

## **Minipilot Study on Self-Collected Vaginal Swabs for Human Papilloma virus DNA Testing for a Sample of Young Albanian Women**

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### **Abstract**

Self-sampling of cervicovaginal cells for HPV testing has the potential to increase cervical cancer screening coverage in this population, but only if it is acceptable to women. We sought to determine acceptance of and preference for self-collection of cervicovaginal samples for HPV testing in comparison with provider-collection, and to explore demographic characteristics of preference for self-collection among a sample of Albanian young women. Women aged 18–24 years were invited. Both self-collected and provider-collected specimens were collected with cottonbud swabs, and women completed a short written questionnaire immediately after specimen collection. Logistic regression was used to estimate predictors of preference. Of the 109 eligible women who were approached to participate, 93 (85%) accepted. Self-sampling was preferred by 56% of the women over provider-sampling. Self-sampling has the potential to increase cervical cancer screening coverage, but any implementation of self-sampling should be concurrent with an education campaign on the importance of cervical cancer screening, the relationship between HPV virus and cervical cancer, and the accuracy of self-sampling.

### **INTRODUCTION**

Human papillomavirus (HPV) is now well established as the necessary cause of cervical cancer (1) Implementation of efficient strategies to study, prevent and control HPV genital tract infection, including vaccination, requires a simple and easy method for HPV detection (2). Self-sampling has several advantages compared with physician-collected samples for detection of HPV genital infection. Self-sampling is a less costly and non-invasive collection procedure.

Self-collected samples can be more easily obtained in settings with limited resources or in populations difficult to reach. Numerous studies have reported lately that self-obtained samples of the anogenital tract in women were accurate and suitable for DNA testing (3-7).

As recently highlighted in a European population, the most common reason claimed by women for not attending screening was that they felt “uncomfortable with vaginal examination.” This evidence suggests that self-sampling, which bypasses this internal examination, should be further explored as a strategy to increase the coverage of cervical screening and follow-up programs (8). Given the need to increase the proportion of women participating in hr-HPV screening programs, considerable efforts are focused on the incorporation of noninvasive self-sampling methods as well, as reported by several groups previously [9,10,11,12]. Self-sampling has been shown to be comparable to provider-directed sampling for the detection of virological (13) and disease endpoints (14,15,16) although self-sampling has a somewhat lower sensitivity to detect cervical

disease than provider-sampling. However, for a self-sampling-based program to increase screening coverage and therefore reduce cervical cancer mortality, it is important that women find it acceptable. Although studies suggest that women generally report a high acceptance of self-sampling, preference for self sampling has been shown to range from 27% to 94% in different populations (17,18,19,20,21,22). Given the variability of women's attitudes toward self-sampling and their ability to collect adequate samples (17,18,21,22,23,24,25), it is important that the comparability and acceptability of self-sampling be assessed in a population before it is integrated into their cervical cancer screening program. This paper aims to evaluate the socio-demographic and behavioural predictors of preference and examine reasons for sampling method preference among 18-24 year old Albanian women.

## METHODS

Women aged 18-24 years were recruited for this self-sampling study between January 2015 and March 2016 when they came to a public women's center in Tiraan, for visits requiring a Pap test. Participants were asked to collect a sample of cervicovaginal cells unsupervised, in the examination room just before the gynecologist conducted a pelvic examination that included direct cervical cell sampling. Women were asked to put one foot up on a chair, insert a sterile cottonbud from Digene Female Swab Specimen Collection Kit (Qiagen, Gaithersburg, MD)

into the vagina as far as it would go, and hold the cottonbud in place for 20 seconds. After that, gently rotate the cottonbud six times and slowly remove it and place into the tube with STM medium. Participants completed a short standardized questionnaire after both methods of specimen collection were finished. Women were asked which sampling method they preferred, and about the reasons for their preference. Socio-demographic characteristics, reproductive and sexual history, medical history, and lifestyle factors for participants were obtained from a questionnaire. The covariates used in this study were age, marital status, employment status, education level, smoking status, alcohol use, history of Pap smear testing, self reported history of sexually transmitted infections, age at first sexual intercourse, and number of lifetime sexual partners. Logistic regression was used to estimate the odds ratio (OR) and 95% confidence intervals (95% CIs) for the association between preference for self-collection and each covariate. History of Pap smear testing in the previous three years was also included. A multivariate logistic regression was performed using all variables selected for inclusion in the final model.

## RESULTS

A total of 111 women were approached to participate in the self-sampling study, with 16 women (14.4%) declining to participate. Two woman approached did not meet study eligibility criteria and were therefore excluded. Of the 109 women who were eligible, 93 women (85.3%) agreed to participate. The sampling-method preference questionnaire was completed by 86 of the 93 study participants (92.5%). Self-sampling was preferred by 48 (55.8%; 95% CI [44.7%, 66.5%]) of these respondents while the other 38 (44.2%; 95% CI [33.4%, 55.3%]) women preferred provider collection. Table 1 presents the socio-demographic, lifestyle, reproductive, and sexual history characteristics of study participants by sampling method preference. No socio-demographic or lifestyle

characteristics were found to be significantly associated with preference for self-sampling. Table 2 displays women’s reasons for sampling method preference, grouped into themes based on responses to the questionnaire.

The most common reason for preferring self-sampling was that it was faster and more convenient than provider-sampling (25%). Grouped into this dimension of “convenience” were three responses by women who noted the convenience of performing the self-sampling at home. The privacy aspect of self-sampling was the most important reason for preferring self-collection for 11 (23%) women. The dimension of “more comfortable” was the primary reason for preference of self-sampling for nine women (18.8%), and it included the responses of self-sampling being “less embarrassing” and “less painful” than provider-sampling. Seven women (14.6%) preferred self-sampling because it was easy to do and nine women (18.8%) did not give a reason for their preference. The most common reason for preferring provider sampling was the fear of collecting a sample incorrectly and the belief that a provider does it more accurately (31.6%). Eight women (21.1%) stated that their reason for preferring provider-sampling was that it was easier to have a provider to collect the sample. Five women (13.2%) gave responses that fit into the dimension of “uncomfortable with self-sampling” as their reason for preference for provider collection. This dimension included responses like “it feels weird doing it,” “don’t like to do it,” and “afraid to hurt myself.” Two women (5.3%) found provider-sampling more convenient, because they had other reasons to visit the clinic and could have multiple tests done at one time. A large proportion (29%) did not give a reason for their preference for provider-collection.

**Table 1: Association between preference for self-sampling and sample characteristics**

Characteristics	Sampling Method Preference		
	All Woman (N=93)	Self-sampling (n=48)	Provider - sampling +(n=38)
<b>Marital Status</b>			
Single/divorced	44 (47.30)	19 (39.6)	18 (47.4)
Married/living with partner	46 (49.5)	27 (56.3)	19 (50.0)
Missing	3 (3.2)	2 (4.2)	1 (2.6)
<b>Employed</b>			
No	23 (24.7)	12 (25.0)	9 (23.7)
Yes	65 (69.9)	32 (66.7)	28 (73.7)
Missing	5 (5.4)	4 (8.3)	1 (2.6)
<b>Current smoking</b>			
No	20 (21.5)	13 (27.1)	6 (15.8)
Yes	70 (75.3)	33 (68.8)	31 (81.6)
Missing	3 (3.2)	2 (4.2)	1 (2.6)

<b>Alcohol use</b>			
No	30 (32.3)	16 (33.3)	13 (34.2)
yes	60 (64.5)	30 (62.5)	24 (63.2)
Missing	3 (3.2)	2 (4.2)	1 (2.6)
<b>History of Pap test in previous three years</b>			
No	31 (33.3)	13 (27.1)	15 (39.5)
Yes	61 (65.6)	34 (70.8)	23 (60.5)
Missing	1 (1.1)	1 (2.1)	0 (0.0)
<b>Self-reported history of STI</b>			
No	28 (30.1)	14 (29.2)	11 (28.9)
Yes	61 (65.6)	31 (64.6)	26 (68.4)
Missing	4 (4.3)	3 (6.3)	1 (2.6)
<b>Age of first sexual intercourse (mean SD)</b>			
	14.61 (1.8)	14.76 (1.7)	14.62 (1.9)
<b>Lifetime of sexual partners</b>			
<3	51 (54.8)	29 (60.4)	19 (50.0)
≥3	27 (29.0)	13 (27.1)	11 (28.9)
Missing	15 (16.1)	6 (12.5)	8 (21.1)

**Table 2: Reasons for sample method preference grouped by response of 86 women**

<b>Response theme</b>
n (%)
<b>Preference for self – sampling (n=48)</b>
Self – sampling was faster and more convenient 12 (25.0)
Self – sampling was more private 11 (22.9)
Self – sampling was more comfortable 9 (18.8)
Self – sampling was easy to do 7 (14,6)
Did not respond 9 (18.8)
<b>Preference for provider – sampling (n=38)</b>
Worried about ability to do self-sample 12 (31.6)

Provider – collection is easier to do 8 (21.1)
Uncomfortable with self-sample method 5 (13.2)
More convenient 2 (5.3)
Did not respond 11 (28.9)

## DISCUSSION

We found that among all sample, 56% preferred self-sampling to provider-sampling of cervico vaginal cells. Women's reasons for their sampling method preference helped explain why self-sampling preference was not higher. Women's lack of confidence in their ability to collect their own sample was found to be an important reason for preferring provider-sampling in this population, as almost a third of the women who preferred provider-sampling felt this way. Women in our study also felt that it was easier to have a clinician perform the test (22%) and it was more convenient to go to the clinic to address all health concerns at once (5%). This indicates that although these women do not necessarily prefer self-sampling, they might not object to performing self-sampling if necessary. This is not the case for all women, as 14% of women preferred provider-sampling because they were uncomfortable with the self-sampling method. Women in this study reported that they preferred to collect their own specimens because it was more convenient (25%), private (23%), and comfortable (19%) than when sampling was performed by a clinician. Some women reported that they preferred self-sampling because it was easy to do (15%).

We did not find an association between marital status and the preference for self-sampling, although these associations have not been found consistently in the literature (Anhang et al., 2005; De Alba et al., 2008; Karwalajtys, Howard, Sellors, & Kaczorowski, 2006; Khanna et al., 2007). The association between history of Pap smear within three years and preference for self sampling was large in magnitude. Moreover, although only 56% of women in the study preferred self-sampling, 85% of eligible women agreed to collect a sample and enter the study. This indicates that more women would self-obtain a sample if required. The majority of women in the study preferred self-sampling. Socio-demographic characteristics, reproductive and sexual history, medical history, and lifestyle factors for participants were obtained from a questionnaire. One limitation of our study is its small sample size and consequently low precision. We therefore cannot rule out an association between preference for self-sampling and other covariates, such as history of Pap smear testing. This study is the first to look at the attitudes of Albanian young women toward self-sampling. It is important to highlight that acceptance and preference for self-sampling does not automatically correspond to future screening behavior. In conclusion, self-sampled vaginal HPV DNA detection is a woman-friendly acceptable additional tool that could be implemented to increase participation to cervical cancer prevention programs. Further standardization and optimization of vaginal HPV self-sampling, and detection techniques in the future might enable its effective incorporation in cervical cancer screening.

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