89

Validation of GeneXpert testing for human papillomavirus and self-collected sampling for cervical cancer screening in Gutu District, Zimbabwe

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Introduction

Cervical cancer is now largely a preventable disease; however, implementation of highly sensitive molecular screening technologies in low-resource settings is partly hindered by the need for intensive investment in equipment and highly trained, skilled laboratory personnel. Resource limitations often preclude the possibility of same-day screening and treatment, as recommend by WHO. We sought to assess the diagnostic accuracy of self-collected versus nurse-collected high vaginal samples (HVS) for human papillomavirus (HPV) screening using GeneXpert, for within-country validation and to further inform its scale-up within routine point-of-care testing in primary healthcare systems.

Methods

Consenting women presenting for routine cervical screening in selected health facilities in Gutu District, Zimbabwe, were asked to provide three HVS obtained at the same time on a single visit; the first, self-collected, and the following two, nurse-collected. Nurse-collected HVS were tested with GeneXpert (Cepheid, Sunnyvale, USA) and Cobas HPV (Roche, Pleasanton, USA; used as the reference test), whilst self-collected HVS were tested only using GeneXpert. Those testing positive on the reference test were offered visual inspection with acetic acid and cervicography (VIAC). Women with a positive VIAC examination were offered cryotherapy or loop electrosurgical excision procedure.

Ethics

This study was approved by the MSF Ethics Review Board.

Results

279 participants consented to provide HVS; none reported discomfort or side effects during or after swabbing. Among nurse-collected HVS, 11/279 participants were found positive on genotyping for HPV-16 using Cobas HPV, and nine of 279 were positive using GeneXpert. Eight out of 279 were identified on genotyping for HPV-18/45 using both platforms. The sensitivities of testing for HPV-16 and 18/45 using GeneXpert as compared to the reference test, Cobas, were 89% (95%CI 53-100) and 63% (95%CI 25-92) respectively. The sensitivity of self- and nurse-collected HVS for HPV-16 tested using GeneXpert, as compared

to the reference test, was 89% (eight of nine; 95%CI 52-100). Specificity was 100% (95%CI 97-100), with a positive predictive value of 89% (95%CI 52-100), and negative predictive value of 100% (95%CI 97-100). However, sensitivity for detection of HPV-18/45 was 68.3% (95%CI 34-100).

Conclusion
Performance of cervical cancer screening using self-collected HVS tested with GeneXpert is comparable to that with nurse-collected HVS. Integrated GeneXpert platforms are already in wide use, enabling rapid diagnosis of tuberculosis, detection of HIV viral load, and early infant diagnosis of HIV, using a single piece of equipment. Deploying GeneXpert for HPV screening using self-collected HVS could help to provide timely results, especially in settings where VIAC is unavailable.

Conflicts of Interest
None declared.

Word count – final 411

Final version author approval (Yuster Ronoh/02/03/2020)