African Journal of Public Health and Health Systems

Evaluating the GeneXpert Platform for the Concurrent Diagnosis of COVID-19 and Influenza in Western Cape Primary Care Clinics: A Research Protocol

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Published: 14 August 2009 | **Received:** 24 May 2009 | **Accepted:** 05 July 2009

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DOI: 10.5281/zenodo.18529401

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Abstract

The clinical presentation of COVID-19 and influenza is often similar, complicating diagnosis and management in primary care. Rapid, accurate differential diagnosis is essential for patient care and infection control. Multiplex molecular platforms like GeneXpert allow for simultaneous testing, but their real-world performance in resource-limited primary care clinics needs assessment. This protocol describes a study to evaluate the field performance of the GeneXpert Xpress SARS-CoV-2/Flu assay for concurrent COVID-19 and influenza diagnosis in Western Cape primary care clinics. The primary objective is to determine the assay's sensitivity, specificity, and turn-around time against standard laboratory RT-PCR. Secondary objectives are to assess user acceptability and identify operational barriers to implementation. A cross-sectional diagnostic accuracy study will be conducted. Consecutive patients presenting with influenza-like illness at selected clinics will be recruited. Two paired nasopharyngeal swabs will be collected: one for immediate on-site GeneXpert testing and one for referral to a central laboratory for standard RT-PCR. Operational data, including time to result, will be recorded. Clinic staff will complete acceptability questionnaires. Data will be analysed to calculate diagnostic accuracy metrics and summarise operational and acceptability findings. As this is a protocol, no empirical findings are available. The study is designed to generate findings on diagnostic performance, such as sensitivity and specificity, and on operational themes including user acceptability and logistical challenges. The anticipated conclusion will synthesise evidence on whether the GeneXpert platform provides a reliable and feasible point-of-care solution for differential diagnosis of COVID-19 and influenza in the study setting, informing potential scale-up decisions. Based on the outcomes, recommendations will be made regarding the implementation of multiplex testing in primary care clinics. These will focus on testing algorithms, staff training requirements, and necessary logistical support. GeneXpert, COVID-19, influenza, diagnostic accuracy, point-of-care testing, primary health care, South Africa. This protocol outlines a necessary evaluation of integrated testing in a resource-limited primary care setting. The findings will contribute practical evidence for health system decision-makers considering the deployment of multiplex molecular platforms at the point of care.

Keywords: *GeneXpert, point-of-care testing, differential diagnosis, primary healthcare, South Africa, influenza, COVID-19*