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A Methodology for Assessing the Diagnostic Accuracy of a Rapid Typhoid Test Versus Blood Culture in Febrile Paediatric Outpatients in Dar es Salaam, 2005

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Abstract

Typhoid fever is a major cause of illness in febrile children in sub-Saharan Africa. Blood culture, the diagnostic reference standard, is frequently inaccessible in resource-limited outpatient settings, leading to empirical clinical management. Rapid diagnostic tests offer a potential alternative, but their accuracy requires rigorous field assessment prior to adoption. This methodology article describes the design of a study to determine the diagnostic accuracy of an immunochromatographic rapid test for typhoid fever, using blood culture as the comparator, in febrile paediatric outpatients. A cross-sectional study was employed. Febrile children aged under 15 years presenting to participating outpatient clinics were consecutively enrolled. A single venous blood sample was obtained from each participant for concurrent testing with the index rapid diagnostic test and automated blood culture. Culture isolation of Salmonella Typhi constituted the reference standard. Sensitivity, specificity, and predictive values were to be calculated with 95% confidence intervals. The sample size was determined to ensure precise estimates of test accuracy. This being a methodology article, no empirical findings are presented. The described protocol is designed to generate robust estimates of the rapid test's sensitivity and specificity within a routine outpatient setting. The outlined methodology provides a structured and practical framework for evaluating the field performance of a typhoid rapid diagnostic test against a microbiological gold standard. It addresses practical challenges inherent in conducting diagnostic accuracy studies in high-volume African outpatient settings. Researchers conducting similar evaluations should prioritise comprehensive training in blood culture procedures and test interpretation to minimise operator-dependent error. Subsequent studies should incorporate assessments of cost-effectiveness and the impact of test deployment on clinical practice. Diagnostic accuracy, typhoid fever, rapid diagnostic test, blood culture, paediatrics, outpatient, sub-Saharan Africa, methodology This article provides a detailed methodological blueprint for conducting field evaluations of typhoid rapid diagnostic tests in resource-limited outpatient settings, aiming to standardise approaches and improve the quality of evidence informing their use.

Keywords: *Diagnostic accuracy, Typhoid fever, Febrile children, Sub-Saharan Africa, Blood culture, Rapid diagnostic test, Paediatric outpatients*

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