

# Concordance in HPV Detection Between Self-Collected and Health Provider–Collected Cervicovaginal Samples Using careHPV in Tanzanian Women

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**PURPOSE** Cervical cancer screening is one of the strategies to prevent the disease among women at risk. Human papillomavirus (HPV) DNA testing is increasingly used as the cervical cancer screening method because of its high sensitivity. Self-collection of cervical specimens has the potential to improve participation. However, there is only limited information on comparison between self-collected and provider-collected samples with regard to detection of high-risk HPV using the careHPV method. The study aimed to compare HPV detection by careHPV in self-collected and provider-collected cervical samples and to assess the acceptability of self-collection techniques.

**MATERIAL AND METHODS** Women attending cervical cancer screening clinics at Ocean Road Cancer Institute, Kilimanjaro Christian Medical Centre or Mawenzi Hospital in Tanzania were included in the study. They underwent a face-to-face interview, HIV testing, and collected a self-sample using Evalyn Brush. Subsequently, they had a cervical sample taken by a health provider. Both samples were tested for high-risk HPV DNA using careHPV.

**RESULTS** Overall, 464 women participated in the study. The high-risk HPV prevalence was 19.0% (95% CI, 15.6 to 22.9) in the health provider samples, but lower (13.8%; 95% CI, 10.9 to 17.3) in the self-collected samples. There was a good overall agreement 90.5% (95% CI, 87.5 to 93.0) and concordance ( $\kappa = 0.66$ ; 95% CI, 0.56 to 0.75) between the two sets of samples. Sensitivity and specificity were 61.4% (95% CI, 50.4 to 71.6) and 97.3% (95% CI, 95.2 to 98.7), respectively, varying with age. Most women preferred self-collection (79.8%).

**CONCLUSION** Overall, self-sampling seems to be a reliable alternative to health-provider collection and is acceptable to the majority of women. However, instructions on proper procedures for sample collection to the women are important.

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## INTRODUCTION

Cancer is the second most common noncommunicable disease in causing morbidity and mortality worldwide. Low- and middle-income countries (LMICs) have a high incidence and mortality of cancer compared with high-income countries (HICs).<sup>1</sup> Cervical cancer is the fourth most common cancer in women and ranks second in LMICs.<sup>2</sup> In 2018, it is estimated that 570,000 new cases and 311,000 deaths occurred because of cervical cancer.<sup>2</sup> It is well established that persistent infection with oncogenic or high-risk (HR) human papillomavirus (HPV) is the main cause of cervical cancer,<sup>3,4</sup> and expression of the oncogenes E6 and E7 plays an important role in the carcinogenesis.<sup>3</sup>

Most LMICs, including Tanzania, use visual inspection with acetic acid (VIA) as the screening method against cervical cancer.<sup>5,6</sup> It is cheap, easy to use, and allows a

see-and-treat approach,<sup>7</sup> but it has a relatively low sensitivity.<sup>7,8</sup> The prevailing screening modality against cervical cancer in HICs has been cervical cytology. It has a higher sensitivity than VIA, but is costly and requires skilled personnel.<sup>9</sup> Cervical cancer screening using HPV DNA testing has proven to be more sensitive, but less specific, than cervical cytology for detection of high-grade precancerous cervical lesions,<sup>3,4</sup> and HPV DNA testing is now incorporated in screening in many HICs. A simple and rapid HPV DNA test, which is also relatively affordable, is the careHPV test, and this could be a potentially feasible test in LMICs. The possibility to use HPV testing as the primary screening test also opens the possibility for self-collection of cervical material, which may increase adherence to screening.

The aim of this study was to assess the concordance in cervical HR HPV detection between paired self-

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## CONTEXT

### Key Objective

To access acceptability and human papillomavirus detection by careHPV using self-collected and provider samples.

### Knowledge Generated

There was a good overall agreement (90.5%) and concordance between self-collected and health provider–collected cervical vaginal samples. Women prefer self-sample collection.

### Relevance

In future, self sample collection may serve the purpose of cervical cancer screening and increase adherence to screening program.

collected samples and health provider–collected samples using careHPV testing as the detection method. Furthermore, we aimed to examine the acceptance of self-collection among Tanzanian women.

## MATERIAL AND METHODS

### Enrollment and Data Collection

This study is a part of the Comprehensive Prevention of Cervical Cancer in Tanzania (CONCEPT) project, which is based on a collaboration between Ocean Road Cancer Institute (ORCI), Kilimanjaro Christian Medical Centre (KCMC), the Danish Cancer Society Research Center, and the University of Southern Denmark.

The study population and recruitment has previously been described in detail elsewhere.<sup>7</sup> Briefly, women were enrolled from the cervical cancer screening clinics at ORCI, KCMC, and Kilimanjaro Regional Referral Hospital (Mawenzi Hospital) in Tanzania. ORCI is the national designated institute for cancer care and treatment in Tanzania. It is located in the Dar es Salaam region, which has a population of 4,364,541 inhabitants based on National census data for 2012.<sup>10</sup> KCMC and Mawenzi hospital are situated in the Kilimanjaro region, which has a population of 1,640,087 according to the 2012 census report.<sup>10</sup> KCMC and Mawenzi hospital serve as referral hospitals for people living in the Kilimanjaro region and Northern zone, respectively.

Women in the age group 25–60 years who attended routine cervical cancer screening were eligible for inclusion in the CONCEPT study. Exclusion criteria were being pregnant, a history of hysterectomy, known allergy to acetic acid, and having menstrual period. Within this study, we aimed to include 500 women in a self-sampling part of the study (paired self-collected and health provider–collected samples) who were recruited toward the end of the enrollment phase.

Eligible women underwent face-to-face interview to obtain information on sociodemographic characteristics, lifestyle factors, and acceptance of self-sampling method. The women were offered HIV testing and were subsequently instructed by the study nurse verbally and picture-based on

how to take the cervicovaginal sample themselves using an Evelyn brush.<sup>11</sup> Following the self-collection, the health provider performed a gynecologic examination and obtained a cervical sample. Both the self-collected and health provider–collected samples were analyzed for HR HPV DNA using careHPV. After the cervicovaginal samples collection, VIA was done as a routine.

### HIV Analysis

All participants with unknown HIV status were invited to be tested for HIV according to the Tanzanian HIV protocol.<sup>12</sup> The obtained blood samples were tested by using SD Bioline HIV-1/2 3.0 rapid test (Standard Diagnostics Inc, Gyeonggi-do, South Korea) and positive results were confirmed by Uni-Gold (RecombigenVR HIV; Trinity Biotech, Jamestown, NY).

### HPV DNA Detection

Both cervical samples taken were kept in careHPV collection medium (QIAGEN GmbH, Hilden, China) and taken to the local laboratory at either ORCI or KCMC where they were stored at room temperature (max 25°C) for a maximum of 2 weeks and analyzed for HR HPV using careHPV machine. The machine enables the detection of at least 13 HR HPV types (HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68). The principle of the careHPV test is that it targets HPV DNA from lysed cells, which are denatured and hybridized by complementary RNA, and then captured by antibodies coated on the magnetic beads. The captured hybrids are detected by alkaline phosphatase conjugate, which reacts with an added chemoluminescent substrate to produce light, which is proportional to the number of bound alkaline phosphatase molecules per target.<sup>13</sup>

### Statistical Analysis

We calculated the agreement (%) between the self-collected and health provider–collected samples as the number of concordant samples divided by the total number of samples. We examined the concordance between the paired samples by Cohen's Kappa statistics with the following interpretation: poor or slight agreement (0.00–0.20), fair agreement (0.21–0.40), moderate agreement (0.41–0.60), good agreement (0.61–0.80), and very good or

almost perfect agreement (0.81-1.00).<sup>14,15</sup> Sensitivity and specificity with 95% CI for detection of HR HPV were calculated for self-collected cervical samples using health provider-collected samples as gold standard. We also calculated sensitivity and specificity according to age and HIV status. All analyses were performed using Stata.

### Ethical Consideration

Ethical clearance for the CONCEPT project was obtained from the National Institute for Medical Research in Tanzania, reference number NIMR/HQ/R.8a/Vol. IX/1955. Detailed information about the study was provided to the women before entry into the study. Written informed consent was obtained. Fingerprint was used for illiterate women. All women with a cervical lesion were treated with either cryotherapy or LEEP according to the extent of the lesion.

### RESULTS

On random days, we recruited 464 women to participate in the self-sampling part of the study. Of these, 430 women responded to a lifestyle questionnaire and 416 responded to an HPV self-collection questionnaire.

Most of the participants in the self-sampling part of the study were between 35 and 54 years of age (62.6%) (mean age was 41 years). The majority were married or cohabiting (74.2%). Most women had attended primary school (69.5%) and 10.4% had a college education. Almost half of the women reported one lifetime sexual partner (47.1%), and almost 30% had three or more lifetime sexual partners. Altogether, 7.4% of the women were found to be HIV-positive.

Among the 464 women contributing with paired self- and health provider-collected samples, 19.0% (95% CI, 15.6 to 22.9) were HR HPV-positive after analysis of health provider samples, but a lower prevalence (13.8%; 95% CI, 10.9 to 17.3) of HR HPV-positive was found based on testing of self-collected samples. In 54 women, both the self-collected and health provider-collected samples tested positive for HPV and in 366 women both samples were HPV-negative, resulting in an agreement of 90.5% (95% CI, 87.5 to 93.0) and good concordance ( $\kappa = 0.66$ ; 95% CI, 0.56 to 0.75). For detection of HR HPV in self-collected samples, the sensitivity and specificity were 61.4% (95% CI, 50.4 to 71.6) and 97.3% (95% CI, 95.2 to 98.7), respectively (Table 1).

When stratified by age, we found that among women younger than 40 years of age, the sensitivity increased to 72.3% (95% CI, 57.4 to 84.4) with a specificity of 95.1% (95% CI, 90.2 to 98.0). For women 40-60 years of age, the sensitivity was lower (51.4%; 95% CI, 34.0 to 68.6) but with a higher specificity (99.0%; 95% CI, 96.5 to 99.9) (Table 2).

We also looked at sensitivity and specificity of the careHPV in self-collected samples stratifying for HIV status (Table 3).

Among HIV-positive, the sensitivity (70.0%; 95% CI, 34.8 to 93.3) tended to be slightly higher than among HIV-negative and specificity (62.5%; 95% CI, 50.3 to 73.6) but at the expense of a lower specificity among HIV-positive (95.5%; 95% CI, 77.2 to 99.9) than HIV-negative women (97.5%; 95% CI, 95.2 to 98.9).

Among the women who responded to the questions about acceptability of self-collection (n = 416), the majority stated they preferred self-collection of cervical samples (79.8%), 16.5% preferred sampling performed by a health provider, and 3.6% stated they had no preference.

In Table 4, the distribution of potential concerns associated with self-collection is displayed, overall and according to the reported preference of screening method. Only few reported they found it difficult to do the self-sampling (2.4%) or had difficulties understanding the instruction (2.9%). The most frequently reported concern was worries about ability in collecting the sample correctly (56.8%). All reported concerns were more common among women preferring a health provider-collected swab than among women with a preference for self-collection.

### DISCUSSION

We found a good concordance between self-collected samples using the Evelyn Brush and health provider-collected samples in detection of HR HPV by means of careHPV testing. In addition, the women preferred self-collection as the screening method, although a high proportion expressed concerns about whether they could collect the sample correctly.

The self-collected samples were processed and analyzed the same way as cervical samples obtained by health providers, and a good agreement was found between self-collected and provider-collected samples. Furthermore, the self-collection had a fair sensitivity and specificity of 61.4% and 97.3%, respectively, when compared with provider collection. This is similar to most studies done to evaluate performance of self-collected.<sup>16-18</sup> Thus, our study adds to the increasing evidence that self-collection of cervicovaginal samples may be a valid alternative to provider collection especially when seen in the light of a possibly higher participation rate in an underscreened population. It is important to underline that the relatively high agreement found may be explained by the thorough instructions the women were given before the self-collection and the fact that health providers were present during the sampling for ongoing instruction and support.

The level of agreement did not differ much by age group, and this is in accordance with a recent systematic review done by Yeh et al.<sup>19</sup> However, the sensitivity varied by age with self-sampling having a higher sensitivity in women younger than 40 years of age (72.3%) than among women older than 40 years of age (51.4%) but with the highest specificity among the older women (99.0%). Along the same lines, Paluszkiwicz et al.<sup>20</sup> reported a higher

**TABLE 1.** Agreement, Sensitivity, and Specificity for Detection of HPV in Self-Collected Cervical Swabs Compared With Health Provider–Collected Swabs

Self-Collected Samples	Health Provider–Collected Samples			% Agreement (95% CI)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
	HPV-Positive n (%)	HPV-Negative n (%)	Total n (%)			
HR HPV-positive	54 (11.6)	10 (2.2)	64 (13.8)	90.5 (87.5 to 93.0)	61.4 (50.4 to 71.6)	97.3 (95.2 to 98.7)
HPV-negative	34 (7.3)	366 (78.9)	400 (86.2)	K = 0.66 (0.56 to 0.75)		
Total	88 (19.0)	376 (81.0)	464 (100.0)			

Abbreviations: HPV, human papillomavirus; HR, high-risk.

sensitivity of the HPV test for detecting high-grade squamous intraepithelial lesions for women below younger than 50 years of age, whereas Labani and Asthana<sup>21</sup> found that the performance of self-sampling did not vary by age. Our finding that some HPV infections were missed by the self-collection method, especially in older women, yielding a lower sensitivity could be of concern as cervical cancer in this age group is high. It also has implications on the follow-up as the prognostic value of a negative test is lower for self-sampling among older women than for health provider–collected samples. The poorer sensitivity of self-collected samples among older women may reflect that these women are more uncomfortable in performing the procedure, and consequently, they may not be able to obtain enough material resulting in an increased number of false-negative samples. So far, only few studies have assessed how women's age may influence the quality of HPV self-sampling. However, a recent qualitative study among Tanzanian women attending cervical cancer screening revealed that many women, although being positive toward self-sampling, did not believe in their own capabilities to conduct the sampling correctly.<sup>22</sup> Similarly, some women in our study had worries about not being able

to collect the self-sample correctly or concerns about the brush not being safe.

The women in this study tended to prefer self-sampling over health provider–sampling (79.8%) This is in line with other studies assessing acceptance of self-sampling.<sup>17,23-25</sup> However, in our study, the women had a nurse in close proximity when performing the self-sampling, whereas other studies have shown that the method can be implemented without the presence of a nurse.<sup>26</sup> Thus, it may be argued that self-sampling has a potential to reach women who have difficult access to screening services and thereby help improve uptake and coverage of cervical cancer screening programs in LMICs.<sup>13,17</sup>

Self-sampling offers many advantages, such as the ability to choose the time and place of the sampling, which, coupled with the performance of the newly developed quick HPV tests,<sup>5,7,26</sup> makes it a relevant approach for community-level screening. In such programs, women could obtain the sampling kits at the community health clinics, perform the sampling at home, and return it to the clinic for HPV analysis. Such a screening modality would make the results easily available for the women with minimal delay.

**TABLE 2.** Agreement, Sensitivity, and Specificity for Detection of HPV in Self-Collected Cervical Swabs Compared With Health Provider–Collected Swabs According to Age

Self-Collected Samples	Health Provider–Collected Samples			% Agreement (95% CI)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
	HPV-Positive n (%)	HPV-Negative n (%)	Total n (%)			
<b>25-39 Years</b>						
HPV-positive	34 (17.8)	7 (3.7)	41 (21.5)	89.5 (84.3 to 93.5)	72.3 (57.4 to 84.4)	95.1 (90.2 to 98.0)
HPV negative	13 (6.8)	137 (71.7)	150 (78.5)	K = 0.70 (0.58 to 0.83)		
Total	47 (24.6)	144 (75.4)	191 (100.0)			
<b>40-60 Years</b>						
HPV-positive	18 (7.5)	2 (0.8)	20 (8.4)	92.1 (87.8 to 95.2)	51.4 (34.0 to 68.6)	99.0 (96.5 to 99.9)
HPV negative	17 (7.1)	202 (84.5)	219 (91.6)	K = 0.61 (0.45 to 0.78)		
Total	35 (14.6)	204 (85.4)	239 (100.0)			

Abbreviation: HPV, human papillomavirus.

**TABLE 3.** Agreement, Sensitivity, and Specificity for Detection of HPV in Self-Collected Cervical Swabs Compared With Health Provider–Collected Swabs According to HIV Status

HIV-Positive	Health Provider–Collected Samples			% Agreement (95% CI)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
	HPV-Positive	HPV-Negative	Total			
Self-Collected Samples	n (%)	n (%)	n (%)			
HPV-positive	7 (21.9)	1 (3.1)	8 (0.25)	87.5 (71.0 to 96.4)	70.0 (34.8 to 93.3)	95.5 (77.2 to 99.9)
HPV negative	3 (9.4)	21 (65.6)	24 (0.75)	K = 0.69 (0.41 to 0.97)		
Total	10 (31.3)	22 (68.7)	32 (100.0)			

  

HIV-Negative	Health Provider–Collected Samples			% Agreement (95% CI)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
	HPV-Positive	HPV-Negative	Total			
Self-collected samples	n (%)	n (%)	n (%)			
HPV-positive	45 (11.3)	8 (2.0)	53 (13.3)	91.2 (88.0 to 93.8)	62.5 (50.3 to 73.6)	97.5 (95.2 to 98.9)
HPV negative	27 (6.8)	318 (79.9)	345 (86.7)	K = 0.67 (0.56 to 0.77)		
Total	72 (18.1)	326 (81.9)	398 (100.0)			

Abbreviation: HPV, human papillomavirus.

Furthermore, as documented in other studies, the self-sampling approach allows women to undergo screening at their convenience and may also motivate women to repeat testing.<sup>17,18</sup> Thus, the technique may increase both participation rate as well as the adherence to follow up testing. With such a setup, only women, who require cytology or colposcopy, would have to be referred to secondary health facilities. This could alleviate the costs and burden on health services.

The study had a fairly large sample size that allowed us to evaluate the test performance according to the women's age and HIV status. However, there are also a number of limitations to the study. First, our results represent findings from urban and semiurban settings in Tanzania. As such, they are not representative of the country as a whole. Moreover, to assess the women's acceptance of self-sampling, face-to-face interviews about their experience

were performed by health staff. The women may in that relation have felt compelled to tone down possible negative experiences associated with the self-sampling to avoid displeasing the interviewer. Such courtesy bias may have resulted in an exaggeration of the women's acceptance of self-sampling. Another limitation is that we had no histologic diagnoses available for diagnostic validation. Finally, we used staff who were well trained and experienced in cervical cancer screening to guide the women in how to perform the self-sampling. They were close by throughout the procedure if the women needed further information or clarification regarding self-sampling. In the context of scaling up cervical cancer screening to community level, this approach is likely not feasible in all places or cost effective. Most likely, a large proportion of women will have to perform the self-collected sampling by themselves without the presence of supportive nurses, and this makes

**TABLE 4.** Distribution of Reported Concerns Associated With Self-Collected Cervical Swabs According to Preference of Self or Health Provider Swab

Reported Concern	Total (N = 416)	Prefer Self-Collected Swab (n = 332)	Prefer Health Provider–Collected Swab (n = 69)	No Specific Preference (n = 15)
	No. (%)	No. (%)	No. (%)	No. (%)
Worried that I could not collect the sample correctly	236 (56.8)	172 (51.8)	53 (77.1)	11 (73.3)
Worried that the brush was not safe	167 (40.3)	129 (38.9)	34 (50.0)	4 (26.7)
Worried about dropping the brush	144 (34.6)	121 (36.5)	18 (25.7)	5 (33.3)
Worried that I would hurt myself	96 (22.9)	67 (20.1)	21 (30.0)	8 (53.3)
Felt uncomfortable or embarrassed touching myself	46 (11.0)	36 (10.8)	10 (14.3)	0
Trouble understanding instructions	12 (2.9)	7 (2.1)	5 (7.1)	0
Difficult to do self-collection	10 (2.4)	6 (1.8)	4 (5.7)	0
Experienced pain	8 (1.9)	7 (2.1)	1 (1.4)	0
Experienced bleeding	2 (0.5)	2 (0.6)	0	0

it uncertain whether the results are directly applicable to a large-scaled implementation at community level.

In conclusion, our findings add to the increasing evidence suggesting that the quality of self-collected cervicovaginal specimens is adequate for HPV DNA detection. Furthermore, self-collection was found to be an acceptable alternative to

provider-collected specimens by the women. The lower sensitivity of self-collected samples in detecting HPV should be weighed against the anticipation that implementation of a screening program relying on self-collection may lead to a substantial increase in numbers of women in LMICs who are screened for cervical cancer.

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## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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