

**Women's preference of specimen collection methods for human papillomavirus detection:
A cross-sectional study of HIV-positive and HIV-negative women in Mombasa, Kenya.**

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Abstract

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Self-collection of genital specimens for HPV detection may increase cervical cancer screening uptake in Sub-Saharan Africa. We hypothesized that women would prefer self-collection to clinician-collection of genital specimens. To assess this, and their preference between two different self-collection cytobrushes, 200 women were enrolled in a cross-sectional study in Mombasa, Kenya. Participants provided self-collected specimens using the Evalyn cytobrush (Rovers) and the Viba cytobrush (Rovers) stored in Aptima media (Hologic). A clinician also collected specimens. A post-examination questionnaire assessed preferences for the different methods of specimen collection. The majority of women preferred clinician-collection to self-collection (68% versus 32%, $p<0.01$). For self-collection, the Evalyn brush was preferred to the Viba brush (53% versus 27%, $p<0.01$). There was no association between preference for self-collection and preference for self-collection cytobrush. Further research to understand and address obstacles to self-collection may be needed to improve the uptake of this approach.

Background

Screening and treating pre-cancerous changes are effective means to prevent invasive cervical cancer. Most high-income countries have successfully implemented screening using the Papanicolaou (Pap) smear, resulting in substantial declines in incidence and mortality over the past 40 years [1-3]. Despite success with Pap smears, the test presents a number of major limitations. Among the most important is the low sensitivity (50%-70%) of a single Pap smear to detect high grade cervical intraepithelial neoplasia (CIN 2+). As a result, repeat testing is recommended to improve performance [4, 5]. In addition, evaluation of cervical cytology is subject to high inter-performer variability, leading to variable accuracy [5, 6].

Detection of human papillomavirus (HPV) in genital specimens has emerged as an alternative for primary cervical cancer screening [1, 7-11]. The causal relationship between genital HPV infection and invasive cervical cancer is well established [12, 13]. Human papillomavirus has been identified in more than 99% of cervical cancer cases, and persistent HPV infection is necessary for development and progression of cervical lesions leading to cancer [12, 13]. Of the more than 150 HPV subtypes identified, 18 are recognized to have a high potential for neoplasia. These high-risk HPV (hrHPV) subtypes contribute to more than 95% of all cervical cancer cases [14].

High-risk HPV testing has a significantly greater sensitivity than Pap smears in detecting high-grade cervical lesions (CIN 2+) [8, 11, 15]. An additional advantage is that self-collected genital specimens for HPV detection have demonstrated a sensitivity and specificity that parallels that of

clinician-collected specimens for detecting high-grade cervical lesions (CIN 2+) [9, 10, 16].

This is particularly important as women in some settings report that they prefer self-collection, citing greater comfort and less embarrassment compared to clinician-collection of genital specimens [17].

Most data on women's preference between self-collection and clinician-collection of genital specimens are derived from Europe and North America. In contrast, little is known regarding preference between collection methods among women in sub-Saharan Africa, where cultural and religious beliefs concerning genital self-examination are notably different. These differences may influence the acceptability of self-testing. Interestingly the few Sub-Saharan African studies on self-testing for other conditions, including HIV/AIDS suggest that acceptability could be high, and self-testing could be of great benefit to improving care [18, 19]. Understanding sub-Saharan African women's preference between self-collection and clinician-collection of specimens will help to guide future interventions, including effective messaging.

Our study, conducted in a cohort of high-risk women in Mombasa, Kenya, assessed women's preference for self-collection versus clinician-collection of genital specimens for detection of hrHPV. We also explored women's choice between two different self-collection devices, the Evalyn and the Viba cytobrushes. We hypothesized that women would prefer self-collection over clinician-collection. In addition, we hypothesized that the Evalyn cytobrush would be preferred in comparison to the Viba cytobrush for self-collection of specimens.

METHODS

Study design: We conducted a clinic-based, cross-sectional study of HIV-positive and -negative women participating in a cohort study of women at high risk of sexually transmitted infections (STIs) and HIV in Mombasa, Kenya. Study procedures were integrated into the ongoing follow-up procedures for the cohort [20, 21]

Study visit procedures: Clinical procedures, including self-collection of HPV specimens, were performed at the Ganjoni Health Centre in Mombasa. Women were invited to participate in this sub-study during routine cohort visits. A study nurse briefly introduced the study to eligible cohort participants and invited participation. Women who agreed were referred to the study counselor, who provided further information, responded to any questions, and obtained written informed consent.

For self-collection of genital specimens, women were led to a private room. A study nurse provided brief instructions for specimen collection, after which the women were left to collect specimens in private. Pictorial diagrams with detailed instructions on self-collection were also available. Self-collection was performed using two devices, the Evalyn cytobrush (Rovers®, Netherlands) and the Viba cytobrush (Rovers®, Netherlands). The physical characteristics and specimen handling differ between these two devices (Figure 1).

The Evalyn cytobrush is pink in color, consists of a plunger, containing white bristles at the tip, a transparent casing and a transparent cap. For self-collection, women were instructed to squat,

pull the plunger down into the clear casing to protect the bristles, and insert the brush into the vagina. Next they pushed the plunger back up, and rotated the brush through five complete turns in the same direction for specimen collection. Each complete rotation was accompanied by an audible click on the device. Self-collection using the Evalyn brush was “dry,” in that there was no need to place the specimens in a cryovial containing media before or during transportation to the laboratory.

The Viba brush is smaller in size, and consists of a blue handle and a white tip containing bristles made of a similar material as the Evalyn brush. The brush was accompanied by a cryovial containing 1 ml of Aptima media (Hologic). Just below the white tip of the Viba brush was a clear casing surrounding the handle. After self-collection, the women directed the tip of the cytobrush into the cryovial and gently pushed the clear casing against the white tip, so that the tip was pushed into the vial. They tightly screwed back the lid onto the vial and placed it in a plastic bag for transportation.

After self-collection, women were led to a separate examination room where a clinician performed a speculum-assisted pelvic examination, including collection of a specimen for HPV detection. Clinician-collection of genital specimens was performed using Hologic’s Cervical Specimen Collection and Transport (CSCT) kit, which contained a collection device, cleaning swab, and a vial containing liquid transport media. The CSCT brush consists of a green plastic handle and a white tip containing bristles similar to those on the self-collection devices. After self-collection, the clinicians broke off the tip of the brush into the cryovial containing Aptima

media. A visual inspection under acetic acid and Pap smear collection were also performed at the same time.

All clinicians in this study had extensive training and experience in genital examination, including performing speculum examinations and collection of genital specimens as part of the parent cohort. In addition, in preparation for this study, all clinicians underwent refresher training on HPV specimen collection, VIA, and Pap smear collection. Clinical staff also completed refresher training on standard operating procedures (SOPs) for the study once every year.

Post-examination questionnaire to assess women's preference: Following the clinical examinations, women participated in a structured interview using a standardized questionnaire to assess their preferences for different methods of specimen collection. For the question on self-collection versus clinician-collection, women were asked, "If you were to be tested for HPV infection again, how would you like the specimen to be collected?" They gave their answers as either self-collection or clinician-collection.

To assess women's preferences between the Evalyn and Viba cytobrushes, they were asked, "Which of the two brushes you collected yourself did you like best?" They were then asked to select one of three possible responses; "I liked the blue brush (Viba brush)," "I liked the pink brush (Evalyn brush)," and "I liked them both equally". To explore women's perceptions of specific characteristics of the two brushes, they were asked four questions. Their responses to these questions were graded on a 5-point Likert scale, with a range from one for "strongly agree"

to five for “strongly disagree.” The four questions were: “Was the brush comfortable to insert?” “Were you concerned about hurting yourself with the brush?,” “Were you concerned about using the brush properly?”, and, “Were the instructions for self-collection using the brush easy to understand?”

Sample size: We included 200 women in the study, 100 HIV-negative and 100 HIV-positive. The sample size was based on detecting a difference in sensitivity for identifying high grade lesions between self-collected specimens versus clinician-collected specimens. The results of our analyses comparing the sensitivity of self-collection versus clinician-collection are presented elsewhere. For this secondary analysis focused on participant preferences, we estimated the power to detect a significant difference in proportion of women who prefer self-collection versus clinician-collection of genital specimens. With 200 women, we estimated >90% power to detect a difference of 10% or more in the proportion of women who prefer self-collection compared to clinician-collection of genital specimens using a two-sided hypothesis test and an alpha of 0.05.

Statistical analysis: Analyses were performed using STATA version 13. Baseline descriptive characteristics of study participants included number and proportion for binomial variables and mean and standard deviations for continuous variables. The primary aim of the study was to test the hypothesis that women would prefer self-collection to clinician-collection of genital specimens. To test the difference in proportions for each category, we performed an exact binomial probability test, under the null hypothesis that women would prefer each specimen-collection method equality (i.e., $p=0.50$ for selecting self-collection or clinician-collection). To determine which self-collection cytobrush was most preferred, we compared the proportion of

women who preferred the Evalyn brush to those who preferred the Viba brush and those who preferred them both equally. To determine the statistical significance of this difference, we performed a one-sample t test, under the null hypothesis that the average preference would equal 0.5, and thus be equidistant between the Viba brush (scored at 0) and the Evalyn brush (scored at 1).

Logistic regression analyses were performed to explore the predictors of preference for self-collection of genital specimens. The variables tested were identified *a priori* through a review of the literature. We included factors associated with high risk of developing high-grade cervical lesions as well as those associated with self-testing and screening for cervical cancer. These included women's age at first sexual intercourse [22], current age [23], level of education [24, 25], marital status [24], parity [23], and religion [26].

To explore the predictors of preference for the Evalyn brush, Viba brush, and preference for both equally, we performed an ordered logistic regression analysis, with responses distributed between 0 for the Viba brush, 1 for no preference, and 2 for the Evalyn brush. The predictors included in the models were similar to those included in our analysis of predictors of preference for self-collection versus clinician-collection. Odds ratios greater than 1 in this analysis indicated a preference for the Evalyn brush, while odds ratios less than 1 indicated a preference for the Viba brush. We performed chi-squared tests to explore whether there was an association between preference for self-collection and preference for a particular collection device. Finally, to better understand women's preferences for specific collection devices, we explored their perceptions about characteristics of the two brushes. Median and interquartile ranges were used

to summarize the responses to each question that was graded on a Likert scale. Wilcoxon signed-ranks tests were performed to analyze differences in paired responses to each of these questions for the Evalyn brush compared to the Viba brush.

Results

Between August 2013 and April 2014, a total of 200 women were enrolled. Of these, 199 (99%) participated in the post-examination interview and were included in this study. Their baseline demographic and clinical characteristics are shown in Table 1.

Of 199 women studied, 63 (32%) reported preference for self-collection compared to 136 (68%) who reported preference for clinician-collection of genital specimens (exact binomial probability test, $p < 0.001$). Baseline demographic and clinical characteristics were broadly similar between women who preferred clinician-collection and those who preferred self-collection. HIV status was not associated with preference for specimen collection method (Chi-square test, $p = 0.27$). Results from univariate logistic regression analyses of predictors of preference for self-collection of genital specimens are presented in Table 2. Of the potential predictors evaluated, only age at sexual debut was significantly associated with preference for self-collection. Increasing reported age at sexual debut was associated with a significantly greater odds of preferring self-collection (odds ratio [OR] 1.17, 95% confidence interval [CI] 1.02 – 1.33, $p=0.03$).

For self-collection, 105 (53%) women reported preference for the Evalyn cytobrush, 50 (25%) preferred the Viba cytobrush and 44 (22%) liked both cytobrushes equally ($p=0.05$; one-sample t test). In univariate ordered logistic regression analyses, none of the covariates examined were

significantly associated with preference for a particular self-collection method (Table 3). In addition, we found no association between preference for specimen collection method (self-versus clinician) and preference for self-collection cytobrush (Chi-square test, $p = 0.69$).

Table 4 presents the responses to questions comparing women's experience with the Evalyn and the Viba cytobrushes and p-values from the test for differences in paired responses to each of these questions. For the questions "Were the instructions for self-collection using the brush easy to understand?" and "Were you concerned about using the cytobrush properly?" women rated both cytobrushes equally. For the question "Were you concerned about hurting yourself with the brush?" responses were more positive for the Evalyn brush compared to the Viba brush. For the question "Was the brush comfortable to insert?" median scores were similar between the two brushes, although a significantly higher proportion of women reported discomfort with the Viba brush.

Discussion

In this study of HIV-positive and HIV-negative Kenyan women participating in a cohort study with regular screening for genital infections, significantly more participants preferred to have genital specimens for HPV testing collected by a clinician rather than to self-collect. Among the self-collection devices, the majority of women preferred the Evalyn cytobrush to the Viba cytobrush. While most women found both cytobrushes comfortable during use and the instructions easy to follow, a significant proportion expressed fears about performing self-collection properly using both brushes. In addition, a substantial proportion of women had concerns about hurting themselves when using the Viba brush.

Our findings contrast with several studies, mostly from the US and Europe, that have reported women's preference for self-collection compared to clinician-collection of genital specimens for HPV testing [9, 27, 28]. A meta-analysis of studies conducted in Europe and North America also reported that uptake of cervical cancer screening in some settings improved when self-collection of genital specimens was included [9]. On the other hand, a study from Cameroon [29], and another conducted in India, Nicaragua, and Uganda [30], reported that women preferred clinician-collection of genital specimens for HPV testing compared to self-collection. In the study from Cameroon [29], a majority of the women reported that self-collection was comfortable and that they were less embarrassed during self-collection. However, they did not trust the validity of the test, and therefore preferred to have a clinician collect the specimens [29].

Our results suggest that women in this Kenyan population may have similar concerns about their ability to collect specimens. When asked, "Were you concerned about using the cytobrushes properly?" most of the women agreed somewhat (Table 4). In contrast, the women's responses were favorable when asked if self-collection was comfortable and if the instructions for self-collection were easy to follow. It is probable that the women had concerns about the validity of the specimens if they did not perform self-collection properly.

Our study has several strengths. Few other studies have evaluated women's preference between the different methods of genital specimen-collection in sub-Saharan Africa. This region contributes the greatest burden of cervical cancer disease globally, and reports the lowest proportion of reproductive-aged women screened annually. Further, none of the previous studies

on self-collection among African women explored their preferences between different types of specimen collection devices. The finding that women reported a preference for one cytobrush over the other is important for the potential scale-up of self-collection programs in this population. Our study was also conducted in a cohort of women who are at a particularly high risk of STIs, including HPV. No prior studies have been conducted in a high-risk population in Africa. Such groups face a greater risk of invasive cervical cancer, and may also have different preferences for specimen collection methods, compared to women in the general population.

One limitation of our study was that self-collection of genital specimens was conducted in a clinic setting. Women had to present to a health facility to self-test. Part of the challenge of cervical cancer screening in sub-Saharan Africa is poor access to health facilities. It is plausible that women's preferences would be different if they were offered the additional convenience of self-collecting specimens at home. It is also important to recognize that this study was conducted in a group of women who were part of an ongoing cohort study in which they undergo frequent pelvic examinations with collection of genital specimens for STI screening. It is possible that the women in this population have grown more comfortable with clinical examinations compared to women in the general population. On the other hand, given that these findings are similar to those reported in other studies from Africa, it is possible that many women from this region prefer to have clinicians collect genital specimens for HPV testing.

In conclusion, our findings suggest that high-risk women in sub-Saharan Africa may prefer clinician-collection of genital specimen for HPV testing rather than self-collection. Areas with inadequate health infrastructure, especially those with few trained clinicians, would benefit

greatly from scale-up of self-collection for cervical cancer screening. In this regard, educating women in this region about the reliability of self-collected specimens for HPV detection would be important to enhance uptake of self-collection of genital specimens for cervical cancer screening.

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Figure 1: The Evalyn cytobrush (left side) and the Viba cytobrush with cryovial containing Aptima media (right side).

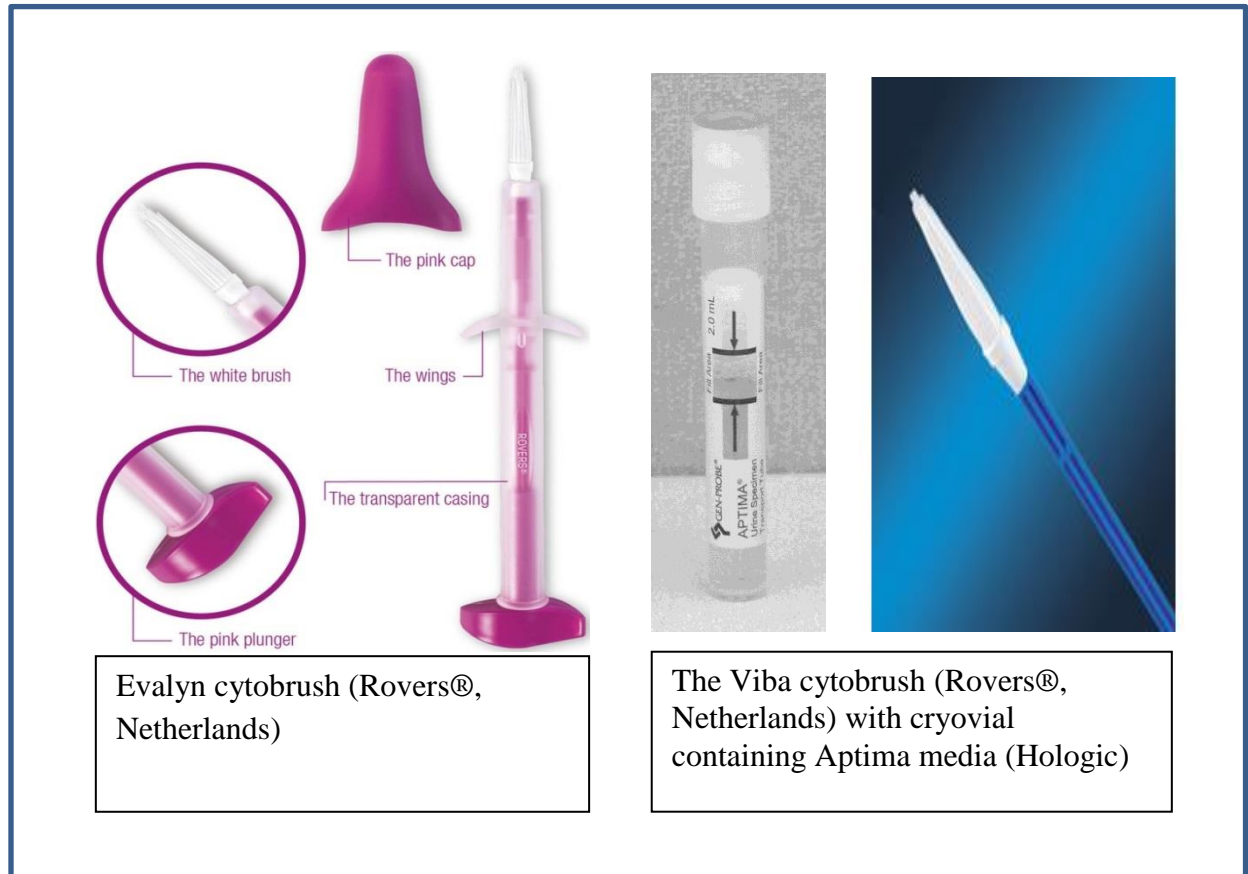


Table 1: Baseline characteristics of 199 female sexual workers from Mombasa, Kenya

Characteristic	Mean (SD) or Number (percent)
Age (years)	37.6 (9.5)
Age at first sex (years)	16.9 (2.3)
>8 years of education (At least some high-school)	91 (46%)
Multiparous	183 (92%)
Ever married	120 (60%)
Religion	
Christian	176 (89%)
Muslim	18 (9%)
Other*	5 (3%)
Using modern contraception other than condoms alone	
No contraceptive method	63 (32%)
Hormonal contraceptive use	53 (27%)
Non-hormonal contraceptive use	83 (41%)
HIV-positive	101 (51%)

*Traditional African religions and no religious affiliation

Table 2: Univariate logistic regression exploring predictors of women’s preference for clinician-collection versus self-collection of genital specimens

Variable	Number (Percent) of women who prefer self-collection N=199	Women who prefer clinician-collection n=136 Mean (SD) or Number (Percent)	Women who prefer self-collection n= 63 Median (IQR) or Number (Percent)	Odds Ratio (95% CI)	p-value
Age (years)		38.2 (9.7)	36.4 (9.1)	0.98 (0.95 – 1.01)	0.23
Age at first sex (years)		16.6 (2.2)	17.4 (2.4)	1.17 (1.02–1.33)	0.03
Parity					
Nulliparous	44%	9 (7%)	7 (11%)	Reference	
Multiparous	31%	127 (93%)	56 (89%)	0.57 (0.20-1.60)	0.28
Education					
8 years and less	27%	79 (58%)	29 (46%)	Reference	
>8 years	37%	57 (42%)	34 (54%)	1.62 (0.89 – 2.96)	0.11
Marital status					
Never married	30%	55 (40%)	24 (38%)	Reference	
Ever married	33%	81 (60%)	39 (62%)	1.10 (0.60 – 2.04)	0.75
HIV status					
HIV-negative	35%	64 (47%)	35 (56%)	Reference	
HIV-positive	28%	72 (53%)	28 (44%)	0.71 (0.39 – 1.30)	0.27

Religion				
Christian	122 (90%)	54 (86%)	Reference	
Muslim	18 (9)	8 (13%)	1.81 (0.68 – 4.83)	0.24
Other*	5 (3)	1 (2%)	0.56 (0.06 – 5.17)	0.61

*Traditional African religions and no religious affiliation

Table 3: Univariate ordinal regression results exploring predictors of women’s preference for the Evalyn cytobrush compared to the Viba cytobrush

Variable	Univariate Analysis	
	Odds Ratio (95% CI)	p-value
Age (years)	1.00 (0.97 – 1.03)	0.94
Age at first sex (years)	1.00 (0.89 – 1.13)	0.98
Parity		
Nulliparous	Reference	
Multiparous	2.69 (0.99-7.32)	0.56
Education		
No high school education	Reference	
At least high school-level	1.20 (0.70 – 2.04)	0.99
Marital status		
Never married	Reference	
Ever married	1.10 (0.64 – 1.89)	0.53
HIV status		
HIV-negative	Reference	
HIV-positive	0.59 (0.35 – 1)	0.53
Religion		
Christian	Reference	
Muslim	1.59 (0.61 – 4.09)	0.34
Other	0.22 (0.04 – 1.27)	0.09

*Traditional African religions and no religious affiliation

Ordered Outcomes: prefers Viba = 0, prefers them both equally =1, prefers Evalyn brush = 2

Table 4: Median scores and interquartile range for responses to questions on experience when using the cytobrushes and p-values from the Wilcoxon signed ranks test for differences in each paired response.

Question	Evalyn Median(IQR)	Viba Median (IQR)	p value
Were the instructions on using brushes easy to understand?	1 (1-1)	1 (1-1)	0.08
Were you concerned about using the brush properly?	2 (1-4)	2 (1-4)	0.15
Were you concerned about hurting yourself?	4 (1-5)	2 (1-5)	0.0004
Was the brush comfortable to insert?	1 (1-1)	1 (1-4)	< 0.001

(1 strongly agree, 2 agree somewhat, 3 neutral, 4 disagree somewhat, 5 strongly disagree)