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Factors influencing Malawian women's willingness to self-collect samples for HPV testing For submission to Journal of Family Planning and Reproductive Health Care

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Abstract

Background—Malawi has the highest incidence of cervical cancer in the world. Only 3% of Malawian women have ever been screened for cervical cancer. Self-collection of samples for human papillomavirus (HPV) testing could increase screening among under-screened and hard-to-reach populations. However, little is known about the acceptability of self-collection in rural African settings.

Aim—We aimed to characterize Malawian women's willingness to self-collect vaginal samples for HPV testing and to identify potential barriers.

Design—We used data from the baseline wave of a community-based cohort study, collected from July 2014 – February 2015.

Setting—Participants were enrolled from the catchment area of a clinic in rural Lilongwe District, Malawi.

Methods—We enrolled women ages 15 - 39 years ($n=824$). Participants answered questions assessing willingness to self-collect a sample for HPV testing, concerns about testing and other hypothesized correlates of willingness to self-collect.

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Results—Two-thirds of women (67%) reported willingness to self-collect a vaginal sample in their homes. Awareness of cervical cancer, supportive subjective norms, perceived behavioral control, and clinician recommendations were all positively associated with increased willingness to self-collect samples for HPV testing. Identified barriers to self-testing endorsed by women included: concerns that the test might hurt (22%), that they might not do the test correctly (21%), and that the test might not be accurate (17%).

Conclusions—This study suggests that self-collection for HPV testing could be an acceptable cervical cancer screening method in this rural population. Findings identify modifiable beliefs and barriers that can inform the development of effective screening programs.

Keywords

Cervical cancer; self-collection; Human Papillomavirus DNA Tests; Human papillomavirus; screening

Introduction

Malawi has the highest age-adjusted incidence rate of cervical cancer in the world, at 76 cases per 100,000 women compared to an incidence rate of 43 cases per 100,000 women in eastern Africa overall and only 14 cases per 100,000 women globally.[1] Among those who are diagnosed with cervical cancer in Malawi, 60% will die from the disease.[1,2] In many countries, screening programs have successfully reduced the incidence and mortality of cervical cancer. However, despite rolling out a national cervical cancer screening program in Malawi using visual inspection with acetic acid (VIA) in 2004, access and utilization remains limited with only 3% of women ever screened for cervical cancer.[1] Cervical cancer screening programs are rare in Malawi and other low-resource regions for many reasons, including lack of health delivery infrastructure and trained personnel, limited health budgets, and competing healthcare priorities.[3,4] With recent advancements in testing for human papillomavirus (HPV), which is responsible for nearly all cases of cervical cancer [5], the establishment of more accessible screening programs in conjunction with existing VIA programs is now possible.

HPV testing identifies presence of HPV infection using a clinician- or self-collected cervical or vaginal sample. HPV testing is now considered a complementary method in conjunction with a Pap test or even a first line screening method. The World Health Organization (WHO) recommends HPV testing as the primary method of cervical cancer screening in places where Pap testing has not been established.[6] Both self-collected and clinician-collected samples for HPV testing have been shown to have sensitivity and specificity comparable to Pap testing in identifying cervical intraepithelial neoplasia grade 2 or higher (CIN 2+).[7,8] HPV testing protocols also allow for a longer interval between screenings, as this approach detects disease progression earlier than cytology.[9] Importantly for an unscreened or under-screened population, one HPV test more effectively reduces cervical cancer incidence than one Pap test, potentially because of the higher sensitivity in detecting lesions with a high potential for malignant transformation.[10] For women who are considered at high risk of HPV infection (e.g. HIV-infected women or women who engage in sexual risk behaviors

such as a higher number of partners [11,12]) or those who cannot access routine screening, self-collection of vaginal samples can lead to increased screening.[13]

While several studies have examined the validity and reliability of self-collected vs. clinician collected samples for HPV testing [8], research on the *acceptability* of self-collected samples for HPV testing is much more limited. The existing data generally suggests that women find self-collection acceptable and easy to perform.[14–16] We sought to examine the willingness of women in rural Malawi to self-collect a vaginal sample for HPV testing.

The Theory of Planned Behavior (TPB) is a widely-used framework for understanding individual's intentions and willingness to engage in health behaviors, including cancer screening and prevention behaviors.[17] Briefly, the TPB is comprised of three conceptual constructs: *attitude toward the behavior*, which considers behavioral beliefs and the individual's evaluation of behavioral outcomes; *subjective norms*, which include how the individual perceives influential others' opinions about the behavior and motivation to comply with those influential others; and *perceived behavioral control* which is the individual's perceived power to engage in a particular behavior.[17,18] The TPB has been used to examine women's intentions related to cervical cancer screening [19–21], but to our knowledge the present study is among the first to incorporate TPB concepts to understand the acceptability of self-collecting samples for HPV testing in a non-clinic setting in a low-resource setting. We aimed to characterize Malawian women's willingness to self-collect a vaginal sample for HPV testing and to identify the barriers that will need to be addressed before a cervical cancer screening program relying on self-collected samples can be successfully implemented.

Methods

Study design and population

This analysis used data from the baseline wave of a community-based cohort study on sexual and reproductive health decision making in rural Lilongwe District, Malawi from July 2014 to February 2015. The cohort study used two-stage, stratified, cluster sampling to select villages to enable enrollment of 1,000 women of reproductive age (aged 15-39 years). All women in the selected villages in the eligible age range were invited to participate. A subset of enrolled women received a series of questions on cervical cancer and cervical cancer screening (the questions went to a subset of participants because they were added to the survey after data collection began). Trained research assistants traveled to each selected village and conducted face-to-face interviews in Chichewa with all consenting women. Data were recorded on tablet computers using the Magpi electronic data capture system (Magpi, Washington, DC) and uploaded nightly to an internet-based storage system.

Measures

We used the TPB to develop survey questions related to women's willingness to self-collect a vaginal sample for HPV testing in a non-clinic setting.

At the start of the series of questions, interviewers asked all women if they had ever heard of cervical cancer (yes/no). For those women who were not familiar with cervical cancer,

interviewers explained that it “is a disease that attacks the cervix, which is part of the female reproductive system,” and then proceeded with the survey. Before questions about self-collecting a vaginal sample for HPV testing, interviewers provided a brief description of the procedure indicating that: self-collection may help test for cervical cancer even if a woman doesn't have symptoms; a woman could collect the sample by inserting a swab into the vagina; and that she could do this on her own at home, then give the sample to a health surveillance assistant to take to the clinic for testing.

Outcome—Our primary outcome was women's reported willingness to self-collect a vaginal sample for HPV testing in a non-clinic setting, if she were to be offered the opportunity (1=definitely not willing to 5=definitely willing) which we dichotomized into ‘willing’ (‘definitely willing’ and ‘probably willing’ responses) and ‘not willing’ (‘not sure,’ ‘probably not willing’ and ‘definitely not willing’) for analysis. To assess potential barriers to self-collection for HPV testing, interviewers also asked women what concerns they had about self-collection. For this item, research assistants did not prompt participants with possible options, but rather recorded all concerns for later analysis.

Correlates—Survey items asked each woman how serious she thought it would be if she had cervical cancer (1=not serious at all to 4=very serious); how worried she was about getting cervical cancer in the future (1=not at all worried to 4=very worried), and if she felt the test would protect her health (1=strongly disagree to 5=strongly agree). We assessed supportive subjective norms using a scale comprised of 2 items asking whether a participant thought her partner or other people important to her would approve of her self-collecting vaginal samples for HPV testing, if given the opportunity (1=strongly disagree to 5=strongly agree; $\alpha=0.90$). We also asked if she would self-collect if a clinician recommended she do so (1=strongly disagree to 5=strongly agree). We assessed perceived behavioral control, with a scale composed of 3 agree-disagree items asking if a participant: was confident that she could self-collect a vaginal sample correctly; confident that testing for cervical cancer at home could protect her health, and thought self-collection would be convenient (1=strongly disagree to 5=strongly agree; $\alpha=0.90$).

The survey also assessed demographic, sexual health and behavioral factors that could influence women's willingness to self-collect samples for HPV testing. Specifically, we included age, education, marital status, household income, lifetime number of sexual partners, and parity in the model. We also considered healthcare utilization in the past year and condom use, but due to limited variability in the responses, we could not include these factors in multivariable analyses.

Statistical Analysis

We first ran descriptive statistics to assess the characteristics of study participants and women's top concerns about self-collection of vaginal samples for HPV testing. We then ran separate unadjusted logistic regression models of the association between each independent variable of interest— age, education, marital status, household income, lifetime number of sexual partners, parity, awareness of cervical cancer, worry about cervical cancer, supportive subjective norm score, clinician recommendation, and perceived behavioral control score —

and the binary willingness measure as the outcome of interest. We did not include perceived severity of cervical cancer in model building because of lack of variation in responses. We used backwards selection with a 0.05 significance level to develop our fully-adjusted, multivariable logistic regression model. Model fit was assessed using the Hosmer-Lemeshow goodness of fit test.[22] All analyses were conducted using Stata 12.0 (Statacorp, College Station, TX).

Ethical approval

This project received ethical approval from the Ohio State University Institutional Review Board and the University of Malawi College of Medicine Research and Ethics Committee.

Results

Of the 824 women who were offered the questions on cervical cancer and screening, 82% were married, 98% were HIV-uninfected by self-report, and 13% had less than 2 years of education (Table 1).

At the time of the survey, 85% had heard of cancer and 71% had heard of cervical cancer specifically. Nearly all women (93%) felt it would be very serious if they had cervical cancer, and 75% of women were moderately to very worried that they could get cervical cancer in the future (Table 2). Women generally felt self-collection could protect their health (mean 3.9 ± 1.3 ; Table 2).

Most women (67%) reported being willing to self-collect a vaginal sample for HPV testing (Table 2). Sixty-two percent of women reported that they were definitely willing, and 5% reported they were probably willing. Twenty-four percent of women reported that they were definitely not willing to self-collect a vaginal sample for HPV testing. In unadjusted analyses, higher age, higher parity, awareness of cervical cancer before the survey, higher supportive subjective norm score, clinician recommendation for self-collection, and higher perceived behavioral control were all significantly associated with increased willingness to self-collect a sample for HPV testing (Table 3). After adjustment for all variables that were bivariately associated with willingness, all effect estimates were attenuated. In the final multivariable model, women who were aware of cervical cancer had greater odds of being willing to self-collect a vaginal sample for HPV testing (OR 1.81; 95% CI: 1.25, 2.62), and those who perceived higher levels of supportive subjective norms had twice the odds (OR 2.00; 95% CI: 1.55, 2.59) of being willing to self-collect a sample for HPV testing (Table 3). Clinician recommendation (OR 1.34; 95% CI: 1.00, 1.78) and higher perceived behavioral control (OR 1.90; 95% CI: 1.30, 2.78) were also significantly associated with increased willingness to self-collect in the multivariable model.

When asked about their concerns about self-collection for future HPV testing, women's most common response was that they did not have any concerns (42%). Women who did have concerns reported that they thought the test might hurt (22%), that they might not do the test correctly (21%), that the test might not be accurate (17%), and that they would rather go to a health facility (5%) than self-collect outside the clinic.

Discussion

Self-collection of vaginal samples for HPV testing is a novel approach to cervical cancer screening, with great potential to expand access to a broader population, particularly in low-resource settings. The present study provides insight into the acceptability of, and potential concerns about, this strategy among a sample of rural Malawian women, a population with elevated incidence of cervical cancer and associated mortality. We found that the majority of women reported being willing to self-collect a vaginal sample for testing in a non-clinic setting, and a plurality did not express any concerns about the self-collection procedure. We also found that prior cervical cancer awareness, more supportive subjective norms, increased perceived behavioral control, and the weight of a clinician recommendation were all significantly associated with increased willingness. Future screening programs should consider these factors to maximize uptake and, consequently, impact. Additionally, programs relying on self-collection will need to address women's concerns that the test might hurt, that the test may not be accurate, and provide detailed instructions so the woman is confident that she is doing it correctly.

Our finding that two-thirds of women report being willing to self-collect a vaginal sample for HPV testing is consistent with previous research. In other settings, when offered self-collection, women have found the procedure acceptable and report that they would be willing to do so again in the future.[14–16,23–29] In one multi-site study, the majority of women in India and Uganda preferred self-collected vaginal sampling while women in Nicaragua equally preferred self-collection and clinician-collection of samples.[15] While two-thirds of women in our study reported being willing to self-collect a sample, women at all three of these previous studies had higher willingness than in our study. This may be due, at least in part, to greater comfort with the procedure when actually given the opportunity to test.[15] In another low-resource setting, among rural Thai women, 99.8% of women agreed to self-collect a vaginal sample for field-based HPV testing, 91% would self-collect in the future, and 96% would recommend the test to a friend.[24] Compared to our findings, in other settings where women were actually given the opportunity to self-collect, willingness and future intention to self-collect was even higher than what we found in our study.

While previous studies illustrate the acceptability of self-collection, the present study extends this work by identifying correlates of willingness that can be used to guide the development of future screening programs. Similar to other studies, we found that the TPB provided an effective framework to identify correlates of women's willingness to self-collect a vaginal sample and that most demographic and sexual behavior variables were not significantly associated with women's willingness to self-collect.[26,28–31] The factors we identified are informative for determining intervention points to increase utilization of screening programs. For example, based on our findings and similar to findings among Cameroonian and Mexican women [23,32], raising awareness of cervical cancer could lead to increased uptake of self-collected vaginal samples for HPV testing. Qualitative research among Malawian women found that cervical cancer knowledge was limited and thus this may be an important place to intervene to increase screening.[33] In line with our findings on the importance of perceived behavioral control, a study among urban Ugandan women that also utilized the TPB similarly found that perceived behavioral control was associated

with increased willingness to self-collect, [34] thus screening programs may benefit from building women's skills and confidence in their ability to self-collect samples.

Despite generally high acceptability of self-collection for HPV testing, we found that some women have concerns about the test and collection procedure. The top concerns found in the present study are consistent with findings from previous research in multiple settings suggesting that women may be concerned about pain or injury, [15,34,35] failing to self-collect an adequate sample, and the reliability or accuracy of a self-collected sample compared to one collected by a clinician [15,35,36], Programs implementing self-collected samples may be able to address these concerns. For example, future programs should emphasize that self-collection is as valid for HPV testing as clinician-collection.[8] Additionally, other research has found that self-collection procedures are more successful in programs in which community health workers were present [13] compared to those where women self-collected on their own [23], thus future programs may benefit from involving health workers to mitigate women's concerns about correct collection procedures, and to answer questions that may arise.

Limitations of our study include our reliance on self-reported data, which is subject to social desirability bias. To minimize this bias we trained all research assistants prior to data collection. We also conducted a sensitivity analysis adjusting for interviewer and found it did not significantly change estimates. As we asked women about their willingness to self-collect a vaginal sample for HPV testing, rather than offering women the opportunity to self-collect samples, our findings may overstate actual self-collection behavior.[37] Future research should examine whether women will self-collect a sample when presented with an opportunity to do so. Our study was nested within a larger study (which was limited to women between the ages of 15-39 years), so our findings about willingness to self-test for HPV reflect the views of that population. HPV testing is recommended for an older population (> 30 years).[6] Currently in Malawi, HPV testing is neither the standard of care nor widely available. Thus it may be that by the time HPV testing were to be available, the women we interviewed will have reached the recommended age range for this screening method. Lastly, our study was conducted among women in single geographic area and may not be generalizable to women in other regions, in more urban settings, or areas with established cervical cancer screening programs.

Our study provides important information about women's willingness to self-collect vaginal samples for HPV testing, and identifies concerns that may impede successful implementation of future screening programs using this technology. Future research should assess actual self-collection in this population with the ultimate goal of implementing an accessible screening program and reducing the high incidence of and mortality from cervical cancer in this high-burden population.

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Key messages

1. Two-thirds of women reported being willing to self-collect vaginal samples for HPV testing.
2. Study findings identify modifiable, theoretically-informed correlates of women's willingness that can be targets for future interventions.
3. Cervical cancer screening programs should address concerns about self-collecting samples that were identified in this study.

Table 1
Participant characteristics

	n ^a	(%)
Marital status		
Married	672	(82)
Single	152	(18)
Education		
< 2 years	106	(13)
2-4 years	248	(30)
5-8 years	342	(41)
Some secondary	128	(16)
Household income ^{a,b}		
<5,000 MWK	281	(38)
5,000-19,999 MWK	253	(34)
>20,000 MWK	202	(27)
Age (median, IQR)	25	(20, 31)
Lifetime # of sexual partners		
0 partners	70	(9)
1 partner	411	(50)
2 partners	210	(25)
3 partners	133	(16)
Parity (median, IQR)	2	(1, 3)
HIV status ^{a,c}		
HIV +	15	(2)
HIV -	683	(98)
Abnormal genital discharge in the last 12 months ^{a,c}		
Yes	101	(12)
No	722	(88)
Genital ulcers in the last 12 months ^{a,c}		
Yes	69	(8)
No	753	(92)
Ever had an STI ^{a,c}		
Yes	74	(9)
No	747	(91)

^aSome variables do not total to 824 due to missing data

^b5000 MWK=US \$11.37

^cBased on self-report

MWK= Malawian kwacha; USD= United States dollar; IQR= interquartile range; HIV= Human Immunodeficiency virus; STI= sexually transmitted infection

Table 2
Attitudes towards cervical cancer and screening

	N	(%)
Awareness of cervical cancer	582	(71)
Willingness to self-collect samples		
Definitely willing	513	(62)
Probably willing	43	(5)
Not sure	30	(4)
Probably not willing	41	(5)
Definitely not willing	197	(24)
	Mean	(SD)
Seriousness of cervical cancer ^a	3.9	(0.4)
Worry about cervical cancer ^a	3.1	(1.2)
Subjective norms ^b	3.6	(1.4)
People important to me approve of self-collection ^{b,c}	3.6	(1.4)
My partner approves of self-collection ^{b,c}	3.6	(1.5)
Clinician recommendation ^b	3.9	(1.3)
Perceived behavioral control ^b	3.6	(1.3)
Self-collection can protect my health ^{b,d}	3.9	(1.3)
Confident can perform self-collection correctly ^{b,d}	3.4	(1.5)
Self-collection would be a convenient way to test for cancer ^{b,d}	3.6	(1.4)

^aRange = 1-4

^bRange = 1-5

^cItem included in the subjective norms scale

^dItem included in the perceived behavioral control scale

Table 3
Correlates of women's willingness to self-collect a vaginal sample for HPV testing

	Unadjusted		Adjusted	
	OR	(95% CI)	OR	(95% CI)
Age	1.04	(1.02, 1.06)*		
Education				
< 2 years	0.69	(0.41, 1.18)		
2-4 years	0.71	(0.48, 1.04)		
5-8 years	Ref			
Some secondary	1.07	(0.79, 1.45)		
Relationship status				
Single	Ref			
Married	1.20	(0.87, 1.64)		
Household income ^a				
<5,000 MWK	Ref			
5,000-19,999 MWK	1.06	(0.74, 1.51)		
>20,000 MWK	1.37	(0.95, 1.96)		
Lifetime # of sexual partners				
0 partners	0.76	(0.57, 1.03)		
1 partner	Ref			
2 partners	0.91	(0.62, 1.34)		
3 partners	1.40	(1.02, 1.91)*		
Parity	1.13	(1.04, 1.23)*		
Awareness of cervical cancer	1.83	(1.36, 2.45)*	1.81	(1.25, 2.62)*
Worry about cervical cancer	1.12	(0.97, 1.29)		
Subjective norms	3.34	(2.71, 4.12)*	2.00	(1.55, 2.59)*
Clinician recommendation	2.84	(2.31, 3.49)*	1.34	(1.00, 1.78)*
Perceived behavioral control	3.49	(2.61, 4.66)*	1.90	(1.30, 2.78)*

^a5000 MWK=US \$11.37

* p<0.05

USD=United States dollar; MWK= Malawian kwacha