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Implementation of external quality assurance for point of care early infant HIV diagnosis in Kenya

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Background: Early Infant HIV Diagnosis (EID) in Kenya depends on high expertise centralized molecular testing that has often led to protracted turn-around time and missed opportunities for timely initiation of HIV infected infants on life saving anti-retroviral therapy. Emergence of molecular Point Of Care Tests (POCT) is a promising technological solution to challenges of centralized EID testing. However, assurance of quality EID POCT results in the field setting remains an important concern for most national HIV programs. Indeed, scalability of EID POCT largely depends on utilization of staff with limited expertise on molecular testing. In 2017, Kenya MOH introduced EID POCT to bridge the unmet EID testing demands. We describe the results of external quality assurance for POC EID in Kenya.

Method: The MOH piloted EID POCT (Alere Q and GeneXpert) in 22 remote health facilities in nine of 47 Kenyan counties. To monitor quality of EID POCT, the National HIV Reference Laboratory (NHRL) enrolled the 22 facilities into EQA program, developed and distributed EQA standard operating procedures and job-aids and trained two personnel on EID EQA procedures. Each facility spotted a Dry Blood Spot specimen (DBS) using left over specimen from 10% (every 10th) and all infants with HIV-negative and HIV-positive results, respectively. The DBS were shipped to NHRL (the central EID testing laboratory) located in Nairobi. DBS samples were retested at NHRL using Roche CAP-CTM HIV1 Qual v2. data was analysed using SAS version 9.4 to characterize performance as well as inform necessary corrective and preventive actions. Patient baseline viral load results were used to facilitate discordance resolution.

Result: Between August 2017 and June 2018, 207 EQA specimens were retested at NHRL. Of these, 42 (20.4%) were concordant positive while 161 (78.2%) were concordant negative on both POCT and conventional EID, 3 (1.5%) were false positives and 1 (0.5%) was a false negative. This yielded a sensitivity of 97.7% (95% CI: 94.3%-100%) and a specificity of 98.2% (95% CI: 95.0%-100%). Of the three with false positive results on POCT, one had baseline detectable viral load results from conventional viral load testing platform while another was a transcription error by the POCT testing laboratory. Accounting for the transcription error, specificity increased to 98.8% (94.7% -100%). The other two infants with discrepant results were retested and the results of the POC agreed with that of the gold standard. Overall, the kappa statistic was 0.957 (95% CI: 0.932-0.980).

Conclusion: There was good concordance between POCT and conventional EID platform. Centralized retesting is a low cost, scalable viable option forensuring quality testing in the early phases of EID POCT implementationin Kenya.

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