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Establishing target product profiles for Lassa fever diagnostics: A collaborative approach to guide innovation and public health investment

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Introduction

Lassa fever (Lf), a viral hemorrhagic illness endemic to parts of West Africa, presents a significant public health challenge due to its nonspecific clinical presentation and lack of widely accessible diagnostic tools. Despite its threat, no standardized Target Product Profiles (TPPs) currently exist to guide the development of diagnostic assays for Lf. This gap hampers product development, regulatory evaluation, and procurement planning. This initiative, FIND-led was aimed at establishing TPPs for Lf diagnostic tools to inform the development and implementation of diagnostics for Lf.

Methods

A structured, multi-stakeholder process was employed to draft and finalize the Lf TPPs. A core writing team from FIND led the drafting process in collaboration with a broader TPP Development Group composed of technical experts in diagnostics, clinical management, and outbreak response, as well as representatives from civil society organizations. The process included a Welphi survey, a structured communication technique used to achieve consensus through multiple rounds of feedback. The draft TPPs specified intended use cases, target populations, and diagnostic parameters categorized as "Minimal" and "Optimal". Attention was given to key diagnostic settings, including point-of-care, near-patient, and reference laboratory environments.

Results

Two distinct TPPs were developed: one for screening/diagnostic use, aiming to enable isolation and treatment during the same clinical encounter, and another for confirmatory testing, intended for use at reference laboratories. These TPPs address performance metrics, operational considerations, and pricing thresholds. Consensus across stakeholders was achieved through the collaborative Welphi process. Modelling was performed to validate performance thresholds and support prioritization of test attributes.

Conclusion

The development of TPPS for Lf diagnostics is a pivotal step toward improving outbreak preparedness and routine disease management in endemic regions. By setting clear and realistic expectations for diagnostic development, the TPPs will catalyze innovation, streamline regulatory approval, and guide procurement decisions.