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A community-based approach to cervical cancer prevention in western Kenya: An AMPATH feasibility project

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Abstract

Objectives: Centralized programs have been ineffective in reducing the burden of cervical cancer among Kenyan women. A community-based pilot study was initiated to screen Kenyan women for cervical cancer and to vaccinate their children against human papillomavirus (HPV).

Methods: Women were educated about cervical cancer prevention at community meetings. Women then provided self-collected vaginal swabs for oncogenic HPV testing using the Roche Cobas Assay. All women were then referred to the local clinic for Visual Inspection with Acetic Acid (VIA). Women were offered the quadrivalent HPV vaccine for their children if and when it became available for the study.

Results: Women in western Kenya were invited to participate in community meetings. A total of 200 women were enrolled: 151 (75.5%) were HIV-uninfected and 49 (24.5%) were HIV-infected; the median age for all women was 42 years. High-risk (HR)-HPV types were detected in 49 of swabs from all 200 participants (24.5%) including 20.5% of HIV-uninfected women and 36.7% of HIV-infected women (P = .022). VIA was performed on 198 women: 192 had normal examinations and six had abnormal examinations. Five cervical biopsies revealed two cases of CIN 2 and one CIN 3. Although all mothers were willing to have their children (N = 432) vaccinated, the HPV vaccine could not be delivered to Kenya during the study period.

Conclusions: Kenyan women were willing to attend community meetings to learn about prevention of cervical cancer, to provide self-collected vaginal swabs for HPV testing, to travel to the Webuye Clinic for VIA following the collection of swabs, and to have their children vaccinated against HPV. HR-HPV was prevalent, especially in HIV-infected women. As a result of this pilot study, this community-based strategy to prevent cervical cancer will be continued in western Kenya.

Keywords

Cervical cancer screening, self-collected vaginal swabs, Kenya, HIV

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Introduction

Cervical cancer is common among women living in Kenya.[1-3] This malignancy is caused by oncogenic human papillomavirus (HPV) and is preventable through effective screening of women and vaccination of children against HPV. However, regularly screening is rare among Kenyan women, which is done by Visual Inspection with Acetic Acid (VIA).[3,4] While HPV vaccines are available in Kenya, very few children and adolescents have been vaccinated due to high costs, lack of vaccine availability, difficulties with delivery infrastructure, and other obstacles.[5,6]

The traditional model of centralized and clinician-based cervical cancer prevention has not worked well in most of Kenya due to a shortage of clinics, physicians, nurses,

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cytotechnologists, and pathologists. This study was designed to test the hypothesis that screening Kenyan mothers/grandmothers for cervical cancer and vaccinating their children/grandchildren against HPV can be performed in a community setting. The feasibility of this approach was also tested. This pilot study of a novel community-based approach to cervical cancer prevention in western Kenya was designed to combine screening of adult women in community meetings using HPV DNA testing of self-vaginal swabs and HPV vaccination of children of women attending these meetings. The pilot study was conducted through the Academic Model Providing Access to Healthcare (AMPATH).[7]

Methods

Enrollment of study participants at community meetings

Ethical approval was obtained from the Institutional Review Board of Indiana University School of Medicine and the review boards at Moi Teaching Referral Hospital (MTRH), Moi University, Eldoret, Kenya, and the Kenya Medical Research Institute's Scientific and Ethics Review Unit. Written informed consent was obtained from all participants, and all were given a written copy of the signed consent in either English or Swahili.

This was a pilot study to determine the feasibility of screening of adult Kenyan women for cervical cancer and vaccinating children against HPV, all performed in a community setting. The feasibility objectives were to (1) determine if women would attend the community meetings, (2) determine if women perform self-collected vaginal swabs for HR-HPV testing, (3) determine whether the self-collected swab specimens would be adequate for testing, (4) determine whether the results of the Roche Cobas Assay could be transmitted to the study coordinator, and (5) determine whether women would permit their children to be vaccinated against HPV. No actual quantification of these parameters was done before the study began; this was a feasibility study, and success for each of these parameters was arbitrarily decided.

Webuye is a community located in the western region of Kenya, on the highway to Uganda.

The total population of Webuye village is approximately 25,000; it was estimated that there are approximately 5000 to 6000 women between the ages of 30 and 55 years. A community entry strategy was utilized to introduce the study and to invite women to community meetings.

Prior to study initiation, a female Kenyan counselor was trained about cervical cancer, how to educated women about this malignancy, and how to instruct women in performance of self-collected swabs. Village chiefs, village elders, women deemed to be community leaders, and leaders of the local church were then approached by the counselor and study coordinator to discuss the goals, strategy, and risks and benefits of the study. Discussions focused on the importance of early screening for cervical cancer, the use of self-collected swabs for screening, and vaccination of children against HPV.

After these meetings with community leaders, women in the community were informed of the study by word-of-mouth and with posters distributed within the community. They then came to the scheduled community meetings. The counselor and the study coordinator organized and led community meetings, where women were educated about cervical cancer and instructed in the performance of self-collected vaginal swabs using an instructional brochure (available in both Swahili and English) that was developed for the project. For the study, a total of six community meetings were held (25 to 40 women attended each meeting) between February 2019 and December 2020. To be eligible for the study, women had to be between the ages of 30 and 55 years and non-pregnant. The HIV status of women was self-reported then verified by inspection of AMPATH medical records. A total of 227 women attended the meetings and were invited to participate in the study, and 200 women agreed to enroll.

Due to concerns about transmission of Covid-19 infection, community meetings after March 2020 were held in the open air, under tree shade or in tents where good air circulation was assured. Moreover, all participants were expected to wear masks and adhere to measures of physical distancing of 1.5 meters or more from the next person. The study team provided hand sanitizers and facemasks for use during study activities.

Self-collected vaginal swabs

Following instruction and distribution of the brochure, women performed the self-collection in a private setting (behind a screen) using an Evalyn Brush (Rover Medical Devices, Oss, The Netherlands), placing the brush into a prelabeled collection tube without liquid media. The swabs/collection tubes were then given to the counselor. Swabs were delivered by motor vehicle courier at ambient temperature to a commercial laboratory in Nairobi (Lancet Laboratories, Nairobi, Kenya), because the platform for the Roche Cobas Assay was not yet available at Moi University or MTRH. Swabs were then placed in PreservCyt and cellular material was eluted, and the Roche Cobas Assay was performed.

Testing swabs for oncogenic HPV

Swabs were tested for oncogenic or "high-risk" (HR) HPV DNA using the Roche Cobas Assay, a test that provides specific HPV 16 and HPV 18 detection as well as detection of any of 12 additional HR-HPV types (HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and is an FDA-approved test for cervical cancer screening in the United States.[8-12] Results of the assay were delivered electronically to the study coordinator in Eldoret, and data were entered into a RedCap database created for this project.

Screening for cervical cancer by VIA

HPV DNA test results were not used to triage women for VIA. All 200 women were asked to travel to the clinic for VIA, because this is the current standard of care in the region. Women with a VIA examination that revealed acetowhite areas suggesting dysplasia ("abnormal VIA") were treated according to established local algorithms. VIA-positive women were categorized into cryotherapy-eligible and non-cryotherapy eligible groups. For women to be cryotherapy-eligible they were required to be non-pregnant and have an acetowhite lesion visible in its entirety, covering $<75\%$ of cervix, no evidence of abnormal blood vessels, no anatomical lesion/defect to prevent the cryoprobe from flush contact, and no evidence of invasive cervical cancer. Cryotherapy-eligible women were treated immediately with cryotherapy without cervical biopsy, a programmatic "see-and-treat" strategy designed to reduce loss to follow-up. Those who are cryotherapy ineligible were rescheduled, usually in 2 to 3 weeks' time, for colposcopy and biopsy, and management depending on the histological findings. Women with CIN 2 and CIN 3 were treated with Loop Electrosurgical Excision Procedure (LEEP). The LEEP specimens were sent to the laboratory for histopathological evaluation. The women were then re-evaluated 6 months post-LEEP. A pelvic examination was done, and for those whose squamo-columnar junction (SCJ) was visible, VIA was performed. For those whose SCJ was not visible, a swab for cytological (Pap) smear was taken. Those who screened positive then had a biopsy taken, and if histology results were CIN 2 or CIN 3, they underwent a repeat treatment with LEEP. In the event of suspected cancer, based on visual assessment or biopsy results, women were sent to the Gynecologic Cancer Clinic at MTRH.

Results of the Roche Cobas Assay were shared with all 200 participants through phone communication or one-on-one meetings between participants and the study counselor. Women who had HR-HPV positive results were scheduled to return to the clinic for a colposcopy and biopsy procedure that was performed by a gynecologic oncologist. HPV-based screening is not generally available in Kenya, and this pilot study was designed to explore the feasibility of this screening method. In the meantime, VIA will remain the screening method of choice for these women.

HPV vaccination

The project had planned to offer vaccination against HPV (quadrivalent HPV vaccine, Merck and Co., Inc.) to children/grandchildren (boys and girls), ages 10 through 26, of women attending the community meetings. Vaccine was not available due to several logistical issues; therefore, no child received vaccination during the study period.

Statistical analyses

Age, distribution of HPVs (any HPV, HPV 16, HPV 18, and HPV non-16/18), results of VIA examination and biopsy were reported and compared among HIV-infected and HIV-uninfected participants. Age was summarized using median and interquartile range (IQR), and compared using t-test between HIV-infected and HIV-uninfected participants. HPV, VIA, and biopsy results were summarized using frequency and percentage. These parameters were then compared using chi-square tests or Fisher's exact tests between HIV-infected and HIV-uninfected participants, as shown in the table legends.

Results

Enrollment of study participants at community meetings

Six community meetings were held in the Webuye area. Nearly all women invited from the local community attended one of the meetings, and all women who attended the meetings agreed to enroll in the study. Enrollment was stopped at 137 women in the spring of 2020, because the Covid-19 pandemic made it difficult to hold community meetings. Therefore, the number of women enrolled as of 1 March 2020 was 137. Enrollment was continued as of 15 November 2020, with cautionary measures described above. Two community meetings were held in the Webuye area in December 2020, and 63 additional women were enrolled. These women were sent for VIA, and self-collected vaginal swabs were delivered to Lancet Laboratories in Nairobi for performance of the Roche Cobas Assay for HR-HPV DNA detection.

Of 200 women, 151 (75.5%) were HIV-uninfected and 49 (24.5%) were HIV-infected. The median age (and IQR) for all 200 women in the study was 42 years (33.0, 48.0); HIV-infected women were slightly older than the HIV-uninfected women, but this difference was not significant (Table 1).

Self-collected vaginal swabs and HR-HPV testing

Following the educational session on cervical cancer and prevention, all 200 women provided self-collected swabs. Swabs were transported to the laboratory in Nairobi and tested for HR-HPV using the Roche Cobas Assay. Swabs from all 200 women were positive for human beta-globin, indicating that 100% were adequately performed.

Table 1 provides HPV detection data on the 200 women. HPV of any of the HR-HPV types in the Roche Cobas Assay ("Any HPV") was detected in 49 of all 200 participants (24.5%), including 31 of 151 (20.5%) of HIV-uninfected women and in 18 of 49 (36.7%) of HIV-infected women ($P=.022$). The Roche Cobas Assay provides individual typing information for HPV 16 and HPV 18. As shown in Table 2, detections of HPV 16 and HPV 18 were not different between HIV-uninfected and HIV-infected women. Non-HPV 16/18 types were detected in 35 of 200 participants (17.5%) including 19 of 151 (12.6%) HIV-uninfected women and in 16 of 49 (32.7%) HIV-infected women ($P=.001$).

Table 1. Age and HPV distribution in 200 women enrolled in the study.

Variable	Overall N = 200	HIV-uninfected N = 151	HIV-infected N = 49	P-value
Median age (IQR)	42.0 (33.0, 48.0)	40.0 (31.0, 48.0)	44.0 (36.0, 48.0)	0.062[a]
Any HPV,[b] n (%)				0.022[c]
Negative	151 (75.5%)	120 (79.5%)	31 (63.3%)	
Positive	49 (24.5%)	31 (20.5%)	18 (36.7%)	
HPV 16, n (%)				0.782[c]
Negative	186 (93.0%)	140 (92.7%)	46 (93.9%)	
Positive	14 (7.0%)	11 (7.3%)	3 (6.1%)	
HPV 18, n (%)				0.720[d]
Negative	197 (98.5%)	149 (98.7%)	48 (98.0%)	
Positive	3 (1.5%)	2 (1.3%)	1 (2.0%)	
HPV non-16/18,[e] n (%)				0.001[c]
Negative	165 (82.5%)	132 (87.4%)	33 (67.3%)	
Positive	35 (17.5%)	19 (12.6%)	16 (32.7%)	

HPV: human papillomavirus.
[a]P-value from t-test.
[b]HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.
[c]P-value from chi-square test.
[d]P-value from Fisher's exact test.
[e]HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

Table 2. Results of VIA examinations and cervical biopsies.

VIA	All women (N = 200)	HIV-uninfected (N = 151)	HIV-infected (N = 49)	P-value
Normal	192 (96.0%)	145 (96.0%)	47 (95.9%)	0.637[a]
Abnormal	6 (3.0%)	4 (2.6%)	2 (4.1%)	
Not performed	2 (1.0%)	2 (1.3%)		
Cervical biopsy	**All women with abnormal VIA (N = 6)**	**HIV-uninfected women with abnormal VIA (N = 4)**	**HIV-infected women with abnormal VIA (N = 2)**	**P-value**
CIN 1[b]	1 (16.7%)	1 (25.0%)		0.411[a]
CIN 2	2 (33.3%)	2 (40.0%)		
CIN 3	1 (16.7%)		1 (50.0%)	
Microglandular hyperplasia	1 (16.7%)	1 (25.0%)		
Biopsy not performed			1 (50.0%)	

VIA: visual inspection with acetic acid.
[a]P-value from Fisher's exact test.
[b]Cervical intraepithelial neoplasia grade 1.

Results of VIA and cervical biopsy

A total of 198 women (99.0% of 200 women enrolled) traveled to the Webuye Clinic as instructed for cervical cancer screening by VIA. Two women had not yet attended the Webuye Clinic for VIA as of 21 January 2021. VIA was performed on 198 women at the Clinic; 192 VIA examinations were normal and six were abnormal (Table 2). This was fewer abnormal VIA examinations than expected; the clinic generally records approximately 10% to 15% abnormal VIA examinations. There was no significant difference in the percentage of abnormal VIA examinations between HIV-uninfected and HIV-infected women.

Two women of the 200 total did not travel to the clinic for VIA as requested, although the results of the Roche Cobas Assay were shared with these and all participants through phone communication or one-on-one meetings with study counselor. Every attempt was made to contact each woman to provide the results of her Roche Cobas Assay (HR-HPV) testing and to discuss the significance of the test results. Women who had positive Roche Cobas Assay results were scheduled to return to the clinic for a colposcopy and biopsy

Table 3. Details of six women with abnormal VIA examinations.

Subject #	HIV status	HPV 16	HPV 18	Non-16/18 HR-HPV[a]	Cervical biopsy[b]
1	Positive	Not detected	Not detected	Not detected	No biopsy performed
89	Positive	Detected	Not detected	Not detected	CIN[c] 3
98	Negative	Not detected	Not detected	Not detected	CIN 1
121	Negative	Not detected	Not detected	Not detected	Negative
122	Negative	Not detected	Not detected	Not detected	CIN 2
130	Negative	Detected	Not detected	Not detected	CIN 2

HPV: human papillomavirus; VIA: visual inspection with acetic acid.
[a]HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.
[b]Cervical biopsy performed if VIA examination was abnormal per Kenya standard.
[c]Cervical intraepithelial neoplasia.
Numerals refer to the degree, or "grade" of dysplasia from 1 (minimal) to 3 (full thickness, equivalent to carcinoma in situ).

procedure that was performed by a gynecologic oncologist. For the two women who did not travel to the clinic for VIA, one had a negative Roche Cobas Assay and one had a positive Roche Cobas Assay (positive for HR-HPV, not HPV type 16 or 18); normally this later participant would be asked to return for counseling and colposcopy, but she had left the region and could not return, despite the advice of the study counselor's request and advice.

Cervical biopsy was indicated for all six women with abnormal VIA; however, five women underwent cervical biopsy and one woman (Subject 1) relocated to another city and was treated (with cryotherapy) with no cervical biopsy performed (Table 2). Of the four HIV-uninfected women who underwent cervical biopsy, two cases of CIN 2 were identified. One HIV-infected woman underwent cervical biopsy and CIN 3 was identified. Additional details of the six women with abnormal VIA examinations are shown in Table 3. Four of the six women with abnormal VIA examinations had no HR-HPV DNA detected in self-collected vaginal swabs and two women had HR-HPV DNA detected (both had HPV 16 detected).

Because all women in the study did not undergo cervical biopsy, the sensitivity and specificity of HR-HPV testing for detection of underlying CIN 2 or CIN 3 could not be done. In addition, although there was no significant difference in the percentage of abnormal VIA examinations between HIV-uninfected and HIV-infected women, the number of participants in each group was too small to calculate significance.

Vaccination against HPV

Women were asked to provide permission for their children to be vaccinated against HPV. All women with children ages 10 through 26 were willing to have their children vaccinated. Although the HPV vaccine was donated and available for the study, no doses were given because of prolonged delivery issues to Kenya and custom costs. A total of 432 children (227 girls and 205 boys) were included in a registry for possible future vaccination.

Discussion

This pilot study of Kenyan women living in a village setting provided information on several important points related to cervical cancer control and eventual eradication. First, women were eager to attend community meetings to learn about cervical cancer and prevention. Although the response rate to invitation was not calculated, the counselor believed that nearly all invited women attended. In future studies, women will be surveyed at the time of invitation to the community meetings to assess potential barriers to this type of screening that occur prior to the meeting if they refuse to attend. Second, the brochure created for the project was very useful in instruction in self-collection of vaginal swabs. This brochure was deemed both acceptable and useful, as determined by the counselor and study coordinator. Third, women were uniformly willing to provide self-collected vaginal swabs for HPV testing. There were no women who objected to the screening method among the women who attended the meeting, given education on cervical cancer, and shown the detailed brochure.

All self-collected swabs were adequate for HPV testing (Roche Cobas Assay) based on positive human beta-globin amplification. This is a critically important finding, because swabs may not be transported to a laboratory rapidly, and ambient temperature may be potentially damaging to DNA on the swabs. It is very reassuring that amplification of DNA was adequate in all 200 swabs from women in a semi-rural setting, because swabs needed to be driven at ambient temperature for nearly 6 h to Nairobi for processing. In the future, it is expected that the Moi University and AMPATH Laboratory, which is much closer to the Webuye Clinic, will have the capacity to perform the Roche Cobas Assay.

HR-HPV types were detected in 49 of all 200 participants (24.5%) and in a significantly higher percentage of the subset of HIV-infected women. This finding is in agreement with another study conducted in Eldoret using clinician-obtained swabs that were analyzed for HR-HPV using the Roche Linear Array Assay.[13] In addition, other studies indicate a close correlation between clinician-obtained and self-collected vaginal

swabs for HR-HPV testing.[14-16] Non-HPV 16/18 HR-HPV types were also detected in a significantly higher percentage of women who were HIV-infected compared with HIV-uninfected women, also in agreement with previously published findings.[13] Thus, there appears to be consistency between the findings using different sampling methods and a different HR-HPV detection assay.

Women were willing to travel to the Webuye Clinic for VIA following the collection of swabs. Of all women, 99% made this trip, which was not more than an hour for most. It is not completely clear why two women were unable to travel to the Webuye Clinic, although one had left the area, and we believe that the Covid-19 pandemic may have affected some women's ability to travel. Of 198 women who traveled to the clinic for VIA, only six women had abnormal examinations. This is a smaller percentage than has been observed in the Webuye Clinic in recent years; the reason why the women in the study had few abnormal VIA examinations is not clear. In addition, the lack of difference in VIA positivity between HIV-infected and HIV-uninfected women may be attributable to the overall small number of women who had an abnormal VIA examination.

The reason for lower numbers of VIA-positive cases was unlikely due to change in staff performing the procedure, as the same study staff were employed throughout the duration of the study. Cervical cancer screening by VIA at Webuye is conducted by trained and certified registered nurses who have undergone mentorship by program consultants. These nurses have continuously practiced VIA for over a decade. Regular refresher training for the staff who perform VIA are provided as part of quality assurance in the AMPATH screening program. Second, Webuye clinic has been operational for over a decade. In future studies, details of past cervical cancer screening will be obtained for each participant to address this potential study limitation.

As women age, the visibility of SCJ decreases due to its receding in the endocervical canal, making visual assessment impossible. As a standard of care, VIA screening is only utilized for women with type I transformation zones (the SCJ is located in the ectocervix and fully visible) and type II transformation zones (the SCJ has some endocervical component but still fully visible). Women, usually in an older age group, with type III transformation zones (the SCJ is entirely in the endocervical canal and not visible) are not screened with VIA. No women enrolled for this study had a type III transformation zone.

There were several limitations of this pilot study. First, the study focused on Webuye, in the western region of Kenya, and the results may not be generalizable to all of Kenya. Second, the actual response rate of local women to invitation to community meetings was not calculated for this pilot study. This pilot study was not designed to screen all women in the community, but rather to determine if a high percentage of women who were invited would attend the community meetings. Optimally, the response rate should have been calculated, and thus, this a limitation of the pilot study. A larger study in the future study will address this important question. Third, the primary aim of this study was to determine the feasibility of the community-based model for cervical cancer prevention. For this pilot study, we did not have a specific hypothesis related to HPV prevalence of VIA abnormality to test in this stage of program development. Therefore, a power calculation was not performed to determine the optimal number of study participants. Fourth, socio-demographic information was not collected from women participating in this pilot study and would have been useful since various factors could act as barriers to access cancer screening services. A future study will include collection of detailed socio-demographic information. Finally, women were uniformly willing to have their children vaccinated against HPV at community meetings, although no vaccine could be obtained, limiting the value of the overall program. HPV vaccination of children is crucial in reducing the burden of cervical cancer in Kenya. Vaccination against HPV is highly effective in preventing infection, as well as prevention of pre-cancerous and cancers of the cervix caused by vaccine types.[17-20] A future study will include HPV vaccination of children whose mothers are enrolled in the community-based cervical cancer screening program, thus providing the necessary combination of preventive measures that will ultimately lead to eradication of cervical cancer in western Kenya.

Conclusion

In conclusion, this pilot study showed that self-vaginal swabs for HR-HPV testing were acceptable to women attending community meetings in western Kenya, that most women were willing to follow-up for further care in the local clinic, and that women were uniformly willing to have their children vaccinated against HPV at community meetings. Future studies will be performed in which calculations of participant attendance are addressed, and HPV vaccination is provided to girls attending the community meetings.

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Author contributions

Conception and design: OO, PT, KM, SK, TM, MA, AE, YT, and DB. Analysis and interpretation of the data: OO, PT, KM, SK, MA, AE, YT, and DB. Drafting of the paper: OO, PT, KM, SK, AE, YT, and DB. Revising it critically for intellectual content: OO, PT, KM, SK, MA, AE, YT, and DB. Final approval of the version to be published: OO, PT, KM, SK, TM, MA, AE, YT, and DB. All authors agree to be accountable for all aspects of the work.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. Dr Brown receives research funding from several sources including Merck and Co., Inc. Dr Brown serves as a consultant for PDS, Inc.

Ethical approval

Ethical approval for this study was obtained from the review boards at Moi Teaching Referral Hospital (MTRH) and Moi University, Eldoret, Kenya, the Kenya Medical Research Institute's Scientific and Ethics Review Unit (Protocol 0001984), and the Institutional Review Board of Indiana University School of Medicine (Protocol 1712513308).

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Informed consent

Written informed consent was obtained from all subjects before the study. All study participants received a written copy of the consent (English or Swahili).

Trial registration

ClinicalTrials.gov Protocol Registration and Results System
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References

1. Bosch FX and de Sanjose S. Chapter 1: human papillomavirus and cervical cancer—burden and assessment of causality. *J Natl Cancer Inst Monogr* 2003(31): 3–13.
2. Bosch FX and de Sanjose S. The epidemiology of human papillomavirus infection and cervical cancer. *Dis Markers* 2007; 23: 213–227.
3. Kangmennaang J, Onyango EO, Luginaah I, et al. The next sub Saharan African epidemic? A case study of the determinants of cervical cancer knowledge and screening in Kenya. *Soc Sci Med* 2018; 197: 203–212.
4. Huchko MJ, Ibrahim S, Blat C, et al. Cervical cancer screening through human papillomavirus testing in community health campaigns versus health facilities in rural western Kenya. *Int J Gynaecol Obstet* 2018; 141(1): 63–69.
5. Mabeya H, Menon S, Weyers S, et al. Uptake of three doses of HPV vaccine by primary school girls in Eldoret, Kenya; a prospective cohort study in a malaria endemic setting. *BMC Cancer* 2018; 18: 557.
6. Vermandere H, Naanyu V, Mabeya H, et al. Determinants of acceptance and subsequent uptake of the HPV vaccine in a cohort in Eldoret, Kenya. *PLoS ONE* 2014; 9: e109353.
7. Inui TS, Nyandiko WM, Kimaiyo SN, et al. AMPATH: living proof that no one has to die from HIV. *J Gen Intern Med* 2007; 22(12): 1745–1750.
8. Dreyer G, Maske C and Stander M. Clinical evaluation and budget impact analysis of cervical cancer screening using cobas 4800 HPV screening technology in the public sector of South Africa. *PLoS ONE* 2019; 14(9): e0221495.
9. Tranberg M, Jensen JS, Bech BH, et al. Good concordance of HPV detection between cervico-vaginal self-samples and general practitioner-collected samples using the Cobas 4800 HPV DNA test. *BMC Infectious Diseases* 2018; 18: 348.
10. Cook DA, Mei W, Smith LW, et al. Comparison of the Roche Cobas(R) 4800 and digene hybrid capture(R) 2 HPV tests for primary cervical cancer screening in the HPV FOCAL trial. *BMC Cancer* 2015; 15: 968.
11. Abraham J and Stenger M. Cobas HPV test for first-line screening for cervical cancer. *J Community Support Oncol* 2014; 12(5): 156–157.
12. Rao A, Young S, Erlich H, et al. Development and characterization of the cobas human papillomavirus test. *J Clin Microbiol* 2013; 51(5): 1478–1484.
13. Ermel A, Tonui P, Titus M, et al. A cross-sectional analysis of factors associated with detection of oncogenic human papillomavirus in human immunodeficiency virus-infected and uninfected Kenyan women. *BMC Infectious Diseases* 2019; 19: 352.
14. Ogilvie GS, Patrick DM, Schulzer M, et al. Diagnostic accuracy of self collected vaginal specimens for human papillomavirus compared to clinician collected human papillomavirus specimens: a meta-analysis. *Sex Transm Infect* 2005; 81(3): 207–212.
15. Obiri-Yeboah D, Adu-Sarkodie Y, Djigma F, et al. Self-collected vaginal sampling for the detection of genital human papillomavirus (HPV) using careHPV among Ghanaian women. *BMC Women Health* 2017; 17: 86.
16. Kamath Mulki A and Withers M. Human Papilloma Virus self-sampling performance in low- and middle-income countries. *BMC Women Health* 2021; 21: 12.
17. Karube A, Saito F, Nakamura E, et al. Reduction in HPV 16/18 prevalence among young women following HPV vaccine introduction in a highly vaccinated district, Japan, 2008-2017. *J Rural Med* 2019; 14(1): 48–57.
18. Ogilvie GS, Naus M, Money DM, et al. Reduction in cervical intraepithelial neoplasia in young women in British Columbia after introduction of the HPV vaccine: an ecological analysis. *Int J Cancer* 2015; 137: 1931–1937.
19. Hariri S, Bennett NM, Niccolai LM, et al. Reduction in HPV 16/18-associated high grade cervical lesions following HPV vaccine introduction in the United States: 2008–2012. *Vaccine* 2015; 33: 1608–1613.
20. Kjaer SK, Nygard M, Sundstrom K, et al. Final analysis of a 14-year long-term follow-up study of the effectiveness and immunogenicity of the quadrivalent human papillomavirus vaccine in women from four Nordic countries. *Eclinicalmedicine* 2020; 23: 100401.