-Positive Women With CIN

			Treatment Received, No.				
Final Diagnosis	Women Assessed, No.	Women Who Received Treatment, No. (%)	Thermal Ablation	Cryotherapy	LLETZ	Hysterectomy	
Normal	106	20 (18.9)	11	8	0	1	
CIN 1	36	15 (41.7)	14	0	0	1	
CIN 2	15	12 (80.0)	11	0	0	1	
CIN 3	23	20 (87.0)	14	0	2	4	
CIN 2/3	38	32 (84.2)	25	0	2	5	

Abbreviations: CIN, cervical intraepithelial neoplasia; LLLETZ, large-loop excision of the transformation zone.

assessment for screen-positive women.<sup>11</sup> Our study also demonstrated that women who had never been screened before were comfortable with self-collection, provided that they were adequately counseled and a provision was made to collect samples in privacy close to their homes.

The HPV positivity in the current study (6.4%) was similar to that observed in our earlier study which also used self-collected samples.<sup>12</sup> It has been consistently observed in Indian studies that the HPV positivity with any of the validated tests among women age 30 years or older is lower (5% to 10%) compared with other low- and middle-income countries.<sup>6,11,13,14</sup> This may be perceived as an advantage of introducing the HPV test in India, as a limited number of women would require additional evaluation.

Our study clearly demonstrates that recalling screenpositive women for another visit adversely affected compliance. We managed to contact almost all HPV-positive women through the CHWs, but failed to get nearly one third of them to the clinics for additional evaluation. At least among the attendees, a single-visit colposcopy-and-treat strategy allowed us to achieve a high compliance to ablative treatment, with more than 90% accepting immediate treatment. The colposcopy-and-treat strategy led to overtreatment of nearly one third of women. Such overtreatment of HPV-positive women is acceptable as the ablative techniques are safe and may offer a protective effect for these women. HPV-positive women have a high risk of developing high-grade lesions in the future; even if they do not have a lesion at baseline.<sup>15</sup> Treating HPV-positive women irrespective of the presence of a visible lesion significantly reduces their risk of developing CIN 2+ disease in future.<sup>16</sup>

VIA is a more feasible approach compared with cytology with which to triage HPV-positive women. An earlier Indian study showed that the colposcopy referral rates were similar with cytology or VIA triage for HPV-positive women; however, cytology and VIA triage missed 16% and 18% of highgrade CIN lesions, respectively.<sup>17</sup> As VIA is a subjective test, it performs differently in different settings. The training and experience of the providers make a lot of difference in the sensitivity of the test. In our study, we observed that triaging with VIA missed a substantial number of CIN 2+ lesions. As demonstrated in our study as well as earlier studies, a significant proportion of HPV-positive CIN 2+ lesions may appear normal on colposcopy.<sup>18</sup> As a result of the unreliability of colposcopy as a triaging procedure and the difficulties in recalling the women after 1 year, direct

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treatment of all HPV-positive women—screen and treat—will be a better option for limited-resourced settings, like India. Mittal et al<sup>15</sup> have demonstrated that more than three quarters of HPV-positive women without any lesion at baseline do not return for repeat testing at 1 year when advised to do so.

The national cancer control program of India recommends the screening of women with VIA at primary health centers to be performed by trained nurses.<sup>19</sup> VIA showed promising results in research studies, but does not perform equally well when applied in a multiprovider, scaled-up, programmatic context.<sup>20,21</sup> Moreover, training large numbers of nurses to perform VIA, retaining them at the primary health centers, and ensuring the quality of their performance will be a herculean task in countries like India. HPVbased screening can be much more efficient in a large programmatic setting, not only because of its high sensitivity but also because of its objective and throughput nature. The high negative predictive value of the test allows for infrequent screening, thereby saving cost for the program. It is likely that more affordable and truly point-of-care HPV detection technologies will be available in the near future. As demonstrated in our study and in other earlier studies, self-sampling will be the best option to ensure high participation of women in HPV-based screening, especially in areas where trained health providers are few in number and are already overburdened with several competing health programs. Although the Indian national guidelines strongly recommend colposcopy for disease verification in the present VIA-based screening, a simpler screen-andtreat approach will be more suitable if India moves toward HPV-based screening.

As a small demonstration project, our study has the limitation of not being representative of a larger community or population. Additional implementation studies are needed to understand the facilitators and barriers of CHW-driven self-sampling–based HPV screening and its impact on workforce, budget, and other components of the health system.

In conclusion, when an affordable, simple, and point-ofcare HPV detection test is available, countries like India should consider replacing VIA-based screening with HPVbased screening. A pragmatic implementation model should incorporate CHW-driven community mobilization, self-collection of samples, a minimized number of visits, and strong linkage between screening and treatment, with a policy to ensure high coverage of disadvantaged women.

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Accountable for all aspects of the work: All authors

## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

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