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Evaluating the Adoption and Diagnostic Accuracy of a Rapid Test for Typhoid Fever in Blantyre District Outpatient Departments, Malawi

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Abstract

Typhoid fever remains a significant public health burden in Malawi. Diagnosis in outpatient settings often relies on clinical judgement due to limited access to confirmatory blood culture. This leads to antimicrobial over-prescription and hampers disease surveillance. Rapid diagnostic tests (RDTs) offer a potential solution, but their real-world adoption and performance in routine, low-resource outpatient departments (OPDs) are poorly understood. This protocol outlines a study to evaluate the adoption and diagnostic accuracy of a specific typhoid fever RDT within the OPDs of district hospitals in Blantyre District, Malawi. Primary objectives are to: 1) assess the proportion of clinically suspected typhoid cases for which healthcare workers utilise the RDT; 2) determine the test's sensitivity and specificity against blood culture as the reference standard; and 3) identify barriers and facilitators influencing its adoption into routine practice. A cross-sectional, observational study will be conducted. Consecutive patients presenting with suspected typhoid fever at participating OPDs will be recruited. Each participant will provide a blood sample for both the index RDT and reference standard blood culture. Test results will be analysed independently. Healthcare workers will be observed and interviewed using structured guides to assess adoption practices and perceptions. Diagnostic accuracy measures will be calculated with 95% confidence intervals. As this is a protocol, no empirical findings are available. The study is designed to generate data on the RDT's adoption rate and its field-based sensitivity and specificity. Qualitative data on themes influencing adoption will also be collected. The study will provide evidence on the real-world utility of a typhoid RDT in a typical Malawian outpatient setting. Findings will inform policy decisions on the potential scale-up of typhoid RDTs and guide strategies to improve their integration into clinical practice in similar low-resource contexts. typhoid fever, rapid diagnostic test, diagnostic accuracy, implementation research, outpatient department, Malawi. This protocol details a study designed to generate practical evidence on both the diagnostic performance and the operational feasibility of a typhoid RDT, addressing a critical knowledge gap for antimicrobial stewardship and fever case management in low-resource settings.

Keywords: *Typhoid fever, Diagnostic accuracy, Rapid diagnostic test, Sub-Saharan Africa, Outpatient department, Implementation research, Malawi*

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