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Feasibility and Acceptability of Self-sampling for Human Papillomavirus DNA Testing Among Asymptomatic Women in Rural Delta State, Nigeria

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ABSTRACT **Published Online: February 12, 2024**

Background: Self-sampling and human papillomavirus (HPV) DNA testing can be vital tools in cervical cancer screening for hard-to-reach women with limited access to health care in sub-Saharan Africa. This study explored the feasibility and acceptability of self-sampling for HPV testing among asymptomatic women in Orhuwhorun community in Delta State.

Methods: This was a cross-sectional study of 230 women aged between 30 - 65years, enrolled by a multi-stage sampling method. Recruited women were asked to provide self-collected vaginal samples between May and June, 2021. HPV detection and genotyping was done using 21 HPV Geno-Array Diagnostic kit. Participants were asked to complete questionnaires after self-sampling to point out their experiences and acceptability of HPV self-sampling.

Results: An excellent feasibility of self-sampling (95.2%) was observed. The acceptability rate of self-sampling was 93.0%, and 99.6% (229/230) of the participants were confident that they used the device correctly. The quality of self-sampling was satisfactory in 100% of the samples; 21.1% (48/228) of the samples were positive for HPV, including 12.3% (28/228) with high-risk HPV types,2.6% (6/228) with probable high risk HPV types and 1.8% (4/228)with low-risk HPV types. Multiple HPV infection occurred in 10 cases (4.4%).

Conclusion: This study indicates that self-sampling is a feasible and acceptable approach for cervical cancer screening among women in rural Delta State. Thus, the government should consider self-sampling as a valuable strategy in implementing national cancer screening programme.

KEYWORDS: Cervical cancer, human papillomavirus, DNA testing, self-sampling, feasibility, acceptability, Nigeria.

INTRODUCTION

Cervical cancer which is the third most common cancer among females worldwide was estimated at 569,847 new cases and 311,365 deaths in 2018[1]. About 80% of cases occur in low-and middle-income countries (LMICs), with sub-Saharan Africa having the highest burden of the disease [2]. Cancer of the cervix is the second most frequent cancer among women in Nigeria after breast cancer[3]. Nigeria has been ordered as the tenth country with global cervical cancer burden with mortality rate of 22.9 deaths per 100 [4]. Reports showed that about 48 million women are likely to be affected with cervical cancer, 17,550 are diagnosed yearly, 9, 659 die annually and 26 women die on a daily basis in Nigeria[5]. This is frightening as it has become a significant issue of

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public health concern in developing countries. The burden of the disease is worth considering with attendant morbidity and mortality among women in their productive years[6]. According to the World Health Organization, about 90% of cervical cancer can be reduced by regular screening. The relationship between Human Papillomavirus (HPV) and cervical cancer is well established. Due to the slow growing nature of HPV, cervical cancer is regarded as highly preventable and treatable if it can be detected earlier.The most important risk factor for cervical cancers are attributed to HPV 16 or 18 [7]. An estimated HPV prevalence of 11.7% globally and 24% in sub-Saharan Africa have been reported[8]. However, approximately 85% of the global HPV burden has been reported in developing countries, where it accounts for almost 12% of all cancers in females [9]. In Nigeria, the prevalence of HPV varies from 10% reported in Port Harcourt [10] to 26.3% in Ibadan [11] and 37% in Abuja [12]. Epidemiological studies have possible implications for vaccine development [13]. However, HPV vaccines are not yet readily available in Africa, therefore, an easy and feasible CC screening tool is expedient. Among the screening tools, HPV DNA testing is useful for primary CC screening among women aged 30 years and older, and vaginal self-sampling is considered valuable for detecting oncogenic high-risk HPV infection [14],especially in women with limited access to health care living in low-resource countries [15].

HPV self-sampling is a process where a woman who wants to know whether she has HPV infection uses a kit to collect a cervico-vaginal sample, which is then sent for laboratory analysis. [16]. One advantage of HPV testing is that it is the only screening test that can be done with a vaginal sample taken by the woman herself. The WHO endorse hr -HPV DNA testing as the primary cervical cancer screening approach in places where Pap testing has not been established [17].Where programmes are in place, a major obstacle for women across many cultures has been the prerequisite to undergo a speculum examination. Also, the recently lowered costs of HPV DNA testing may make this method of cervical cancer screening a viable screening option in a wide variety of settings.

Research carried out in both developed and developing countries generally suggest good feasibility and acceptability of HPV self-sampling. European studies have shown that women from Germany (89%), Netherlands (91%) and Italy (94%) perceived self-sampling as easy [18], and women from the Netherlands (75%), Italy (78%) and the US (79%) preferred self-sampling over a clinician-based examination [19]. Research on feasibility and acceptability of HPV self-sampling in Nigeria is limited. With a comprehensive approach to prevent, screen and treat, cervical cancer burden can be significantly reduced as a public health problem within a generation. We sought to assess the feasibility and acceptability of self-collected vaginal samples for HPV testing in rural Delta State.

METHODS

Study Location

The study took place in Orhuwhorun community in Udu Local Government Area (LGA), one of the 15 rural LGAs in Delta State. Delta State is one of six states in the oil-rich South-South region of Nigeria. According to the 2006 census figures, Udu LGA has a population of 142,480, Orhuwhorun inclusive. Orhuwhorun has grown to be the second most prominent and fastest developing town in the Udu LGA following the establishment of Delta Steel Company housing complex built in the 1970s for its workers.

Study Design and Population

This was a cross-sectional study conducted among 230 women between the ages of 30 to 65 years, resident in Orhuwhorun community. World Health Organization recommends HPV testing for women over 30 years of age due to the transient nature of HPV infections in younger women. Women who were pregnant, experiencing monthly menstrual flow, had history of hysterectomy and mental illness were ineligible to participate.

Sample Size Estimation

The formula ($n=z^2pq/d^2$) for one proportion study was used in calculating the sample size, where p was 81.2% (proportion of women who have preference for self-sampling in the future from a study in Ile-Ife, Nigeria). A minimum sample size of 234 was determined. The level of significance was set at 5% ($\alpha = 0.05$).

Sampling Method

Two hundred and thirty rural women were enrolled by a multi-stage sampling method. In the first stage, Udu LGA was selected from the 15 rural LGAs in Delta State by a simple random method. In the second stage, Orhuwhorun was selected from the 10 wards in Udu by using a simple random technique. The third stage involved selecting five streets in Orhuwhorun community from 15 major streets. Finally, a systematic sampling method was used to select one out of every two houses in the selected streets. In the houses where there was more than one eligible female, a participant was selected by balloting.

Study Procedure

Community heads in Orhuwhorun community were duly informed of the purpose and protocol of the research. Thereafter, a digital town crier was engaged to create a jingle on cervical cancer and announce around the clusters selected for the study. Study participants were recruited by a multi-stage random sampling technique and invited to the Orhuwhorun primary health centre. On each day for data collection, a brief health education on cervical cancer and research aim was done, women were taught how to perform the procedure for sampling the upper vagina according to the instructions on the Flobam female sample collection kit as

follow: Wash your hands before opening the product, open the product package on the side of the handle, take the swab out of the package without touching the white swab head, gently insert the swab head into the vagina until resistance is felt (allow 5cm) to ensure optimum sampling, then make 3 full rotations with the swab and remove the swab head from the vagina, break swab head into the HPV DNA collection vial without touching it and close the vial thoroughly. Each participant's sample was labelled with an identification code not name. The samples were kept frozen at -20°C and sent to College of Medicine, University of Lagos for HPV genotyping.

HPV Genotyping

Polymerase chain reaction (PCR) was used to amplify extracted HPV DNA from cervical samples. The amplified DNA amplicons were then hybridized with specific HPV probes located inside the "Hybrimen" under the patented "flow – through hybridization" technology followed by colorimetric result obtained using enzyme immunoassay method which was done using 21 HPV Geno-Array Diagnostic kits (HBGA-21PKG; Hybribio Biochemical Company Limited, Chaozhou, China). The kit detects high-risk types 16, 18, 31, 33, 35, 39, 45, 5 1, 52, 56, 58, 59, and 68, low- risk types 6, 11, 42, 43, 44, and 81 and probable high-risk types 53 and 66. The assay was performed according to the manufacturer's protocol.

Outcome Measure

After self-sampling (SS), the patient was sent to a separate study room where a research assistant, administered a brief questionnaire capturing sociodemographic characteristics, the feasibility and acceptability of the SS procedure. The feasibility section of the questionnaire included items about the ease of collecting samples, comfortability, time consumed and understanding SS instructions. In addition, number of samples satisfactory for HPV detection were analyzed to ascertain feasibility while items about women's confidence in their ability to self-collect a sample, future preference for SS and whether they would recommend SS to a friend, were used to assess acceptability. Questions were developed based on previous literature and work of the study authors.

Data Analysis

Relevant data were coded and entered into Microsoft Excel. Statistical analyses were conducted using IBM SPSS statistics version 25 (IBM Corp., Armonk, NY, United States).Descriptive statistics were used to report the sociodemographic characteristics of participants. Using questionnaire data, we calculated frequencies to describe feasibility and acceptability of self-sampling. Prevalence and distribution of HPV were also reported. The data were presented as frequency distribution tables. The questionnaire was developed based on previous literature and aim of this study.

Ethical Considerations

This project received ethical approval from the Research Ethics Committee of the University of Port Harcourt (UPH/CEREMAD/REC/MM73/014) and the Ministry of Health Research Ethics Committee (MOHREC) Asaba, Delta State with reference number HM/596/T/139. Permission was sought from Udu LGA primary health authorities and informed consent was obtained from the participants while confidentiality was assured. Research was done in accordance with the Helsinki Declaration.

RESULTS

A total number of 230 questionnaires were administered to recruited women and all 230 were consistent and filled, giving a response rate of 100%. Laboratory analysis was conducted on 228 samples as two samples were missing.

Socio-demographic Characteristics of Respondents

Table 1 shows that the mean age of respondents was 41.08 ± 8.45 years**,** 112(48.7%) were within 30 and 39years, 76(33%) were within 40 and 49years, 34(14.8%) were within 50 and 59years while 8(3.5%) were within 60 and 65years age group. Most of the respondents were married 209(90.9%), 12(5.2%) were single, 4(1.7%) were separated while 5(2.2%) were widows. The majority 222(96.5%) of the respondents were Christians, 5(2.2%) were Islam while 3(1.3%) were traditional worshippers. The Table also shows that 102(44.3%) had only completed their secondary school education, 78(33.9%) had attained tertiary level of education, 42(18.3%) stopped at primary school while 8(3.5%) did not go to school. The majority 165(71.7%) of the respondents were artisans, 40(17.4%) were civil servants, 14(6.1%) were health workers while 11(4.8%) were full time housewives.

Feasibility of self-sampling for HPV Testing

In Table 2, regarding the theme on how easy it was for study participant to understand self-sampling instruction, the majority 223(97%) reported very easy while 7(3%) reported difficult. On comfortability of undergoing self-sampling procedure, 218(94.8%) reported very comfortable while 12(5.2%) reported difficult. On the ease of self-collection, 221(96.1%) reported it was very easy while 9(3.9%) reported difficult. Regarding if the procedure was time consuming, 228(99.1%) reported No while only 2(0.9%) reported Yes it was time consuming. Human protein was found in all self-samples hence suitability was 100% for HPV detection.

Acceptability of self-sampling for HPV Testing

Regarding the theme on participants being confident they did the self-sampling procedure accurately, Table 3 revealed that, 229(99.6%) reported Yes, while only 1(0.4%) reported no. Regarding if participant would prefer to use self-sampling as a screening tool in the future, 14(6.1%) reported No while 216(93.9%) reported Yes. Regarding if participant would

recommend self-sampling procedure to a friend, 3(1.3%) reported No while 227(98.7%) reported Yes.

Prevalence and Distribution of HPV Infection

Table 4 reveals that among the 228 self-collected samples, overall HPV infection was 48 (21.1%). 30(13.2%) women had any of these high risk HPV (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 58, 59). The commonest HPV type seen was HPV 52(3.5%), 18(2.2%), 33(1.3%), 39(1.3%) and 58(1.3%). Probable high risk HPV (53 and 66) were found in 6 cases (2.6%) while low risk HPV (6, 42 and 44) were found in 4cases(1.8%). Multiple infection occurred in 10 cases (4.4%).

DISCUSSION

Our finding suggest that self-sampling is an excellent feasible method of cervical cancer screening in this rural, Nigerian population. All self-samples (100%) in our study were suitabile for HPV testing which agrees with Fall et al [20]in Senegal but slighty differ from that reported in a study in Nigeria (97.5%) and 96% in Ontario [21]. This finding reinforces the evidence that women can be educated to collect samples of adequate quality.On ease of performing SS, this study observed higher percentage (96.1%) compared to 76.3% reported in Ghana [22],80% reported among Haitian and Latina women in Miami [19], 87.9% reported in Ethiopia [23] but comparable with 91% observed in Guatemala [24], 94.0% in Mexico [25] and 98% reported in rural Malawi [26]. When the women were asked if SS insrtuction was difficult to understand,we found similar report in North Carolina [27], where most participants (93.6%) reported no difficulty understanding self-collection instructions. Assessing comfortability of SS, our result was comparable with Flores et al that revealed 88.8% had no discomfort at all, over 90% agreed self-sampling was easy and comfortable in Botswana [28] and 98% reported comfort and ease in Thailand [29] but lesser percentage (79%) found SS comfortable in Guatemala [24].

Perceptions and experience of HPV self-sampling were evaluated in three domains, including confidence in handling procedure, preference for future use as a screening tool and willingness to recommend to a friend. We found self-sampling was widely acceptable, easy to perform and preferred to clinician-collection. Acceptability of SS in this study was 93%. Combined with results from other research, our study provides evidence that self-collection could be used in an outreach capacity to increase screening in hard-to-reach populations. In Argentina, women who were offered the opportunity of self-collection were four times as likely to be screened for cervical cancer than women who were not offered the option to self-collect [30]. In a randomized control trial conducted in Uganda, 98% of women in the HPV self-collection arm were screened for cervical cancer while only 48% were screened in the control arm [31]. A similar result was observed in a randomized control trial conducted in Nigeria where 93% in the self-collection arm submitted self-samples while only 56% in the clinician-collection arm presented themselves to the hospital [32]. An investigation in Guatemala reported a high SS acceptability of 89% [24] and 94% [33]. Absolute acceptance (100%) of SS was observed in rural Madagascar [34]. These findings corroborate our results but differ from a lower level (67%) observed in Miami [19].

World wide variation exists on women's preference for HPV self-sampling in the future ranging from 51% reported in North Carolina [35], 57.7% in Ghana [22], 70% in Thailand [29],80% in Miami [19], 81.2% in Ile Ife [36], 86.3% in a systematic review in Africa [37], 95% in Botswana [28], 96.5% in North Carolina, 96.6% in Mexico [25], 99% in rural Malawi [26], to 100% in Guatemala [24]. Assessing participant's confidence in carrying out SS procedure, our finding totally agree (96.8%) with Flores et al [25]. However, the HPV self-sampling kits were used differently across studies and several factors may have an impact on user's acceptability and preference towards self-sampling such as sociodemographics, religious beliefs, and race/ethnicity or cultural differences [38]. Thus, the underlying variations on the acceptability of self-sampling across studies should be explored in order to incorporate self-sampling as a screening modality for national cervical cancer prevention programme.

HPV prevalence from our study was 21.1% which was close to global data of 22.1% HPV infection in Africa [39]. This was much higher than 10% in Port Harcourt [10]; 17.3% in Ile-Ife [36]; 18.5% in Cameroon [15]; 19.5% in Awka [40] and 19.9% in Malawi [41]. However, our result was comparable to 22.7% reported in Ethiopia [23]; 23.5% in the Republic of Congo [42]; 25.4% in Burkina Faso [43]; 26.3% in Ibadan, Nigeria [11] but much lower than 31.6% reported in Madagascar [44]; 33.2% in Benin Republic [45]; 34% in Rwanda [46]; 37% in Abuja [12]; 50.8% in Guinea [47] and 76% in Morocco [48]. It was also observed from our research that HPV positivity was highest among women of 30 - 40 years age range and lowest among 50 – 60 years age range. The finding of the highest proportion of HPV infection among the 30 to 40 years age group corroborated a similar finding in Lagos [49] and Ibadan [11]. Part of the reasons that was proposed for this finding was that a fraction of the spouses or partners of these women may continue to have multiple sexual contacts and thereby re-infecting themselves and these women in the process [11].

A study conducted in North Carolina [27], reported high-risk HPV prevalence was 12.4% which is consistent with our finding. Lesser rates of 10.0% and 6.2%were reported in Thailand [50] and Ile-Ife [51] while much higher rates (22.8%) were found in Mexico [25] and Lagos (36.5%) [52] with the most predominant sub types being HPV 31 (25.0%), 35 (8.0%) and 16 (3.5%). The commonest HPV type obtained from Ajenifuja et al investigation was HPV 58 (2.6%) with multiple HPV genotypes in 5 cases (2.6%),

but HPV 52(3.5%) was most frequent in our study with multiple HPV in 10 (4.4%) cases. An investigation in Senegal [20] revealed high-risk HPV types found were HPV 16, 18, 31, 58, and 66, which is almost consistent with our finding. Of note, 4.5% of low-risk HPV types (HPV 22, 62, 70, and 81) were identified which is contradictory to 1.8% (6, 42 and 44) in this present study. Again, no multiple infection was seen which is in contrast with our result. This variations could be related to the genotyping technique used in the studies.

This study is one of the few that has conducted a community–based HPV self-sampling among asymptomatic rural women in Nigeria. Community based study findings are representative of the general population unlike hospital-based study. Our sample size was moderate, providing opportunity for 230 women to get screened for cervical cancer. Its worthy of note, that this study also included Pap smear test, detection of six other sexually transmitted infections for all participants and colposcopy for abnormal cytology or HPV positive cases. These results will be reported in subsequent publications. A limitation of our study is the use of interviewer administered questionnaires which may have skewed responses to some of the sensitive questions on sexual history towards what was perceived to be more socially acceptable. However studies have shown that the influence of biased responses are minor and do not affect overall results [32].

CONCLUSION

Data from epidemiologic studies provide support for evidence-based decisions in health policy making to incorporate self-sampling strategies into cervical screening programme. Our study forms a basis for promoting cervical cancer screening and increasing the knowledge of HPV.A target of World Health Organization's global strategy towards eliminating cervical cancer as a public health problem is to screen 70% of women between 30 and 45years by 2030. Self-sampling is a feasible and acceptable method to increase women's participation in screening programmes.

What is known about this topic

- The most important risk factor for cervical cancer is infection by the human papillomavirus (HPV) .
- HPV self-sampling is acceptable in some developed and developing countries because it is easy to perform with minimal discomfort.

What this study adds

- The commonest HPV DNA in this study was HPV 52. This is of epidemiologic importance as it is a high-risk type.
- This study adds new findings to the body of knowledge on self-sampling in the local population. We found that more women are willing to do self-sampling at the clinic rather than at home.
- The excellent feasibility and acceptability found could be a framework to support the activities of policy makers in reducing cervical cancer burden in Nigeria and other parts of sub-Saharan Africa through HPV testing.

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Competing Interests

Flobam self-collection kits and consummables were donated by Molecular Diagnostics, Lagos State, Nigeria. Prof. Banjo Adekunbiola is a board member at Molecular Diagnostics, Nigeria.The remaining authors have no competing financial interest.

Authors Contributions

All authors have contributed to this work. All the authors have read and agreed to the final manuscript.

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Table 1: Socio-demographic characteristics of respondents

Characteristics	Frequency (n=230)	Percentage (%)
Age years		
30 – 39	112	48.7
40 – 49	76	33.0
50 – 59	34	14.8
60 – 65	8	3.5
Mean age	***41.08 ± 8.45years***	
Marital Status		
Single	12	5.2
Married	209	90.9
Separated	4	1.7
Widows	5	2.2
Religion		
Christianity	222	96.5
Islam	5	2.2
Traditional Worshippers	3	1.3
Educational Level		
None	8	3.5
Primary	42	18.3
Secondary	102	44.3
Tertiary	78	33.9
Occupation		
Civil servant	40	17.4
Health Worker	14	6.1
Artisan	165	71.7

Table 2: Feasibility of self-sampling for HPV testing

Characteristics	Frequency (n=230)	Percentage (%)
How easy was it for you to understand the SS instruction?		
Very easy	223	97.0
Difficult	7	3.0
How comfortable was the self-sampling procedure?		
Very easy	218	94.8
Difficult	12	5.2

How easy was the procedure of self-collection?		
Very easy	221	96.1
Difficult	9	3.9
Was the procedure time consuming?		
No	228	99.1
Yes	2	0.9
Self –collected samples suitable for HPV detection		
Invalid	0	0.0
Valid	228	99.1
Missing	2	0.9
Total	230	100.0

Table 3: Acceptability of self-sampling for HPV testing

Characteristics	Frequency (n=230)	Percentage (%)
Are you confident you did SS accurately?		
No	1	0.4
Yes	229	99.6
Would you prefer to use SS as a screening tool in the future?		
No	14	6.1
Yes	216	93.9
Would you recommend self-sampling to a friend?		
No	3	1.3
Yes	227	98.7

Table 4: Prevalence and distribution of HPV infection in rural Delta State.

Characteristics	Frequency (n/total)	Percentage (%)
HPV infection	48/228	21.1
High risk HPV types		
Type 52	8/228	3.5
Type 18	5/228	2.2
Type 39	3/228	1.3
Type 33	3/228	1.3
Type 58	3/228	1.3
Type 31	2/228	0.9
Type 16	2/228	0.9
Type 35	1/228	0.4
Types 45	1/228	0.4
Type 51	1/228	0.4
Type 59	1/228	0.4
Total	30/228	13.2
Probable High risk HPV types		
Type 53	4/228	1.7
Type 66	2/228	0.8
Total	6/228	2.6
Low risk HPV types		
Type 44	2/228	0.9
Type 42	1/228	0.4
Type 6	1/228	0.4
Total	4/228	1.8
Multiple HPV infections		
Type 16,51	1/228	0.4
Type 31, 68	1/228	0.4

Type 33,52	1/228	0.4
Type 33,68	1/228	0.4
Type 44, 18	1/228	0.4
Type 51,53	1/228	0.4
Types 11, 33	1/228	0.4
Types 16,18, 31	1/228	0.4
Types 33, 52	1/228	0.4
Types 42, 33,39	1/228	0.4
Total	10/228	4.4