# Performance and Acceptability of Self- Versus Clinician-Collected Swabs for Testing of High-Risk HPV DNA among Women in Mysore, India: Diagnostic Study

Purnima Madhivanan[1], Holly Nishimura[2], Kavitha Ravi[3], Benjamin Pope[1], Vijaya Srinivas[3], Karl Krupp[1], Poornima Jaykrishna[3], and Anjali Arun[3]

[1]The University of Arizona Mel and Enid Zuckerman College of Public Health
[2]Johns Hopkins University Bloomberg School of Public Health
[3]Public Health Research Institute of India

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**Abstract**

Objective: To assess the feasibility and acceptability of self-sampling for HPV testing as compared to clinician-collected sample in a community-based setting in rural Mysore among asymptomatic women. Design: Cross-sectional Study Setting: Rural communities in Mysore, India Population: Women aged over 30 years eligible for cervical cancer screening Methods: Cervical cancer screening was conducted using mobile medical clinics in community based settings. Women self-collected vaginal samples followed by a clinical exam and sample collection for assessing high-risk HPV DNA. Summary statistics were calculated on a range of sociodemographic and health behavior variables. Main Outcome Measures: Measures of sensitivity, specificity, concordance with physician-collected specimens were calculated. Five measures of acceptability (feeling of caring, privacy, embarrassment, genital discomfort, and genital pain) Results: Median age of the respondents was 39 years. The largest percentage of respondents (41.7%, n=50) had a secondary education or above and were married (87.5%, n=105). Most respondents (57.1%, n=68), had never been screened for cervical cancer. The self-collected specimen for HPV DNA had higher specificity (98.1%; 95% CI: 95.5, 100) than it did sensitivity (66.7%; 95% CI: 42.8, 90.6). For all measures of acceptability, the self-collected mean was significantly higher than the clinician-collected mean. Conclusion: This study demonstrated that self-collected sampling performed just as well as clinician-collected samples to screen for HPV DNA. Self-collection was preferred by women living in rural communities, especially when the instructions on collection are provided in a user-friendly, non-judgmental manner.

**TWEETABLE ABSTRACT**

Self-collected sampling performed just as well as clinician-collected samples to screen for HPV DNA.

**KEYWORDS:** Screening, Cervical Cancer, India, Self-collection

**FUNDING SOURCE:**

HN was funded by the NIH National Center on Minority Health & Health Disparities (T37 MD003406). PM and KK were partially funded by NIH Fogarty International Center; National Heart, Lung, and Blood Institute; and National Institute of Neurological Disorders and Stroke (D43 TW010540). PM was also partly funded by NIH National Institute of Allergy and Infectious Diseases (R15 AI28714-01). The funders had no role in the study design, data collection, management, analysis, or interpretation of the data, and preparation, review, or approval of the manuscript.

**INTRODUCTION**

Cervical cancer is the fourth most common cancer in women worldwide, and the seventh overall, with an estimated 570,000 incident cases per year with 311,000 women dying from the disease.[1,2]Approximately nine out of 10 cervical cancer deaths occur in less developed regions.[3,4] Developed countries including those in North America, Europe, Australia/New Zealand, and Japan have been effective in reducing cervical cancer incidence and mortality due to population-based cytologic screening programs.[1,5]Cytology-based screening, conducted as part of a pelvic examination, is a method of detecting pre-invasive neoplasia (also known as pre-cancerous lesions). Detection and treatment of neoplasia at the pre-invasive stage can prevent lesions from becoming cancerous. Advances in cytology-based screening, however, have not translated to less developed regions including countries in Africa, South and Southeast Asia, and parts of Latin America where cervical cancer is the second most common cancer.

To address many of the barriers to cervical cancer screening, the World Health Organization (WHO) recommends low-cost, culturally-acceptable alternatives to cytology such as Human Papillomavirus (HPV) DNA testing.[6] Persistent HPV infection is associated with the vast majority of cervical cancer cases.[6] Tests for HPV DNA are easily reproducible and have higher sensitivity for detecting high-grade cervical intraepithelial neoplasia than cytological tests.[3,4,6-8] A meta-analysis found an overall sensitivity of 80-95% for HPV testing compared to 60-80% for cytologic testing, and an overall specificity of 50-70% for HPV testing compared to 85-95% for cytologic testing.[9] Unlike cytologic testing, HPV testing does not require retesting or multiple visits from the patient. HPV testing also offers an option for self-sampling where cytological testing does not.

Due to the physical and psychological discomfort associated with the pelvic exam necessary for cytologic testing, self-sampling may be an acceptable alternative. Furthermore, Indian women continue to be hesitant and shy about undergoing a pelvic exam culturally. The self-collection method addresses structural issues to resource constraints, lack of staff, and space to provide screening. A recent systematic review of 37 self-collection studies from 24 countries found overall high acceptability.[10] A self-sampling option may be appealing to women that would otherwise not screen.

To address the burden of cervical cancer, the Indian Ministry of Health implemented a nation-wide cancer-screening program in November 2016. India with the world's second largest population, also experiences a large proportion (27%) of the world's cervical cancer deaths annually.[4] Each year 96,922 women are diagnosed with cervical cancer and 60,078 die from the disease.[3,11]The screening program required mandatory oral, breast, and cervical cancer screening for people over the age of 30 in 100 selected districts of India.[12] While preliminary data regarding the overall impact of cancer screening program is not available, three hospital based studies showed promising results.[13-15]If the nation-wide screening program is to be successful in the culturally and economically diverse regions of India, feasibility and acceptability of different screening methods must be identified and addressed.

This study was conducted in a community-based setting in rural communities in the state of Karnataka among asymptomatic women attending a mobile cervical cancer screening program. The objective was to assess the feasibility and acceptability of self-sampling for HPV testing as compared to clinician-collected sample.

## METHODS

### Study Sample/Population

This was a cross-sectional study that collected data between May and August 2017. Two-hundred participants were recruited in order to obtain a sample size of 120. Inclusion criteria for participation was being 30 years or older, who have not undergone cervical cancer screening within the last three years and having the capacity to undergo informed consent process. Women who had had a hysterectomy, currently menstruating, pregnant or had been diagnosed with cervical cancer were excluded from the study. The women who were menstruating were invited to enroll after menstruation.

### Ethical approvals

Only women who were able to give informed consent were recruited to participate in the study. The study research protocol was reviewed and approved by the institutional ethics committees of Public Health Research Institute of India and University of California, Berkeley.

**Funding**

The study was funded by the National Institutes for Health, National Center on Minority Health & Health Disparities (T37 MD003406) and Fogarty International Center; National Heart, Lung, and Blood Institute; and National Institute of Neurological Disorders and Stroke (D43 TW010540). The study was reviewed by external peer review for scientific quality before being approved for funding. In addition, the study was evaluated by the community advisory board at PHRII before implementation. The funder played no role in the conduct of the research or writing of the paper

# Recruitment

The study was conducted at the Public Health Research Institute of India (PHRII) mobile cervical cancer screening program in Mysore, Karnataka, India. A study staff member invited women in the waiting area awaiting a pelvic exam as part of the standard of care for cervical cancer screening, to participate in the study. The mobile clinics were set up in eight rural villages of Mysore District in cooperation with District surveillance officer who represents the District Health and Family Welfare Officer, Mysore.

# Screening

Women who were eligible to participate were seen by a member of the research staff to obtain informed consent in *Kannada* , the predominant language spoken in the region. Participants then answered an interviewer administered brief questionnaire to collect socio-demographic, reproductive, and health data, as well as an assessment of knowledge regarding cervical cancer. After the screening was completed, they completed a short interviewer-administered survey on acceptability of the collection method.

# Procedure

After the screening questionnaire was completed by the study staff member, the participant was asked to self-collect a vaginal swab in the privacy of their homes or in a private space near the mobile clinic. The study participant was provided instruction with visuals on how to perform the self-collection. Briefly, the woman was instructed to insert the swab two inches into her vagina, swirl three times along the upper vaginal wall, then to remove and place the swab into the provided collection tube and return to the research staff. Swab insertion and removal was not witnessed by the research staff member. The cervicovaginal sample was collected using a broom-type collection device (Digene HC2 NA Collection Device) and then placed in a 1ml of specimen transport medium (STM) containing PreservCyt solution to prevent drying of the sample. At the time of receipt, the study interviewer verified if the swab was completely submerged into the solution and the collection bottle was closed correctly.

As part of the standard of care for cervical cancer screening, a clinician performed a pelvic examination. Lubricant was not applied to the speculum prior to insertion. After speculum placement, the cervical os was visualized and a cotton-tipped swab was used to remove any excess secretions. An endocervical specimen was collected by inserting the brush-like collection device into the cervical os and rotating five times. This was placed in the collection device which was then sent to PHRII laboratory by maintaining cold/refrigerated condition for further testing for HPV. After the completion of the examination, the research interviewer administered an acceptability questionnaire about the woman's experiences with the pelvic exam and self-collection processes. The questionnaire was a Likert scale, that ranged from 1 (least favorable) to 5

(most favorable), to evaluate experiences related to perception of care, comfort, privacy, embarrassment, and pain for both collection methods individually. Measures used in the acceptability questionnaire have been previously used in other HPV self-sampling studies. The questionnaire also assessed difficulties encountered during self-collection and questions regarding the ability to perform the self-collection.

**Testing**

The Digene HC2 NA Collection Device was used for both self- and physician-collected sampling. The self-collected and clinician-collected swabs were transported to and tested at the PHRII laboratory. Both the swabs were tested on the *digene* Hybrid Capture 2 HPV DNA Test, Qiagen platform that used an RNA probe cocktail that detects 13 high-risk HPV types (16/18/31/33/35/39/45/51/52/56/ 58/59/68). To prevent false negatives caused by gene deletions, the *digene* HC2 HPV DNA Test uses full genome RNA probes complementary to HPV DNA, specific antibodies, signal amplification, and chemiluminescent detection. Women were given verbal and pictorial instructions prior to testing to use a cervical brush, which was then swirled and stored in the PreservCyt Solution.

**Data Analysis**

Summary statistics were generated for demographic variables. Summary statistics were also generated for clinical characteristics, such as whether the participants had been screened for cervical cancer, the vaginal pH, the severity of the outcome among those who were screened and tested positive on visual inspection with acetic acid (VIA), and the cytology result of those who were VIA positive. Additionally, summary statistics were tabulated for preferences for cervical cancer screening, including gender preference of the provider, collection type preference (physician or self), whether the respondents would test with self-collection again, and whether they would recommend self-collection to a friend. A 2-by-2 table was generated to compare self-collected versus physician-collected specimens. From this table, performance measures and their associated 95% confidence intervals were generated, including sensitivity and specificity, predictive values positive and negative, and the proportion of concordant pairs and the proportion of concordant pairs among those pairs for which the physician-collected sample was HPV DNA testing.

Acceptability measures included: how well cared for respondents felt; how well the respondents' privacy was handled during the tests; the extent to which respondents felt embarrassed during the test; whether the test caused the respondents genital discomfort; and whether the test caused the respondents genital pain.

Data were compared using a paired t-test, or, as appropriate, the Wilcoxon signed-rank test. Cohen's kappa, a measure of agreement between two raters, was also computed. For Cohen's kappa, a value near zero represented agreement being due to random chance, 0.01-0.20 represented slight agreement; 0.21-0.40, fair agreement; 0.41-0.60, moderate agreement; 0.61-0.80, substantial agreement; and 0.81-1.00 almost perfect agreement. All tests were carried out using an $\alpha$=0.05 significance level. Stata version 11.2 (StataCorp, College Station, TX) was used for all analyses except for Cohen's Kappa and its associated confidence interval, for which the ckap command, part of the rel package in R version 3.6.2 (R Core Team 2019), was used.

## RESULTS

Sociodemographic characteristics of the study participants is in Table 1. Among the participants, the median age was 39 (IQR: 32-45), while the median monthly income was 5,000 INR (IQR: 3,000-10,000). The highest percentage of respondents (41.7%, n=50) had secondary or higher education, while the majority (n=113, 95.0%) were Hindu, married (87.5%, n=105), and never smokers (n=113, 94.2%). About three-fifths of respondents (57.1%) reported having never been screened for cervical cancer, 70.8% had a negative VIA result, and 67.5% had a vaginal pH greater than 4.5. All of the respondents who had a VIA positive result had only a mild severity, and more than half had a negative cytology result (57.7%) (S1. Figure).

Overall prevalence of HPV DNA positivity in the clinician collected endocervical swab samples was 12.6% (95%CI: 7.7, 19.9). The self-collected vaginal swab, when compared to the gold standard of the physician-collected endocervical swab for HPV DNA testing, had a greater specificity (98.1%, 95% CI: 95.5, 100) than

it did sensitivity (66.7%, 95% CI: 42.8, 90.6). The overall agreement between the two tests was 94.1% (95% CI: 88.1, 97.3). The Cohen's kappa value was 0.735 (95% CI: 0.342, 1.0) (Table 2).

The vast majority (84.8%) of respondents preferred to have a provider of the same gender for their pelvic examinations, while about three-in-five (59.3%) preferred to self-collect for their HPV DNA test. All said that they would test with self-collection again and recommend self-collection to a friend (Table 3). For each of the five measures of acceptability of self-collection versus physician-collection, self-collection was significantly more favorable than was physician collection (all p-values were less than 0.05). The smallest difference was in how well cared for the participants felt (mean of 3.57 for self-collected versus 3.46 for physician-collected), while the largest difference was in whether the test caused genital pain (mean of 3.42 for self-collection versus 2.85 for clinician-collected). (Table 4)

## DISCUSSION

### Main Findings

This study was designed to inform the feasibility and acceptability for conducting community based cervical cancer screening programs using mobile clinics in rural communities in India. The study has reiterated that self-collection of vaginal samples was feasible and acceptable to women living in rural India. In fact, they preferred self-collection and were comfortable with the process. By using self-collected samples to rule out HPV infection, it is possible to reduce missed opportunities for screening in rural India.

Additional considerations for the feasibility of large-scale HPV self-sampling campaigns concern accuracy of results of the self-sampling process. This study found comparable performance and accuracy of self-collection for detection of high-risk HPV DNA. There have been several studies comparing HPV screening results from self-collected and clinician-collected specimens in low- and middle-income countries with all demonstrating high levels of agreement.[16-22] A review and meta-analysis of 21 studies did not detect statistical significance difference in sensitivity of self-collected specimens compared to clinician-collected specimens. The authors suggested a pooled analysis of sensitivity data to detect whether sampling methods yielded statistically different sensitivities. The majority of studies in the review reported similar specificity for both sampling methods.[23] Clinically, the data suggested that self-sampling of HPV specimens was a viable alternative to clinician-sampling.

### Interpretation in light of other evidence

Consistent with previous studies comparing self-collected to clinician-collected specimens, we found that self-collected HPV specimens have a great potential to be used in community-based, screening programs. A review of nine studies found that participation in a cervical cancer screening program increased from 8.7% to 39% when self-sampling was offered as a screening option.[23]Overall, current data suggest that a self-collection option can increase participation in cervical cancer programs in India, and other low- and middle-income countries. While there have been reports of their successful use in Africa, Latin America and in developed countries, there is limited data of their use in India.[24,25]

This is also one of the few studies that examined the usefulness of self-collected swabs for cervical cancer screening in rural India.[26,27] Furthermore, the laboratory assessments of both modes of sample collection revealed high concordance when comparing specimens collected by self-collection and clinician-collected swabs. Thus, self-collected swabs were acceptable to a substantial group of rural women and were reliable in terms of the detection of HPV DNA making them one of the preferred methods to be used in population based surveillance of reproductive cancers such as cervical cancer.

### Strengths and Limitations

This study should be considered in light of its limitations. First, since this was a pilot study to evaluate the interest and acceptability of using self-collection methods before rolling out the large screening program, the sample size was small. Second, it is possible that there might be information bias as the acceptability information may be influenced by the fact that the women were asked to respond to the survey by an interviewer.

Despite these limitations, this was one of the first studies to examine the feasibility and acceptability of using self-collection techniques in a community based setting in a rural area of India. We used standardized tests to screen for HPV DNA and all study staff were trained to administer the surveys in a non-judgmental manner.

Based on the findings from this study, PHRII has used self-collected swabs as one of the main methods for specimen collection in all their subsequent community studies of cervical cancer screening in rural Mysore, India. This study demonstrated that self-collected swabs were preferred by a large number of women, especially when the instructions on collection were provided in a user friendly, non-judgmental manner.

**Conclusion**

Detection of HPV infection, associated with pre-cancerous lesions, is extremely effective for the prevention of cervical cancer. To reduce the burden of cervical cancer in developing countries such as India, screening methods must be cost-effective and culturally acceptable. Self-collection of specimens for HPV DNA testing is a promising alternative to cytologic testing for developing countries.

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## COMPETING INTERESTS:

The authors declare that they have no competing interests.

## AUTHOR CONTRIBUTIONS :

Dr. Madhivanan had full access to all data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis. All authors accept responsibility for the paper as published.

Study concept and design: Nishimura, Krupp, Ravi, Madhivanan, Srinivas, Arun

Acquisition of data: Nishimura, Ravi, Krupp, Jaykrishna, Srinivas, Arun

Analysis and interpretation of data: Nishimura, Pope, Madhivanan, Jaykrishna, Krupp

Drafting of the manuscript: Madhivanan, Pope, Krupp, Nishimura

Critical revision of the manuscript for important intellectual content: All authors

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## DETAILS OF ETHICS APPROVAL

The study was reviewed and approved by the Institutional Review Boards at University of California, Berkeley (Protocol #2017-03-9670; Dated 4$^{th}$ April 2017) and Public Health Research Institute of India, Mysore (Protocol #2017-04-01-36; Dated 1$^{st}$April 2017).

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**Table 1:** Demographic and Clinical Characteristics Women in rural Mysore, India (N=120)

| Characteristics | n (%) or median (IQR) |
|---|---|
| **Demographic Characteristics** | |
| Age (years) | 39 [32-45] |
| Monthly income (INR) | 5000 [3000-10,000] |
| Education | |
| None | 29 (24.2) |
| Primary (1-4) | 14 (11.7) |
| Middle (5-7) | 25 (20.8) |
| Secondary or above (8 or above) | 50 (41.7) |
| Religion | |
| Hindu | 113 (94.2) |
| Muslim | 6 (5.0) |
| Marital status | |
| Married | 105 (87.5) |
| Widowed | 14 (11.7) |
| Gravidity | |
| Primigravida | 7 (5.8) |
| Multigravida | 104 (86.7) |
| **Clinical Characteristics** | |
| Ever screened for cervical cancer | |

| Characteristics | n (%) or median (IQR) |
|---|---|
| No | 68 (57.1) |
| Yes | 0 (0.0) |
| Don't Know | 51 (42.9) |
| VIA Result | |
| Negative | 85 (70.8) |
| Positive | 26 (21.7) |
| Not completed | 9 (7.5) |
| Vaginal pH | |
| <= 4.5 | 39 (32.5) |
| >4.5 | 81 (67.5) |

**Table 2:** Two-by-Two Table of Self-Collected Specimens Compared to Physician-Collected Specimens for HPV DNA in Mysore, India. (N=119)

| | **Physician-Collected Specimens** | **Physician-Collected Specimens** | **Physician-Collected Specimens** |
|---|---|---|---|
| **Self-Collected Specimens** | Positive | Negative | Total |
| Positive | 10 | 2 | 12 |
| Negative | 5 | 102 | 107 |
| Total | 15 | 104 | 119 |
| | **Estimate** | **95% CI** | |
| **Sensitivity** | 0.667 | (0.428, 0.906) | |
| **Specificity** | 0.981 | (0.955, 1.000) | |
| **PPV** | 0.833 | (0.622, 1.000) | |
| **NPV** | 0.953 | (0.913, 0.993) | |
| **κ-statistic** | 0.735 | (0.342, 1.000) | |
| **Total agreement** | 0.941 | (0.881, 0.973) | |
| **HPV positive agreement** | 0.667 | (0.415, 0.850) | |

**Table 3:** Cervical cancer screening examination preferences (n=118)

| Measure | Measure | n (%) | n (%) |
|---|---|---|---|
| Gender preference for provider | Gender preference for provider | | |
| Male | Male | 1 (0.9) | 1 (0.9) |
| Female | Female | 100 (84.8) | 100 (84.8) |
| No preference | No preference | 17 (14.4) | 17 (14.4) |
| Collection type preference for HPV DNA test | Collection type preference for HPV DNA test | | |
| Self-collection | Self-collection | 70 (59.3) | 70 (59.3) |
| Physician-collection | Physician-collection | 33 (28.0) | 33 (28.0) |
| No preference | No preference | 15 (12.7) | 15 (12.7) |

| Measure | Measure | n (%) | n (%) |
|---|---|---|---|
| Test with self-collection again (n=117) | Test with self-collection again (n=117) | | |
| No | No | 0 (0%) | 0 (0%) |
| Yes | Yes | 117 (100%) | 117 (100%) |
| Recommend self-collection to a friend | Recommend self-collection to a friend | | |
| No | 0 (0%) | 0 (0%) | |
| Yes | 118 (100%) | 118 (100%) | |

*Range from 1 to 5, 1 = least favorable and 5= most favorable

**Table 4:** Acceptability of Self-Collection Compared to Physician-Collection for HPV DNA testing (N=118)

| Acceptability Measure | Self-Collection Mean(SD) | Physician-Collection Mean(SD) | p-value |
|---|---|---|---|
| How well cared for did you feel? | 3.57 (0.7) | 3.46 (0.63) | 0.005 |
| How well was your privacy handled during the test? | 3.61 (0.66) | 3.47(0.59) | <0.001 |
| Did you feel embarrassed? | 3.47 (0.68) | 3.25 (0.63) | <0.001 |
| Did the test cause you any genital discomfort? | 3.47 (0.64) | 3.00 (0.94) | <0.001 |
| Did the test cause you any genital pain? | 3.42 (0.67) | 2.85 (1.06) | <0.001 |

*Range from 1 to 5, 1 = least favorable and 5= most favorable