REASSURED evaluation of the Bioline™ HCV point-of-care testing for diagnosing Hepatitis C Virus infection in primary healthcare settings of Ghana: A diagnostic trial

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Background: Hepatitis C virus (HCV) infection is a silent epidemic requiring a comprehensive and contextualized approach for management. Affordable and accessible HCV point-of-care (POC) diagnostics are essential to meet global HCV goals. However, current evaluation guidelines, such as the WHO prequalification process, emphasize diagnostic performance over usability. The REASSURED criteria provide a holistic approach by considering both test accuracy (sensitivity and specificity) and user-oriented feedback such as ease of use, affordability, and deliverability in real-world contexts. As part of a multinational study in sub-Saharan Africa, this evaluation assessed the Bioline™ HCV POC test in Ghana's primary healthcare (PHC) settings.

Methods: The study had three phases. Phase 1 evaluated the diagnostic performance of the test in 516 individuals from HCV target populations (e.g., incarcerated individuals including drug users and MSM; blood donors, and patients). Phase 2 used mixed methods to assess usability and acceptability among 81 non-laboratory healthcare workers. Phase 3 involved a cost analysis of HCV testing models and their affordability.

Results: The Bioline™ HCV POC test demonstrated high sensitivity (96.7%) and specificity (99.8%), with test efficiency of 99.6% and an ROC area of 0.98. Usability scored 88.7 on the System Usability Scale, with 88% of healthcare workers finding it easy to use, though 83% made pre-testing errors. No PHC clinic offered HCV POC testing; 85.7% referred patients to higher facilities, of which only 40% performed testing. Cost analysis showed Model 3 (Bioline™ POC) was the most economical (USD 62.75) compared to Models 1 and 2 if we can rely on its diagnostic performance without seeking confirmatory testing.

Conclusion: The Bioline™ HCV test showed high accuracy, usability, acceptability, and cost-efficiency but faced barriers such as limited test kit availability and inadequate testing infrastructure. Decentralizing HCV testing can enhance accessibility and align with WHO's goal of eliminating viral hepatitis by 2030.

Disclosure of Interest Statement: "This abstract contains the findings from a three-phase diagnostic trial registered in the Pan African Clinical Trial Registry (PACTR202410837698664) conducted in Ghana as part of one of three trials to be conducted in sub-Saharan Africa (Ghana, Rwanda and South Africa). Mathebula EM is an employee of Abbott Laboratories, the manufacturer of the Bioline™ HCV POC test, as a Scientific Affairs Manager for Africa and a co-supervisor to Duah E in the project. He, therefore, acknowledged that he is aware of his responsibility to take the necessary and

reasonable steps to avoid any potential or perceived conflict of interest during his co-supervision duties in this study. Moreover, as a co-supervisor, his contribution and decisions were reviewed and approved by Mashamba-Thompson T, the main supervisor of the project."