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CLINICAL ARTICLE

Results of a community-based cervical cancer screening pilot project using human papillomavirus self-sampling in Kampala, Uganda

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ABSTRACT

Objective: To examine the feasibility of a community-based screening program using human papillomavirus (HPV) self-sampling in a low-income country with a high burden of cervical cancer. *Methods:* A pilot study was conducted among 205 women aged 30–69 years in the Kisenyi district of Kampala, Uganda, from September 5 to October 30, 2011. Women were invited to provide a self-collected specimen for high-risk oncogenic HPV testing by outreach workers at their homes and places of gathering in their community. Specimens were tested for HPV, *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. Women who tested positive for HPV were referred for colposcopy, biopsy, and treatment at a regional hospital. *Results:* Of the 199 women who provided a specimen, 35 (17.6%) tested positive for HPV. The outreach workers were able to provide results to 30 women (85.7%). In all, 26 (74.3%) of the women infected with HPV attended their colposcopy appointments and 4 (11.4%) women were diagnosed with grade 3 cervical intraepithelial neoplasia. *Conclusion:* Self-collection of samples for community-based HPV testing was an acceptable option; most women who tested positive attended for definitive treatment. Self-sampling could potentially allow for effective recruitment to screening programs in limited-resource settings.

1. Introduction

Cervical cancer is almost entirely avoidable through primary prevention with human papillomavirus (HPV) vaccination and secondary prevention through screening; nonetheless, this condition remains a leading cause of morbidity and mortality worldwide, particularly among women in Africa [1–3]. A diagnosis of cervical cancer can be devastating for affected women but it also has appreciable effects on families, children, and communities. Efforts to increase availability of the HPV vaccine represent an important step forward. However, despite the fact that this primary prevention tool is both widely available and cost effective, several million women who have already been infected with HPV will require screening for cervical cancer in the next few decades. In addition, even with an extensive vaccination program, women will still require screening given that the vaccine prevents only 70% of all cervical cancers [4].

Organized cervical cancer screening programs based on cytology have made a crucial contribution to decreasing the incidence and mortality from invasive cervical cancer in high-income countries [5,6]. However, the need for a complex infrastructure to support high-quality cytology screening, as well as the improved detection rate offered by molecular testing for oncogenic HPV genotypes, suggest that the opportunity exists to review cervical cancer screening on a global scale [7,8]. HPV testing has emerged as an effective tool for cervical cancer screening, both alone as a primary screen or in conjunction with cytology [9–11]. Indeed, HPV testing has been shown to identify important precancerous lesions earlier than cytology [9].

International health agencies have challenged researchers to examine inexpensive strategies for cervical cancer screening in low-resource settings where screening is limited but the burden of this preventable disease remains unacceptably high [4]. One strategy at the forefront of this endeavor is self-collection of samples for HPV testing followed by a see-and-treat intervention for women who test positive (i.e. immediate treatment with cryotherapy in the same setting as screening) [12] linked to existing healthcare services [13]. Studies have demonstrated acceptability of self-collection [14], accuracy of self-collection versus clinician collection [15,16], and improved uptake associated with self-collection [17–19]. However, few studies

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have attempted to offer an integrated approach with self-collection, HPV testing, and colposcopy provided as part of the standard community reproductive healthcare service in low- and middle-income countries (LMIC).

The Advances in Screening and Prevention in Reproductive Cancers (ASPIRE) project was developed to examine innovations in cancer prevention for women in LMIC [14]. To date, ASPIRE has focused on self-collection as a new screening paradigm, whereby women can be effectively screened for cervical cancer in a cost-effective manner. This approach would allow women to test themselves in a community-based setting and streamline further evaluation for women who require follow up testing or treatment, thereby allowing judicious use of healthcare resources. The ASPIRE team has previously conducted a community-based forum and survey to determine the acceptability of self-collection among women in Uganda. Notably, 80% of the women who responded to the survey were willing to provide a self-collected specimen for cervical cancer screening [14].

As a next step, ASPIRE developed a pilot project to evaluate community-based HPV self-sampling embedded in an outreach screening program for reproductive tract infections in a hard-to-reach Ugandan community. The aim of the present study was to determine the acceptability, uptake, and outcomes of the pilot program and to compare the actual uptake with the intended uptake previously reported [14].

2. Materials and methods

A pilot study of HPV self-sampling as part of a cervical cancer screening program was conducted. Women in the Kisenyi district of Kampala, Uganda, were consecutively invited to participate in the present study from September 5 to October 30, 2011. Ethical approval was obtained from the University of British Columbia, Vancouver, Canada, and Makerere University, Kampala, Uganda. Oral informed consent was provided by all participants.

Kisenyi is an impoverished area of Kampala with a population of approximately 40 000, which increases up to 3-fold during the day owing to workers arriving. Outreach workers approached women in the community, at their homes, and at places of community gathering, and invited them to participate in the intervention. Women aged 30–69 years, who lived or worked in Kisenyi, and were able to provide a mobile telephone contact number for the HPV test result were eligible to participate. Exclusion criteria were age outside the eligible range, previous hysterectomies, history of cervical cancer, and inability to provide informed consent owing to marked mental-health conditions or cognitive impairment from drug or alcohol use. Any woman not eligible to participate in the present study was advised to attend routine cervical cancer screening at the local health center.

After providing consent, women were asked to give their name, date of birth, and mobile telephone contact number. Regardless of their eventual decision about participation in the present study, all women received an educational intervention on the benefits of cervical cancer screening. They were also advised to attend Kisenyi Health Center for routine preventive healthcare, including cytology screening and HIV testing.

Participants completed a survey exploring demographics and attitudes associated with willingness to participate in cervical cancer screening [14]. The survey was based on a previously published survey—developed by the ASPIRE team—that had been translated

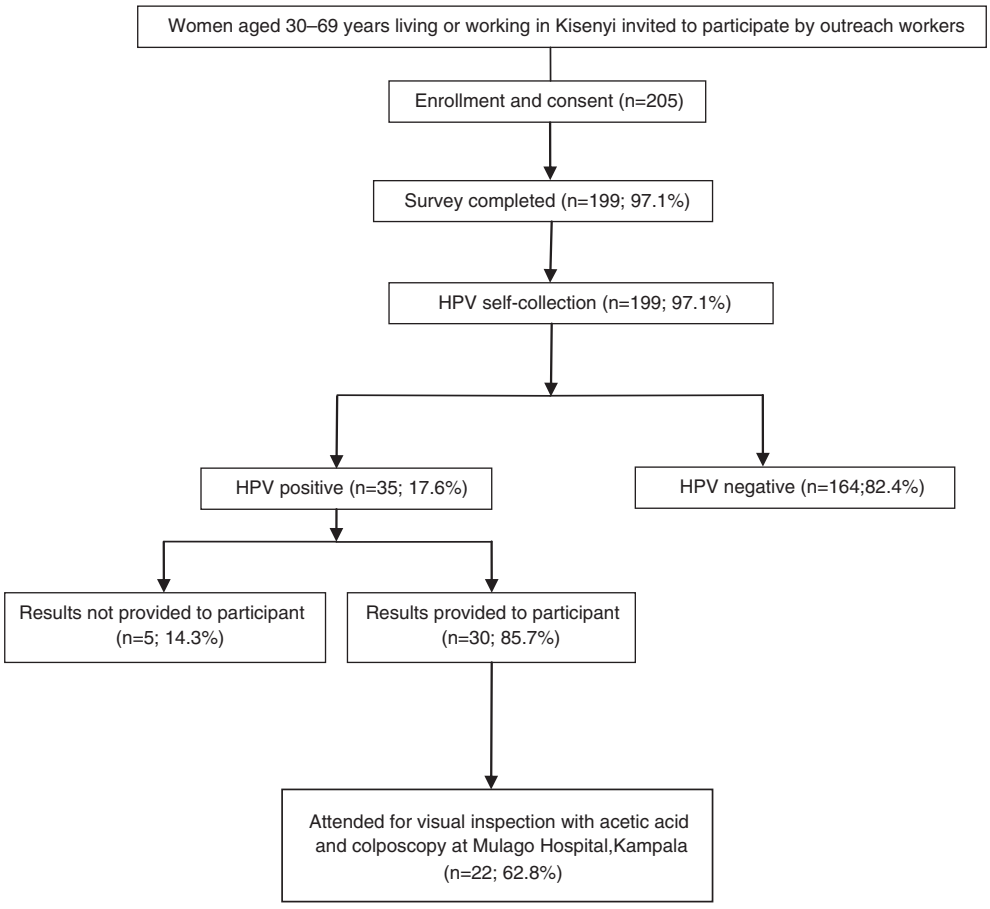

Fig. 1. Flow chart of the study design.

into Luganda and Swahili. Women then received instruction on how to self-collect a cervico-vaginal sample and were asked to provide 2 samples and return it to the outreach worker immediately. Women who were unwilling or unable to provide a self-collected specimen were interviewed and asked to comment on their reasons for not conducting the sampling.

One of the self-collected samples was used for HPV testing, whereas the other was used for evaluating infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. The HPV specimen was collected using a swab and was placed in a tube containing transport medium. Specimens were transported to Mulago Hospital within 24 hours of collection for processing and analysis with the careHPV test (Qiagen, Germantown, MD, USA) [20] using existing delivery systems. If samples could not be processed within 7 days of collection, they were frozen for later analysis. The careHPV kit identifies 14 oncogenic genotypes of HPV but does not distinguish specific subtypes [21]. Specimens were also tested for *C. trachomatis* with GenoQuick (Hain Life Science, Nehren, Germany) and for *N. gonorrhoeae* with the CinnaGen polymerase chain reaction test (CinnaGen, Tehran, Iran) at MBN Laboratories in Kampala.

Outreach workers made arrangements to provide participants with their test results in 2 weeks via their mobile telephone. Women who tested positive for HPV were invited to attend Mulago Hospital for visual inspection and colposcopy. Women were reimbursed for their travel costs and were provided with contact information for the colposcopy nurse. All women who attended follow-up received a colposcopy assessment; directed biopsies were conducted by a trained colposcopic physician. Women with visible lesions by colposcopy were treated with cryotherapy. All women who tested positive for HPV were offered HIV testing through the Infectious Diseases Institute at the Mulago Hospital campus. Women who tested positive for HIV were referred to the Infectious Diseases Institute for treatment and follow up.

Lesions were biopsied and tissue blocks prepared at Mulago Hospital. Initial assessment of the tissue samples was made by pathologists at Mulago Hospital. For quality assurance purposes, the tissue blocks were then transported to SurgPath Medical Consultants, a private pathology service in Kampala, Uganda, where slides were prepared and evaluated by another pathologist. Clinical management was directed by the most severe pathologic diagnosis, with treatment decisions directed by the colposcopists.

Women who tested positive for *N. gonorrhoeae* or *C. trachomatis* were contacted by outreach workers and the resident project physician. Allergies to medication were reviewed, and women provided with a single dose of 2 g of azithromycin for treatment.

Data were analyzed using SPSS version 14.0 (IBM, Armonk, NY, USA). A descriptive analysis was conducted. All women who submitted a swab for HPV testing were included in the final analysis (n = 199). HPV prevalence, receipt of HPV results, attendance at colposcopy, and colposcopy results were evaluated. Prevalence of HPV infection by demographics and attitude were also described. Contingency tables were generated to summarize observations on categorical variables and to assess possible associations between individual characteristics and HPV infection. Tests of association between HPV and individual characteristics (demographics) were based on the χ^2 of independence. A P value below 0.05 was considered statistically significant.

3. Results

Of the 205 women enrolled in the present study, 199 completed the survey and provided a specimen for evaluation (Fig. 1; Table 1). Only 26 of the participants did not have their own mobile telephone and provided a contact number through a neighbor or friend. Secondary level education was completed by 13.2% of the women and 97.1% had been sexually active with male partners.

Table 1
Results of a community-based reproductive health screening program among women in the Kisenyi district of Kampala, Uganda.[a]

Measure	Distribution
Approached and invited to participate in the present study	205
Accepted self-collection of specimens	199 (97.1)
Prevalence of HPV	35 (17.6)
Provided HPV test results[b]	
Yes	30 (85.7)
No	5 (14.3)
Attended the colposcopy appointment	26 (86.7)
Seen by a colposcopist	22
Colposcopy result	
Benign atypia	2 (9.1)
CIN 1	10 (45.5)
CIN 2	1 (4.6)
CIN 3	1 (4.6)
Normal	6 (27.3)
Severely stenosed os	1 (4.6)
Unsatisfactory	1 (4.6)
Pathology results	
Chronic cervicitis	5 (35.7)
CIN 1	3 (21.4)
CIN 2	4 (28.6)
No abnormalities	1 (7.1)
Poorly differentiated SCC	1 (7.1)
Treatment received	
Cryotherapy	3 (21.4)
None	10 (71.4)
Declined	1 (7.1)
Self-reported HIV	20 (9.8)
Prevalence of gonorrhea	3 (1.5)
Prevalence of chlamydia	27 (13.6)
Provided gonorrhea and chlamydia test results[c]	
Yes	21 (72.4)
No	8 (27.6)
Treatment received	
Yes	18 (62.1)
No	11 (37.9)

Abbreviations: CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus; SCC, squamous cell carcinoma.
[a] Values are given as number or number (percentage).
[b] Does not total 35 as some of the responses were missing.
[c] Does not total 30 as 1 participant had both gonorrhea and chlamydia.

Positive HPV tests results were obtained for 35 women (17.6%) and the outreach workers were able to provide results to 30 of them (85.7%; Fig. 1). Follow-up colposcopy appointments were attended by 26 (74.3%) of the 35 women who tested positive for HPV (Table 1); however, only 22 (62.8%) received a colposcopy examination as 4 women had their appointments cancelled (Fig. 1). As shown in Table 1, grade 3 cervical intraepithelial neoplasia (CIN 3) was diagnosed by colposcopy in 1 of these 22 women; however, 4 women had pathology consistent with CIN 3. All 4 women were recommended for treatment with cryotherapy; 3 women received this treatment while the fourth woman declined it. In all, there were 20 self-reported cases of HIV (Table 1). Furthermore, 2 women were diagnosed with *N. gonorrhoeae* and 26 women with *C. trachomatis*; 1 woman was co-infected with both micro-organisms. Of the women with a reproductive tract infection, 62.0% received treatment.

Table 2 shows the prevalence of HPV infection by demographic characteristics. The prevalence of HPV infection was higher among women aged 31–35 years (25.9%) than among the other age groups. Other groups with a high prevalence of HPV infection were women who were divorced, separated, widowed, or had no domestic partner (34.5%); women with the lowest self-reported level of education (23.4%), and women with self-reported HIV infection (31.6%). However, only marital status was significantly associated with HPV prevalence ($P = 0.049$). Women in the high quintiles of the Wealth Index had lower rates of HPV infection than women in the other quintiles.

Table 2
Prevalence of human papillomavirus infection by demographic characteristic among women aged 30–69 years in the Kisenyi region of Kampala, Uganda.[a]

Demographic characteristic	Distribution	Prevalence	95% confidence interval	*P* value [e]
Overall	199	35 (17.59)	12.57–23.60	
Age, y				
26–30	25	5 (20.00)	6.83–40.70	
31–35	58	15 (25.86)	15.26–39.04	
36–40	36	6 (16.67)	6.37–32.81	
41–45	29	3 (10.34)	2.19–27.35	0.435
46–50	24	2 (8.33)	1.03–27.00	
51–55	16	3 (18.75)	4.05–45.65	
56–69	11	1 (9.09)	0.23–41.28	
Marital status[b]				
Single	64	12 (18.75)	10.08–30.46	
Common-law union	84	11 (13.1)	6.72–22.22	0.049
Married	21	2 (9.52)	1.17–30.38	
Divorced, separated, widowed, or no domestic partner	29	10 (34.48)	17.94–54.33	
Education level of the participant				
No schooling or some primary schooling	64	15 (23.44)	13.75–35.69	
Primary schooling with or without some secondary schooling	97	15 (15.46)	8.92–24.22	0.312
Secondary or postsecondary schooling	38	5 (13.16)	4.41–28.09	
Education level of the husband or other domestic partner[b]				
No schooling or some primary schooling	10	2 (20.00)	2.52–55.61	
Primary schooling with or without some secondary schooling	50	10 (20.00)	10.03–33.72	
Secondary schooling	35	4 (11.43)	3.20–26.74	0.797
Postsecondary schooling	25	3 (12.00)	2.55–31.22	
No partner	51	11 (21.57)	11.29–35.32	
Do not know	9	2 (22.22)	2.81–60.01	
Work outside of the home				
No	84	19 (22.62)	14.20–33.05	0.111
Yes	115	16 (13.91)	8.17–21.61	
Live in Kisenyi				
No	38	5 (13.16)	4.41–28.09	0.425
Yes	161	30 (18.63)	12.94–25.52	
Religion[b]				
Christian	117	17 (14.53)	8.70–22.24	0.288
Muslim	77	17 (22.08)	13.42–32.98	
Time to walk to nearest health center, min[b]				
<30	21	21 (17.5)	11.17–25.5	
30–60	8	8 (18.18)	8.19–32.71	0.654
>60	3	3 (10.71)	2.27–28.23	
Have had sexual intercourse with male partner[b]				
Yes	193	33 (17.1)	12.07–23.17	0.185
No	5	2 (40.00)	5.27–85.34	
Ever had a pelvic examination				
Do not know	13	2 (15.38)	1.92–45.45	
No	170	30 (17.65)	12.23–24.22	0.971
Yes	16	3 (18.75)	4.05–45.65	
Tested HIV positive				
No	180	29 (16.11)	11.06–22.31	0.092
Yes	19	6 (31.58)	12.58–56.55	
Willingness to collect own sample for HPV testing				
Willing	189	34 (17.99)	12.79–24.22	0.518
Unwilling	10	1 (10.00)	0.25–44.50	
Wealth Index, quintiles [c]				
Poorest	23	5 (21.74)	7.46–43.70	
Second	41	10 (24.39)	12.36–40.30	
Middle	70	14 (20.00)	11.39–31.27	0.288
Fourth	22	2 (9.09)	1.12–29.16	
Wealthiest	43	4 (9.3)	2.59–22.14	
Ever had sexual intercourse [d]	199 (97.07)			
Ever had a pelvic examination[d]	16 (7.80)			
HIV positive	19 (9.55)			
Willingness to collect own sample for HPV testing [d]	192 (93.66)			
Age at interview, y	37 (32–46)			
Age at first sexual intercourse, y	16 (14–16)			
Number of pregnancies	5 (3–6)			

Abbreviations: HPV, human papillomavirus.
[a] Values are given as number, number (percentage), or median (interquartile range) unless otherwise indicated.
[b] Does not total 199 as some of the responses were missing.
[c] Based on possessions (television, bicycle, radio, DVD player, fridge, and house).
[d] Original sample size 205 (complete cases analysis).
[e] Wald χ^2.

Table 3 shows the prevalence of HPV infection by participants' attitudes. Women who were not concerned about their ability to safely collect a specimen were more likely to test positive ($P < 0.01$), whereas women who felt that their spiritual beliefs would guide their decision to self-sample were less likely to test positive ($P < 0.05$).

Table 3
Prevalence of HPV infection by attitude among women in the Kisenyi district of Kampala, Uganda.[a]

Attitude	Sample size [b]	Prevalence	95% confidence interval	*P* value
I would be embarrassed to collect a sample at home				
No	194	34 (17.26)	12.45–23.62	0.477
Yes	3	1 (0.51)	0.84–90.57	
I am worried that I would not collect the sample properly				
No	192	32 (16.24)	11.69–22.71	0.012
Yes	5	3 (1.52)	14.66–94.73	
I am afraid that HPV testing will show that I have cervical cancer				
No	134	24 (12.18)	11.83–25.47	0.939
Yes	63	11 (5.58)	9.05–29.1	
I am afraid that HPV testing will make other people think I have cervical cancer				
No	192	32 (16.33)	11.69–22.71	0.08
Yes	4	2 (1.02)	6.76–93.24	
I am worried that self-collecting a sample will be painful				
No	181	30 (15.63)	11.47–22.81	0.89
Yes	11	2 (1.04)	2.28–51.78	
I would be willing to have an outreach worker drop off a swab				
No	131	21 (10.82)	10.21–23.45	0.802
Yes	63	11 (5.67)	9.05–29.1	
I would be willing to go to the nearest health center to drop off the swab				
No	136	23 (11.62)	11.03–24.29	0.676
Yes	62	12 (6.06)	10.42–31.37	
I would need my husband's or partner's approval to collect the sample				
No	193	35 (17.68)	12.97–24.31	0.294
Yes	5	0 (0.00)	0–52.18	
My religion or spiritual belief would affect my decision to be screened				
No	197	34 (17.17)	12.26–23.27	0.031
Yes	1	1 (0.51)	2.5–100	
It is possible for a virus to cause cancer				
No	52	9 (4.62)	8.23–30.33	0.977
Yes	143	25 (12.82)	11.64–24.72	
Would you be willing to go to the clinic for a pelvic examination if the self-collected sample was found to be abnormal?				
No	13	2 (1.01)	1.92–45.45	0.823
Yes	185	33 (16.67)	12.61–24.13	
I feel that I need to be tested for HPV				
No	12	2 (1.01)	2.09–48.41	0.925
Yes	186	33 (16.67)	12.54–24	
I feel that I am at risk of having HPV				
No	168	29 (14.65)	11.88–23.84	0.717
Yes	30	6 (3.03)	7.71–38.57	
Only women with vaginal discharge or bleeding need to be screened				
No	185	33 (16.75)	12.61–24.13	0.918
Yes	12	2 (1.02)	2.09–48.41	

Abbreviation: HPV, human papillomavirus.
[a] Values are given as number or number (percentage) unless otherwise indicated.
[b] Original sample size was 205 (complete cases analysis). Does not total 199 as some of the responses were missing.

4. Discussion

The present study was designed to explore the feasibility of a community-based cervical cancer screening program using self-collected specimens for HPV testing as part of an integrated reproductive health screening program. The findings indicate that this approach was highly acceptable to women in an impoverished community in Sub-Saharan Africa, with the majority willing to participate in the program. A previous survey in the same community reported that 80% of women indicated an intention to provide a self-collected specimen for HPV testing [14]. The present study found that a higher percentage of women (97.1%) actually undertook self-sampling, confirming the overall acceptability of the program and indicating an opportunity to broaden implementation of community-based reproductive screening programs in LMIC.

A key part of any quality screening program is to ensure that the care pathway is complete, with women receiving their screening results and then attending any follow up assessments for colposcopy. In the present study, outreach workers successfully provided positive HPV test results to approximately 85.0% of the women, and 26 of the 35 women who required follow-up colposcopy attended the appointment. These findings underscore the necessity for planning the full screening pathway as part of an intervention, as well as the need to evaluate all elements of uptake.

The overall HPV prevalence in the present study was 17.6%; however, there were few significant differences detected on the basis of demographic or attitude characteristics. This finding indicates the need for a broad screening program for HPV, regardless of a woman's background.

Another important aspect of any cervical cancer screening program is the timely and local availability of high-quality HPV testing and pathology services. Specific concerns for HPV testing in LMIC have been the cost of the test and the availability of the technology. In the present study, the team was able to access the careHPV test at a university hospital [20]. In future, basing the laboratory at a local community health center might optimize the accessibility and turn-around time for HPV test results. For tissue biopsy specimens, it is essential to have a good pathology service, with excellent quality assurance, which can prove challenging in LMIC. In the present study, the team was able to work with both university and private sector partners to provide quality assurance evaluations of the tissue samples.

Patient-collected specimens are an important paradigm for reproductive health screening that has yet to be fully optimized in healthcare systems. Although there is the loss of pelvic examination and opportunities for health promotion and screening for other

conditions (e.g. pelvic masses), self-sampling could increase screening uptake among populations that may not participate in current programs and might enable recruitment of women at increased risk of cervical cancer or reproductive tract infections [18,21]. Systematic reviews have confirmed that self-collected HPV testing has high sensitivity and specificity for diagnosis of CIN 2 and CIN 3 [16], while at the same time being very acceptable to the population [15]. Several international studies have shown that use of self-collected HPV specimens in a cervical cancer screening program can increase attendance and participation. For example, a randomized trial compared cytology and self-collected HPV in Mexico [22]. These data suggest that a self-sampling program can optimize cervical cancer screening uptake and offer advantages regarding detection of precancerous lesions.

The prevention of cervical cancer remains an unmet priority with almost one-quarter of a million women worldwide dying each year from an avoidable disease. In the present study, the acceptability of an integrated community-based cervical cancer screening that put control for screening in the hands of women was outlined. Such an approach would allow for judicious use of scarce health resources (both human and financial). The findings of the present study show that women readily accepted this screening method, and that a majority of women, with transportation support, were able to attend for follow-up assessment and treatment of precancerous lesions. At the same time, the program was able to also offer screening and treatment for other reproductive tract infections. Based on these findings, policy makers and researchers should embark on broader community-based implementation, coupled with comprehensive evaluation, to ultimately reduce the burden of cervical cancer worldwide.

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Conflict of interest

The authors have no conflicts of interest.

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