FIELD PERFORMANCE OF POINT-OF-CARE HIV TESTING FOR EARLY INFANT DIAGNOSIS:

Pooled analysis from six countries from the EID Consortium

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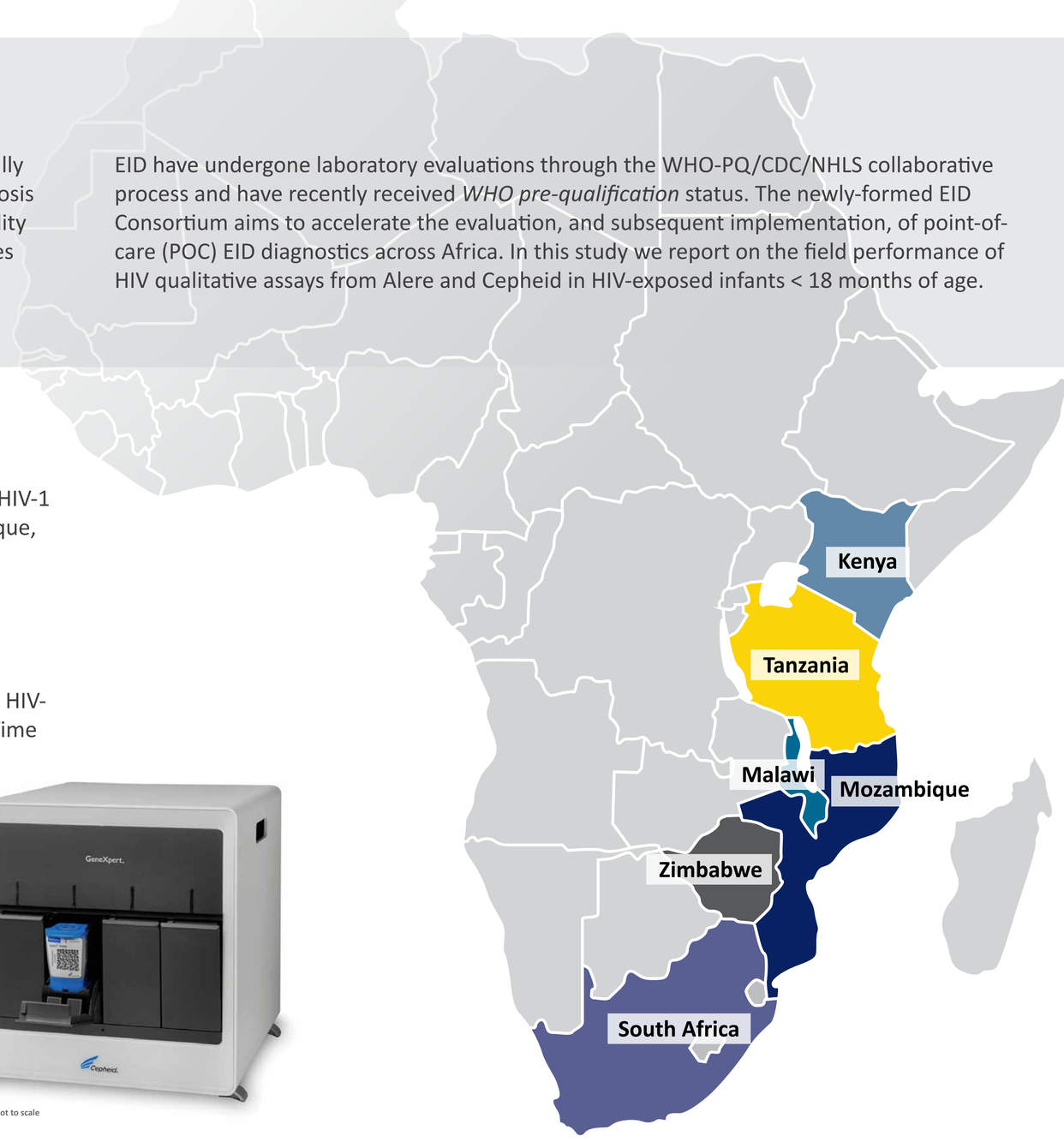
BACKGROUND

The expansion of prevention of mother-to-child transmission programmes has successfully resulted in a reduction in paediatric HIV infections. However, accurate early infant diagnosis (EID) and rapid treatment initiation are both essential for reducing morbidity and mortality in children where vertical transmission has still occurred. Evaluations of new technologies for EID are critical to inform national regulatory approval and uptake, but the low HIV incidence in infants limits timely, adequately-sized evaluation studies. POC platforms for EID have undergone laboratory evaluations through the WHO-PQ/CDC/NHLS collaborative process and have recently received *WHO pre-qualification* status. The newly-formed EID Consortium aims to accelerate the evaluation, and subsequent implementation, of point-of-care (POC) EID diagnostics across Africa. In this study we report on the field performance of HIV qualitative assays from Alere and Cepheid in HIV-exposed infants < 18 months of age.



METHODS

Data from 9 independent field evaluations of Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 qual assays were pooled from on-going studies in 6 countries (Kenya, Malawi, Mozambique, Tanzania, South Africa and Zimbabwe). A range of health professionals from nurses and laboratory technicians to medical doctors operated the devices.

Specimens from HIV-exposed infants < 18 months old were analysed on Alere q HIV-1/2 Detect or Cepheid Xpert HIV-1 qual as per the approved specific site protocol. POC EID results were compared to Roche COBAS AmpliPrep/COBAS. TaqMan (CAP/CTM) HIV-1 Qualitative Test at all sites, with the exception of Malawi, which used the Abbott RealTime HIV-1 Qualitative assay.

Alere Q HIV-1/2 Detect

Image not to scale

Cepheid Xpert HIV-1 Qual

Image not to scale

RESULTS

A total of 1884 samples were tested on the Alere q HIV-1/2 Detect and 2598 samples on Cepheid Xpert HIV-1 qual. Alere q HIV-1/2 Detect achieved a sensitivity of 99.07% (95% CI, 95.48-99.95%) and specificity of 99.94% (95% CI, 99.72-100%) with an overall error rate of 6.4%. Cepheid Xpert HIV-1 qual. yielded a sensitivity of 96.88% (95% CI, 91.73-99.20%) and specificity of 99.92% (95% CI, 99.74-99.99%) with an overall error rate of 4.3%. *See* **Table 1** *below.*

Table 1: Performance of Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 qual

ALERE Q HIV-1/2 DETECT

Alere q	Reference Assay: Positive	Negative	Sum (n=)
Positive	106	1	107
Negative	1	1776	1777
Sum (n=)	107	1777	1884

	Point Estimate	Lower CI	Upper CI
Sensitivity	99,07%	95,48%	99,95%
Specificity	99,94%	99,72%	100,00%

Device Errors	total #	Rate
	128	6,36%

CEPHEID XPERT HIV-1 QUAL

Xpert	Reference Assay: Positive	Negative	Sum (n=)
Positive	93	2	95
Negative	3	2500	2503
Sum (n=)	96	2502	2598

	Point Estimate	Lower CI	Upper CI
Sensitivity	96,88%	91,73%	99,20%
Specificity	99,92%	99,74%	99,99%

Device Errors	total #	Rate
	118	4,28%

CONCLUSION

- The EID Consortium has been able to aggregate data from multiple centres across Sub-Saharan Africa. This is vital to accelerate progress in evaluating POC EID testing in the field.
- The analysis of the data shows that both the Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 qual assays perform well in the field.
- Understanding the performance of these devices in their intended setting provides valuable information to support the implementation of POC testing within existing EID programmes.
- Further work is required to evaluate the impact these new technologies will have on paediatric HIV care. The next question is: *"Where to place POC devices for maximum impact?"*