

## ORIGINAL RESEARCH



# Feasibility, validity and acceptability of self-collected samples for human papillomavirus (HPV) testing in rural Malawi

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## Abstract

### Aim

The World Health Organization (WHO) recently endorsed human papillomavirus (HPV) testing as a cervical cancer screening method in countries without established programs. Self-collection for HPV testing may be an effective way to expand screening. Our objective was to assess the feasibility, validity, and acceptability of self-collection for HPV testing in a population of care-seeking, unscreened women in rural Malawi.

### Methods

We enrolled women reporting to a rural Malawian clinic from January to August 2015. Participants were offered the option to self-collect a vaginal sample and the study clinician collected a cervical sample for HPV testing. Using the clinician-collected sample as the reference standard, we calculated a kappa statistic, sensitivity, and specificity by hr-HPV type. Participants also received a brief survey assessing acceptability of the procedure.

### Results

Among the 199 enrolled women, 22% had any high risk-HPV. Comparing self- and clinician-collected samples for HPV testing, we found generally high agreement ( $\kappa = 0.66-0.90$ ) and high specificity (98%-100%), but varied sensitivity (50%-91%) for different types of hr-HPV. We also found that self-collection was acceptable, with 98% of women reporting it was easy to do and 99% reporting willingness to do so again.

### Conclusions

WHO guidelines recommend that treatment is available immediately after a positive screening test for clinic-based cervical cancer screening programs. Our findings demonstrate that self-collection of samples for HPV testing is a feasible and acceptable method of cervical cancer screening in this rural Malawian population. High agreement between the self- and clinician-collected samples and high levels of acceptability among women in the study suggest that self-collection of vaginal samples for HPV testing may be effectively incorporated into screening programs among rural, largely unscreened populations.

## Introduction

Effective and widespread cervical cancer screening has greatly reduced cervical cancer incidence and related morbidity and mortality<sup>1</sup>. The most commonly used cervical cancer screening method worldwide is a Pap test, which involves the collection of cervical cells for examination under a microscope by a cytopathologist. Pap testing detects abnormal cells in the cervix and enables early detection and treatment of cervical cancer<sup>1</sup>. However, Pap screening programs have low feasibility in limited-resource settings owing to a lack of infrastructure and trained personnel, limited health budgets and competing healthcare priorities<sup>2,3</sup>. To address these barriers, some national screening programs use alternatives to traditional cytology (Pap testing), such as visual inspection of the cervix with acetic acid (VIA). VIA involves unaided (naked eye) inspection of the cervix after application of acetic acid to identify abnormal tissue. While VIA eliminates some constraints of Pap testing, such as cost and need for multiple visits, there can be high variability by provider in the quality of VIA screening<sup>4,6</sup>.

DNA testing for human papillomavirus (HPV) offers an accurate alternative to VIA. The WHO recommends hr-HPV DNA testing as the primary cervical cancer screening approach in places where Pap testing has not been established<sup>7</sup>. Similar to other screening methods, cervical samples are typically gathered by a clinician during the course of a pelvic examination, but samples can also be self-collected by women themselves with a swab. WHO recommends screening with an HPV test and treatment over screening with VIA and treatment where feasible<sup>7</sup>. HPV testing is also recommended as first line screening followed by VIA and treatment<sup>7</sup>.

When successfully introduced, self-collection of samples for HPV testing can increase screening for hard to reach women or women who do not come in for screening tests<sup>8-11</sup>. Self-collected samples have been shown to perform comparably to clinician-collected samples, but published findings suggest that the population and method of collection or testing are important to consider when assessing the utility of self-collected samples<sup>12-15</sup>.





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