Assessment of the Quality Management Systems in Potential Point-of-Care Early Infant Diagnosis Sites: Baseline Findings

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BACKGROUND
• Because of the large number of HIV tests processed in sub-Saharan Africa, any margin of error in data collection, even minimal, might translate to significant numbers of patients misdiagnosed or mismanaged in clinical care. Assessments of quality measures taken to strengthen point-of-care (POC) early infant diagnosis (EID) is crucial, as this is a diagnostic rather than monitoring test.
• Timely treatment initiation among HIV-positive infants remains a major challenge because of current conventional and centralized EID networks in Lesotho and POC technology could help to ensure rapid HIV test results and faster treatment initiation.
• Through a grant from UNITAID, Lesotho is introducing POC EID to ensure that HIV-infected infants have timely access to ART.
• In advance of launching POC EID, EGPAF and UNITAID launched a site-level baseline assessment to identify quality measures in place at each which would allow for smooth POC EID implementation.

METHODS
• In February 2016, a standardized checklist was used to assess the capacity of 15 potential POC EID pilot sites.
• The tool inspected eight quality essentials (QE) relevant to POC testing: 1) possibility of integration of POC service to HIV care; 2) personnel management; 3) physical space; 4) safety; 5) pre-testing phase management; 6) post-testing phase management; 7) equipment and inventory management; and 8) quality monitoring. Percentage scores were determined for each QE.

RESULTS
• Across all sites, high (>70%) average scores were obtained in possibility of integration of POC service to HIV care (75%), pre- and post-testing phases (both 75%), facilities physical space (84%), quality control (84%), and safety (82%).
• Lower (<70%) average scores were obtained in equipment and inventory management (63%) and personnel management (67%) across all sites (Fig 1).
• Of the 15 sites, 13 were enrolled in an External Quality Assurance program.
• All sites had a standardized system for recording and reporting POC results.
• Documentation of personnel training, competency, and certification was lacking in 75% (12/15) of the sites.
• About half (7/15) of the sites did not have documented procedures, such as written SOPs or job aids for ordering and receiving of supplies for EID, equipment maintenance for POC technology, or trouble shooting and repairs.
• Only 26% (4/15) of the sites had regular monitoring and review of POC performance by a supervisor or external monitor.

CONCLUSIONS
• There are gaps within quality management of current POC testing in Lesotho.
• These will need to be addressed before introducing POC EID.
• As the number of facilities offering POC testing grows, measures that ensure that these testing centres conform to international standards of quality (such as the ISO 22870) are required.

Figure 1. Average Performance of 15 Potential POC EID Sites per the Quality Essential Checklist