Title: Task shifting for point-of-care early infant diagnosis testing: Comparison of error rates between nurses and specialized laboratory trained personnel.

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Background: Point-of-care (POC) early infant diagnosis (EID) of HIV allows for sample analysis at peripheral health facility. Unlike conventional testing that requires specialized laboratory personnel, POC EID is near-fully automated and may be operated by non-specialized laboratory personnel. POC EID technologies include internal error controls that detect user errors. High rates of error may suggest inadequate user capacity. To decentralize POC EID, task-shifting to cadres such as nurses is important. We used data from a POC EID project in Zimbabwe to compare the error rates and result return to caregivers for samples run on a POC EID technology (Alere q HIV 1/2 Detect) between nurses and lab personnel (MLSc/Techs) to assess user competence.

Methods: All ten sites in Zimbabwe providing POC EID for routine clinical use were enrolled. Two sites are operated by MLSc/Techs, six by nurses, and two by both cadres. Data from December 2016 to June 2017 were reviewed. Error rates were downloaded from each POC EID machine and exported to excel to analyze errors by type of operator. Turnaround time (TAT) from sample collection to issuing of results to caregiver was extracted from the EID test request form and uploaded into an Excel-based database for analysis.

Results: A total of 1,847 tests were conducted by 45 testers (12 MLSc/Techs and 33 nurses), including 165 errors. Overall error rate was 8.93% (7.69% vs. 9.24%, for MLSc/Techs and nurses, respectively, p=0.36). User error rate was 6.17% (5.22% vs. 6.41%, for MLSc/Techs and nurses, respectively, p=0.38). There was no statistical difference between error rates for MLSc/Techs and for nurses. Over time, both cadres' error rates decreased. 98.75% of results were issued to clients versus 98.92% for MLSc/Techs and nurses, respectively. Overall median TAT was same day (Q_1=0.5, Q_3=2). Tests processed by MLSc/Techs had a TAT of one day (Q_1=0.5, Q_3=3.5) versus same day (Q_1=0.5, Q_3=2.5) for nurses.

Conclusions: Similar error rates and TATs between nurses and lab-tech-operators suggest that non-specialized laboratory trained personnel can perform POC EID equally well as specialized laboratory personnel. Nurse-operated POC EID testing will ensure decentralization and timely return of test results without compromising the quality of testing.

Table 1: Comparison of error rates in the use Alere Q platform for POC EID by type of operator in Zimbabwe, 2017

Error Category	Testing Cadre	Error Rate	P-Value
General Errors	MLSc/Techs Nurse	7.69% 9.24%	0.36
End User Errors	MLSc/Techs Nurse	5.22% 6.41%	0.38

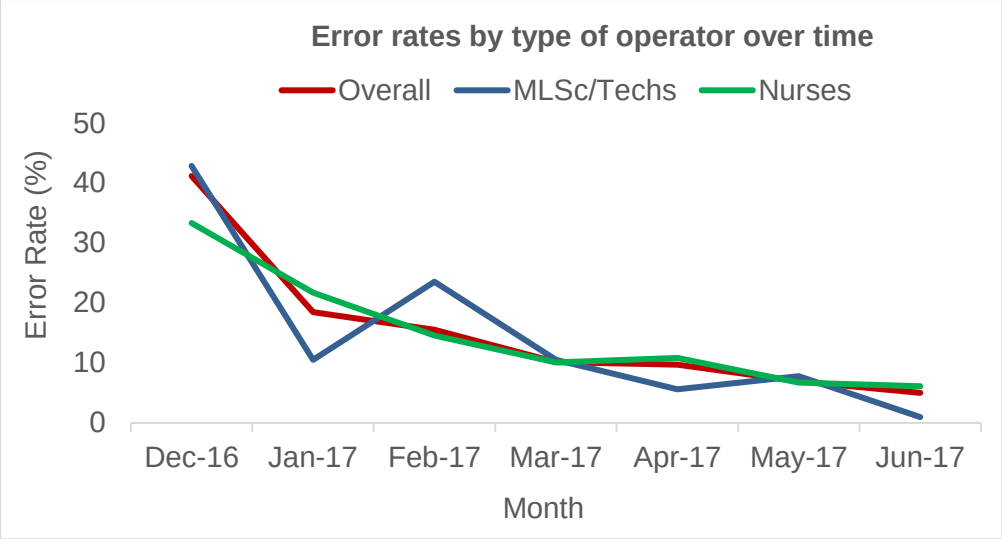

Figure 1: Error rates over the data collection period