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Authors

Huchko, Megan J Ibrahim, Saduma Blat, Cinthia <u>et al.</u>

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Cervical cancer screening through human papillomavirus testing in community health campaigns versus health facilities in rural western Kenya

Megan J. Huchko^{1,*}, Saduma Ibrahim², Cinthia Blat³, Craig R. Cohen³, Jennifer S. Smith⁴, Robert A. Hiatt⁵, Elizabeth Bukusi^{2,6,7}

¹Duke Global Health Institute, Duke University, Durham, NC, USA

²Center for Microbiology Research, Kenya Medical Research Institute, Nairobi, Kenya

³Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, CA, USA

⁴Department of Epidemiology and Biostatistics, University of North Carolina, Chapel Hill, NC, USA

⁵Department of Epidemiology and Biostatistics, University of California, San Francisco, CA, USA

⁶Department of Obstetrics and Gynecology, Aga Khan University, Nairobi, Kenya

⁷Departments of Global Health and Obstetrics and Gynecology, University of Washington, Seattle, WA, USA

Abstract

Objective: To determine the effectiveness of community health campaigns (CHCs) as a strategy for human papillomavirus (HPV)-based cervical cancer screening in rural western Kenya.

Methods: Between January and November 2016, a cluster-randomized trial was carried out in 12 communities in western Kenya to investigate high-risk HPV testing offered via self-collection to women aged 25–65 years in CHCs versus government health facilities. Outcome measures were the total number of women accessing cervical cancer screening and the proportion of HPV-positive women accessing treatment.

Results: In total, 4944 women underwent HPV-based cervical cancer screening in CHCs (n=2898) or health facilities (n=2046). Screening uptake as a proportion of total eligible women in the population was greater in communities assigned to CHCs (60.0% vs 37.0%, P<0.001). Rates of treatment acquisition were low in both arms (CHCs 39.2%; health facilities 31.5%; P=0.408).

^{*}**Correspondence:** Megan J. Huchko, Duke Global Health, Institute, Durham, NC, USA., megan.huchko@duke.edu. AUTHOR CONTRIBUTIONS

MJH was the overall principal investigator of the grant and study; she wrote the protocol and the manuscript. SI and CB supervised the data team, oversaw all data collection and cleaning, performed the data analysis for the present study, and helped with the planning, writing, and revision of the manuscript. CRC, JSS, and RAH assisted with the conceptualization of the model, organization and outline of the tables and manuscript, and revision of the final manuscript. EB assisted with the conceptualization of the study and analysis, was the site principal investigator, oversaw the study activities, and assisted with the revision of the manuscript.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

Discussion: Cervical cancer screening using HPV testing of self-collected samples reached a larger proportion of women when offered through periodic CHCs compared with health facilities. The community-based model is a promising strategy for cervical cancer prevention. Lessons learned from this trial can be used to identify ways of maximizing the impact of such strategies through greater community participation and improved linkage to treatment.

ClinicalTrials.gov registration—NCT02124252.

Keywords

Cervical cancer screening; Community health campaigns; Human papillomavirus testing; Implementation science; Kenya; Self-collection

1 | INTRODUCTION

Cervical cancer is highly preventable through organized screening programs; yet, more than half a million women are diagnosed with the disease every year, with approximately 90% of cervical cancer cases and mortality occurring in low-resource countries.^{1–3} Most low-resource countries lack the funding, personnel, and healthcare infrastructure necessary to implement the programs that have dramatically reduced cervical cancer mortality in wealthier countries. One such country is Kenya, where the cervical cancer incidence is more than 10 times that of the USA,⁴ and only 3% of the eligible population will undergo screening in their lifetime.⁵ To address this disparity, the WHO recommends the adoption of alternative protocols that employ low-cost or simple-to-use screening technologies, with testing for high-risk human papillomavirus (HPV), the oncogenic virus responsible for most cervical cancers, being the preferred strategy.⁶ Testing for HPV provides an easy-to-understand result, is acceptable and accurate when using samples that have been self-collected by women without a pelvic examination, and has become more widely available through low-cost test kits with feasible laboratory requirements.^{7–12}

The impact of a cervical cancer prevention program depends on the screening efficacy and on high rates of population coverage—a challenge in low-resource settings, where uptake of preventive health services is relatively low and clinic staffing and resources are limited.¹³ Community-based health care has been shown to improve access to care and health outcomes in various reproductive and general health contexts compared with strategies in which care is delivered through clinical facilities.^{14,15} Community health campaigns (CHCs) are a potentially high-impact and cost-effective way of providing healthcare interventions.¹⁶ Brief but intense health campaigns consist of targeted mobilization and outreach efforts followed by highly attended health fairs that offer preventive or diagnostic services. By linking only those women who screen positive to facility-based care, CHCs reduce the visit burden for both women and facilities. This allows resources to be directed toward those women who are at highest risk—in this case, women who test positive for HPV.^{14,17,18} The acceptability and uptake of reproductive health services through CHCs, in particular HPV-based screening for cervical cancer, remains unknown.

Using results from preliminary studies and evidence-based interventions as well as data from key stakeholders in the region, we developed an implementation strategy for a WHO-

recommended cervical cancer screening protocol in which HPV testing is followed by cryotherapy for women who test HPV-positive. The strategy included two adaptations: offering HPV testing using self-collected specimens and providing screening through CHCs. The present cluster-randomized trial compared HPV-based cervical cancer screening through CHCs with that in government clinics in western Kenya to determine which strategy will result in the greatest number and proportion of women in the community screened for cervical cancer.

2 | MATERIALS AND METHODS

A two-phase cluster-randomized trial was carried out in western Kenya to evaluate two adaptations of an HPV-based cervical cancer prevention strategy between January 11 and November 30, 2016. The study was conducted in 12 communities in Migori County in the former Nyanza Province of western Kenya. The area borders Lake Victoria, where almost two-thirds of people live on less than \$1 per day. Nyanza has the highest prevalence (15.1%) of HIV in Kenya, accounting for approximately one in four infections in the country.¹⁹ The study population comprised women aged 25-65 years living in Migori County who had an intact uterus and cervix. Cervical cancer screening was carried out using HPV testing of self-collected specimens, followed by referral for treatment with cryotherapy for women who tested HPV-positive. In the present paper, the results of Phase 1 are presented, in which two implementation strategies to maximize the uptake of self-sampling screening were evaluated: CHC-based screening and health-facility-based screening. In Phase 2, strategies to increase linkage to treatment for HPV-positive women will be developed and tested. All women provided written informed consent prior to screening. The present study received ethics approval from the University of California San Francisco, Duke University, and the Kenya Medical Research Institute.

Prior to initiation of the present trial, study staff assessed potential study communities using a combination of census data, health facility information, mapping, and prospective demographic data. For study purposes, "communities" were clusters of villages or sublocations within a defined administrative boundary with a total population between 5000 and 9500. Community size was calculated in two ways: (1) estimates from the 2009 Kenya census²⁰ with projected population growth for 2015; and (2) population catchment areas as defined by the local health facilities assigned to cover these communities. In situations where two adjacent sublocations had populations that together totaled between 5000 and 9500 people, they were combined and defined as one study community (Fig. 1). Communities were considered eligible if they had at least one government health facility with the capacity to offer HPV testing, received support from community leaders for community outreach and/or health campaigns, offered accessibility to health centers via a maintained transportation route, and were not bordering other study sites to limit contamination between arms (buffer zones). Because the target group was women in rural communities, urban settings or communities in which the nearest health center was Migori County Hospital were excluded. Also excluded were communities participating in a clusterrandomized trial of HIV testing through CHCs or for which census data were unavailable.

The size of the target population of women aged 25–65 years in each community was estimated in two ways: (1) a proportion (approximately 25%) of the estimated total population calculated using demographic data from an ongoing cluster-randomized trial; and (2) direct estimates of the number of eligible women by community health volunteers (CHVs) assigned to the health facilities in the study communities. The CHVs provide support for government health facilities through community engagement, health education, and home visits for adherence and reminders. Because the CHVs' estimates were obtained through door-to-door enumeration, these estimates were used as the primary data source for determining the proportion of the population screened, and the calculated proportions were used for confirmation.

The 12 communities were randomized 1:1 using an allocation sequence generated by Stata/MP version 11 (StataCorp, College Station, TX, USA). In communities randomized to the intervention, HPV screening was offered through periodic CHCs. In communities randomized to the control strategy, HPV screening was offered at government health facilities. Women in the health facilities could be approached when they were attending for other services or specifically for cervical cancer screening, with a goal of reaching all women aged 25–65 years. The community outreach strategies, education modules, and health messaging about cervical cancer screening and HPV, including self-collection instructions, were the same in both the control and the intervention communities. In both the control and the intervention of the cervical specimens, with education and screening instructions provided by CHVs.

The CHCs covered each community over a 6-week period, which included 2 weeks of outreach and mobilization, 2 weeks of screening in tents set up in various villages throughout the community, and 2 weeks of result notification and community feedback. Screening at health facilities was offered consistently throughout all 36 weeks of the study.

In both arms, women who reported access to a mobile phone were offered the choice of receiving their HPV test result via text message, phone call, or a return clinic visit. Women who did not have a phone, felt uncomfortable with these options, or did not receive their result via their preferred option received a home visit. Women testing positive in any of the communities were referred to the county hospital for treatment by a team of nurses who had received study-specific training and mentorship. A pretreatment pelvic examination and visual inspection with acetic acid was performed to determine whether a woman was eligible for cryotherapy (the standard), loop electrosurgical excision procedure, or referral for possible invasive cancer.

During the CHCs, participant data were collected directly from the providers and participants onto preprogrammed tablets using Open Data Kit version 1.11.1,²¹ and transferred daily to a data center in Kisumu, Kenya, where the data were stored on a secure server. To capture visits and outcomes from facility-based screening, a member of the research team visited each health facility on a weekly basis to enter data from Ministry of Health registers and study-specific forms into the tablets. Variables collected included age, residence, prior cervical cancer screening, self-reported HIV status, and use of

contraceptives. The data were cleaned on a monthly basis, with reconciliation done in person and through review of the data collection forms.

The HPV DNA test was performed using the careHPV (Qiagen, Gaithersburg, MD, USA) testing system, which provides a qualitative result (positive or negative) for 14 oncogenic HPV types. The specimens from CHCs were transported to Migori County Hospital at the end of each campaign day and stored at room temperature until testing was performed (within 2 weeks as per manufacturer instructions). Specimens collected at the health facilities were stored at room temperature and collected by study staff on a weekly basis. The HPV DNA assays were run in batches of 90 samples with six controls. If plates had errors in the control, indeterminate results for any specimen, or more than six contiguous positives, the entire run was repeated. Results that were indeterminate after two runs were considered indeterminate. Results were reported as positive, negative, or indeterminate onto an assay data sheet.

The study was powered to show a difference in the primary outcome, the number and proportion of women in each arm who underwent testing between the study arms, with β error of 0.10. Secondary outcomes included clinical and sociodemographic variables associated with screening, and changes in screening and treatment rates across time. All analyses were performed using Stata/MP version 12 (StataCorp). The results were checked for distribution, and appropriate tests of association were chosen for analysis and controlled for clustering with an intra-class coefficient of 0.11. *P*<0.05 was considered statistically significant. The Fisher exact test was used to calculate the differences between arms for sociodemographic variables, clinical characteristics (prior cervical cancer screening history, self-reported HIV status, the use of contraceptives), and women's screening experience. The Kruskal-Wallis test was used to evaluate the median (and interquartile range) time in days between screening and notification, screening to treatment access, as well as the time between notification and treatment access. A variance-weighted least squares model was used to explore trends in screening and treatment acquisition across time.

3| RESULTS

Between January and September 2016, 6481 eligible women attended either a CHC or a health facility in the 12 study communities, with final follow-up performed in November 2016. Among the 2943 women who attended the CHCs, 2898 (98.5%) consented to participate in the study and underwent screening. Among the 3538 women seen in health facilities, 2046 (57.8%) consented and underwent screening. Despite the random assignment, there were several significant differences between the participants in the control and intervention communities. Women screened in the CHCs were slightly older (median 38.2 years vs 36.7 years; P<0.001) and more likely to have had prior cervical cancer screening (14.0% vs 8.3%; P<0.001) (Table 1). Women screened at the health facilities were more likely to be HIV-infected compared with those screened in the CHCs (38.0% vs 25.0%; P<0.001).

The proportion of women who agreed to be screened remained steady throughout the entire duration of the study in both arms (Fig. 2). The vast majority (n=1880 [91.9%]) of women in

the health facilities accepted screening during the first visit it was offered. Based on either method of population estimation, the proportion of women accessing screening was greater in the CHC communities (60.0%) than in the health facility communities (37.0%; P<0.001) (Table 2). Almost all women in the CHC and control arms found the self-collection instructions clear (n=2892 [99.8%] vs n=2044 [99.9%]; P=0.828), rated the privacy as adequate (n=2879 [99.3%] vs n=2040 [99.7%]; P=0.077), would test again via self-collection (n=2872 [99.1%] vs n=2023 [98.9%]; P=0.427), and would recommend testing to a friend (n=2881 [99.4%] vs n=2025 [99.0%]; P=0.081).

The overall oncogenic HPV positivity rate among the 4944 participants was 21.1% (n=1043), with a greater proportion of women testing positive in health facilities (n=476 [23.3%]) than in CHCs (n=567 [19.6%]; P<0.001) (Table 2). There was only one indeterminate result from both arms. A positive HPV test was more common among HIV-infected women than among HIV-seronegative women in both arms. Among the 700 HIV-positive women in the CHCs, 234 (33.4%) were HPV-positive, compared to 333 of 2198 (15.2%) HIV-negative women who tested HPV-positive (P<0.001). Among the 771 HIV-positive women in the health facilities, 271 (35.2%) were HPV-positive, compared to 205 of 1275 (16.1%) HIV-negative women (P<0.001). There was no association between HPV status and prior cervical cancer screening.

Preferences for the method of result notification differed by study arm. More women in the CHCs reported having their own mobile phone or a phone they could use (n=2243 [77.4%]) compared with women screened in health facilities (n=1327 [64.9%]; P<0.001). In the CHCs, the majority of women preferred to receive their result by phone, either by text (n=992 [34.2%]) or by phone call (n=1048 [36.2%]) (Table 1). In the health facilities, most women (n=1275 [62.3%]) preferred to return to the health facility to collect their test result.

Overall, treatment acquisition among the HPV-positive women was low in both arms (CHCs 39.2%, health facilities 31.5%; *P*=0.010) (Table 2). The mean time between screening and treatment was 47 days (interquartile range, 31-77 days), with no difference between the study arms (*P*<0.001). During the 9-month study, there was a significant decrease in treatment rates in the health facility arm (*P*<0.001), whereas the rates of women obtaining treatment did not change significantly in the CHC arm (*P*=0.553) (Fig. 3). The steadiness of treatment rates over time in the CHC arm was mainly driven by the high proportion of women treated during the fourth CHC period.

4 | DISCUSSION

In the present study, cervical cancer screening offered through HPV testing of self-collected samples greatly increased screening access in rural western Kenya compared with historical and reported screening rates⁵; however, screening in CHCs reached more women than screening in health clinics. Self-collection of the vaginal specimens was found to be straightforward and comfortable, and almost all women would recommend it to a friend. The prevalence of HPV was higher among women screened in health facilities, likely reflecting the higher proportion of HIV-infected women seen in that setting. Overall, the linkage to treatment in women with a positive HPV test was low in both study arms.

Although cervical cancer screening in CHCs has been piloted in small studies that have used various screening techniques,^{22,23} to the best of our knowledge this is the first large-scale, randomized trial of CHCs for the implementation of HPV testing via self-sampling in Africa. The success of this screening model should be considered as proof of concept or as a starting point for further refinement to maximize its impact. The present trial was designed to also look at the implementation process, and to evaluate the type, magnitude, and impact of the changes that were made to the implementation model throughout the study, along with the costs and cost-effectiveness of both arms.

Some clear areas were identified where screening uptake could be improved to maximize the population health impact. The higher rate of HPV positivity in the health facility arm reflects the fact that the population attending clinics is at higher risk than the population attending CHCs. In the present high-HIV-prevalence setting, a considerable proportion of health facility visits are made for HIV care. A successful community strategy will employ outreach and mobilization efforts that are effective in reaching more at-risk women outside of health facilities, perhaps by coupling HPV screening with other health services.

Another area where the present CHCs could have been more effective is in reaching more women in each village. The overall proportion of the population reached was smaller than that seen in the multidisease campaigns after which the present study was modeled.²⁴ Next steps toward improving the community coverage of CHCs could consist of spending more days in a community or offering multiple health services. The CHCs in the present study were limited to providing cervical cancer screening only, in order to look at this specific model. Future projects should be designed in collaboration with community and Ministry of Health stakeholders, and would likely include integrated services.

The present study has several limitations. Because it was designed to be an implementation trial, the performance of HPV testing for the diagnosis of cervical intraepithelial neoplasia—the immediate pre-cursor to cervical cancer—was not examined. In addition, census and CHV estimates were used to define the eligible population of women, and it is therefore possible that the community impact of screening was over- or underestimated. Finally, no information was collected on why women attended the health facilities, and it was therefore not possible to assess whether women came specifically for HPV testing, for another preventive health service, or for a sick visit. These reasons may have had a differential impact on their decision to get screening.

The present findings provide evidence to inform clinical protocols and government policy around the implementation and evaluation of cervical cancer screening programs in rural areas of Sub-Saharan Africa, where the vast majority of the underscreened population resides. Determination of the optimal method of implementing a cervical cancer prevention cascade in a low-resource setting using patient and provider-driven approaches has the potential to impact screening and treatment rates in those settings where women are most at risk for cervical cancer. There are clear conceptual advantages to adopting a CHC model for cervical cancer screening, one being that this approach takes the workload of screening out of the clinics, leaving the facility and provider resources for women who test HPV-positive. Other advantages include leveraging the CHV workforce in their own communities,

maximizing the efficiencies of transport for staff and supplies, and offering mass screening at one time every 5 years, rather than sustaining a program consistently.

In conclusion, the present study showed that although HPV screening via self-sampling was more effective when conducted in the context of CHCs than in health facilities, there is substantial work to be done to achieve universal coverage. Adaptation of the model to reach more women at risk, completion of a cost-effectiveness analysis, and development of a community strategy in partnership with the Ministry of Health to improve linkage to treatment are the essential next steps for this promising model. Ideally, the optimal model will be a program that can be replicated and sustained to improve healthcare availability in low- and middle-income countries and may dramatically reduce the burden of cervical cancer in the most vulnerable women worldwide.

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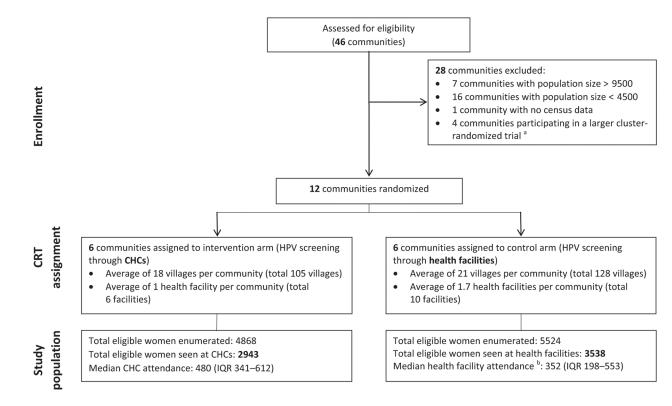


FIGURE 1.

Consolidated Standards of Reporting Trials (CONSORT) flow chart of population enumeration, study allocation, and screening uptake. Abbreviations: CHC, community health campaign; CRT, cluster-randomized trial; HPV, human papillomavirus; IQR, interquartile range. ^a A large cluster-randomized trial employing HIV testing was felt to possibly interfere with participant recruitment, so those communities were dropped. ^b Among eligible women.

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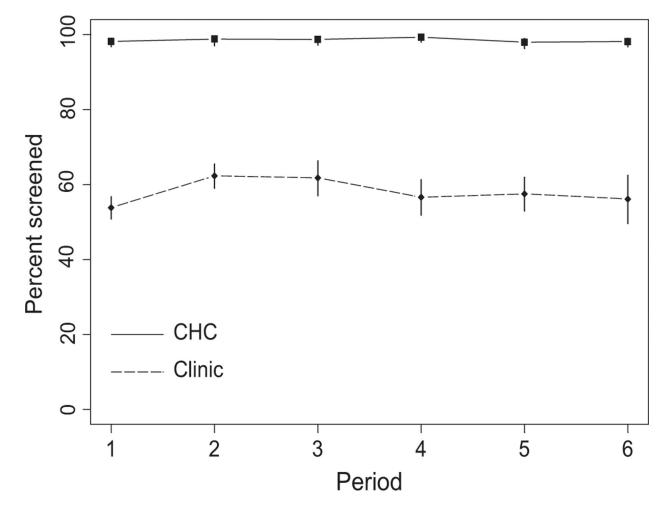


FIGURE 2.

Percent of women who underwent screening for human papillomavirus, by study arm. Abbreviation: CHC, community health campaign.

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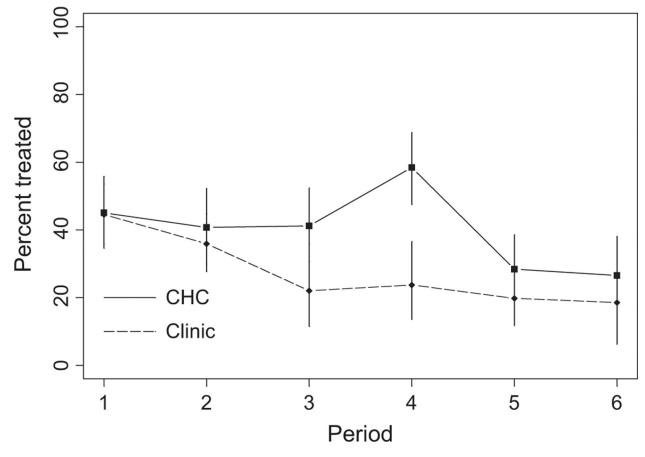


FIGURE 3.

Percent of women testing positive for human papillomavirus who accessed treatment, by study arm. Abbreviation: CHC, community health campaign.

TABLE 1

Clinical and demographic characteristics of women screened for HPV (n=4944).^a

Charactaristia	CHC (2000)	Haalth facility (= 2044)	Duch
Characteristic	CHC (n=2898)	Health facility (n=2046)	P value
Age category, y	706 (27.4)	500 (28 8)	
25-29	796 (27.4)	590 (28.8)	
30–39	964 (33.3)	765 (37.4)	
40-49	616 (21.3)	439 (21.5)	0.001
50–65	522 (18.0)	252 (12.3)	< 0.001
Prior screening for cervical cancer	105 (14.0)	1 (0 (0 2)	
Yes	406 (14.0)	169 (8.3)	0.001
No	2492 (86.0)	1877 (91.7)	< 0.001
Prior cervical cancer screening type (n=575)		1 51 (05.0)	
VIA/VILI	246 (60.6)	161 (95.3)	
Cervical smear	154 (38.0)	6 (3.5)	
HPV	3 (0.7)	0 (0.0)	
Other	3 (0.7)	2 (1.2)	< 0.001
Prior HIV testing			
Yes	2805 (96.8)	2029 (99.2)	
No	93 (3.2)	17 (0.8)	< 0.001
Prior HIV testing result (n=4834)			
Negative	2098 (74.8)	1258 (62.0)	
Positive	700 (25.0)	771 (38.0)	
Don't know	7 (0.2)	0 (0.0)	< 0.001
Current use of contraception			
Yes	1177 (40.6)	882 (43.1)	
No	1721 (59.4)	1164 (56.9)	0.080
Contraceptive type (n=2059)			
Injectable	488 (41.5)	432 (49.0)	
Implant	444 (37.7)	329 (37.3)	
Female sterilization	120 (10.2)	20 (2.3)	
IUCD	62 (5.3)	27 (3.0)	
Pills	34 (2.9)	42 (4.8)	
Male condoms	24 (2.0)	17 (1.9)	
Other	5 (0.4)	15 (1.7)	< 0.001
HPV testing within 6 weeks of first visit			
Yes	2898 (100.0)	1954 (95.5)	
No	0 (0.0)	92 (4.5)	< 0.001
HPV test result			
Positive	567 (19.6)	476 (23.3)	
Negative	2331 (80.4)	1569 (76.7)	
Inconclusive	0 (0.0)	1 (0.1)	0.001
Prior cervical cancer screening among HPV-positive(n=567)			

Prior cervical cancer screening among HPV-positive(n=567)

Characteristic	CHC (n=2898)	Health facility (n=2046)	P value
Prior screening	75 (13.2)	53 (11.1)	
No prior screening	492 (86.8)	423 (88.9)	0.305
Preferred notification method			
Text	992 (34.2)	604 (29.5)	
Phone call	1048 (36.2)	132 (6.5)	
Return clinic visit	288 (9.9)	1275 (62.3)	
Home visit	570 (19.7)	35 (1.7)	< 0.001

Abbreviations: CHC, community health campaign; HPV, human papillomavirus; IUCD, intrauterine contraceptive device; VIA, visual inspection with acetic acid; VILI, visual inspection with Lugol iodine.

^aValues are given as number (percentage), unless indicated otherwise.

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TABLE 2

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	Communi	Community health campaigns	umpaigns					Health facilities	cilities						
Parameter	Oyani (n=1011)	Ongito (n=652)	Nyarongi (n=875)	Nyamanga (n=1071)	Obware (n=674)	Agenga (n=585)	Total (n=4868)	Diruma (n=606)	God Jope (n=657)	Got Kachola (n=2120)	Nyamasare (n=927)	Ondong (n=580)	Winjo (n=634)	Total (n=5524)	<i>P</i> value
Screened															
Total	601 (59.4)	337 (51.7)	461 (52.7)	430 (40.1)	483 (71.6)	$586 \\ (100.2)^{\mathcal{C}}$	2898 (60.0)	450 (74.3)	157 (23.9)	499 (23.5)	328 (35.4)	272 (46.9)	340 (53.6)	2046 (37.0)	<0.001
CHC period 1	601	I					601	144	49	82	87	116	113	591	
CHC period 2	I	337		I	I	I	337	128	36	136	63	73	101	537	
CHC period 3	I		461		I	I	461	52	18	57	54	38	46	265	
CHC period 4	[I	I	430	I	I	430	48	23	88	32	18	35	244	
CHC period 5	I	I		I	483	I	483	62	19	83	68	15	29	276	
CHC period 6						586	586	16	12	53	24	12	16	133	
HPV- positive	91 (15.1)	81 (24.0)	85 (18.4)	89 (20.7)	95 (19.7)	126 (21.5)	567 (19.6)	113 (25.1)	37 (23.6)	125 (25.0)	93 (28.4)	38 (14.0)	70 (20.6)	476 (23.3)	<0.001
Treated	41 (45.0)	33 (40.7)	35 (41.2)	52 (58.4)	27 (28.4)	34 (27.0)	222 (39.2)	25 (22.1)	8 (21.6)	48 (38.4)	36 (38.7)	11 (28.9)	22 (31.4)	150 (31.5)	0.010

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 a Values are given as number or number (percentage), unless indicated otherwise.

b. The numbers shown in this table are based on house-to-house enumeration by the community health volunteers. The results for trend in the proportion of women seen were not different when the census extrapolation method was used.

^C Value exceeds the denominator for Agenga owing to the population enumeration being inaccurate, and underrepresenting the community in this instance.