

EVALUATION OF PERFORMANCE AND USABILITY OF CEPHEID XPERT HIV -1 QUAL ASSAY IN MALAWI

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BACKGROUND

In Malawi, Early-Infant Diagnosis (EID) programmes use dried blood spot (DBS) and HIV PCR with turn-around-times (TAT) of 2-3 months. On average, 33% of exposed infants are lost to follow-up (1). HIV antibody tests are unsuitable for use in children below the age of 12 months as they may give false positive results, due to the presence of maternal antibodies (2). Currently Malawi has only ten central laboratories conducting HIV PCR, thus requiring samples to be transported long distances, with some specimens being lost (1). There is an urgent need for point-of-care tests (POCTs), which can improve TAT and reduce loss to follow-up.

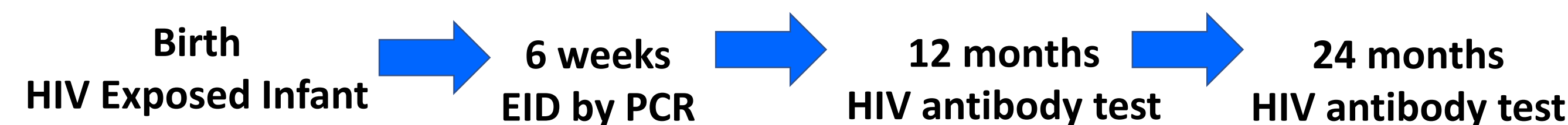
AIM

Evaluate the feasibility, sensitivity, specificity, turn-around-time, acceptability, and usability of a POCT Cepheid Xpert HIV-1 Qual assay (Xpert HIV) using a whole blood protocol (3) in a rural district hospital compared to HIV PCR from DBS .

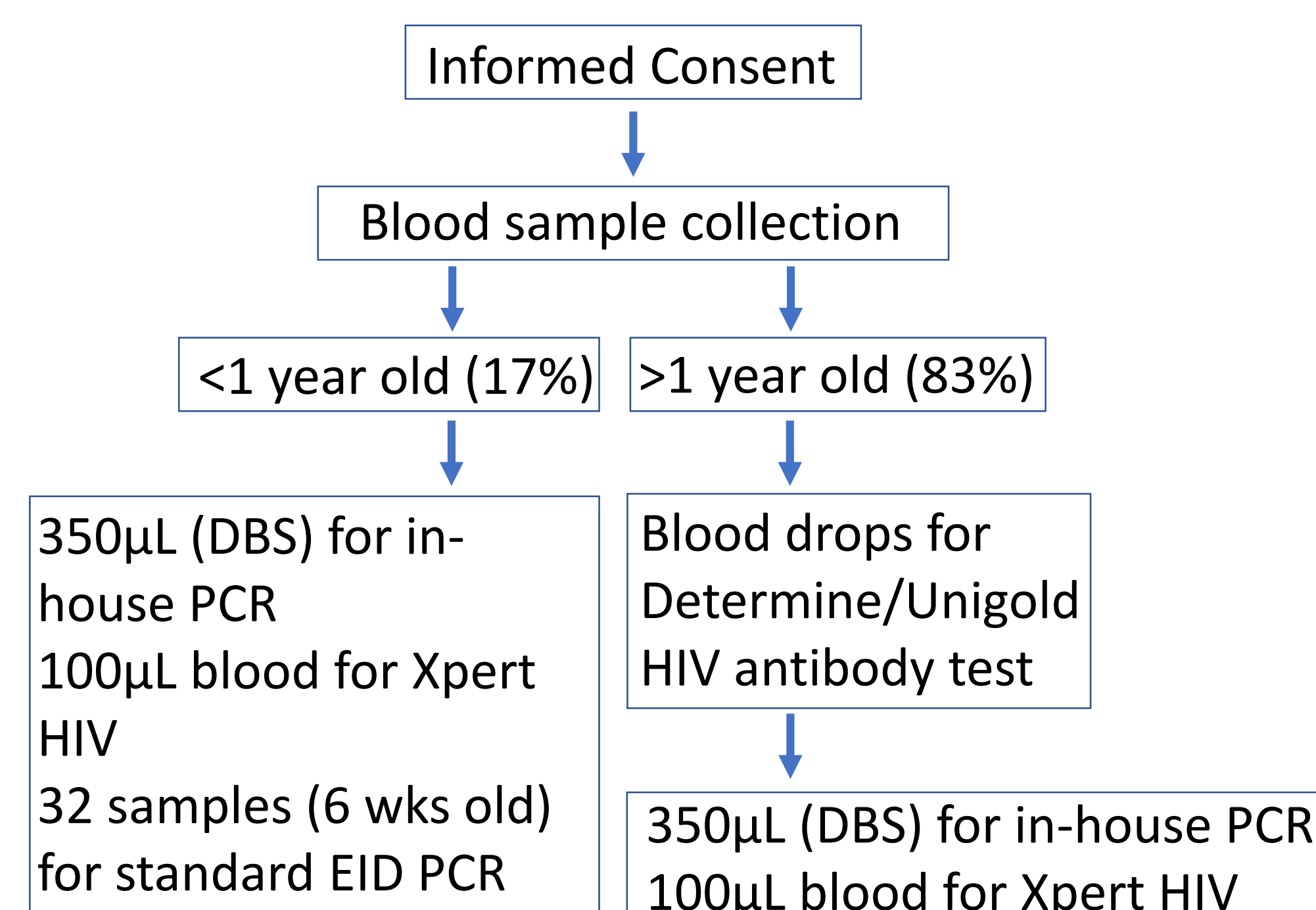
METHODS

- prospective diagnostic study using a bench top Xpert HIV assay.
- consecutively recruited children aged 0-14 years, n=600. attending Mulanje District Hospital (MDH) in Malawi.
- Study period: July-September 2018.
- Usability assessed by semi – structured questionnaires, n=7.
- Acceptability assessed by in - depth interviews (IDI), n=60.

Current protocol of EID in Malawi (Thyolo and MDH)



Study Outline and Demographics



Xpert HIV is better and quicker than conventional PCR in Early Infant Diagnosis of HIV in a district hospital in Malawi

Sensitivity = 100%
 Specificity = 100%
 Turn around Time = 5 hrs

-> It is acceptable to care givers
 -> Easy to use by lab technicians

RESULTS

Turn-around time (TAT)

Assay	Standard EID PCR (Thyolo)	In-house PCR	Xpert HIV at MDH
Median TAT	24 days * (IQR:20; 28 days)	3 days (IQR:1.05; 4.19 days)	5.3 hours (IQR:2.45; 0.19 hours)

*only contains 17/ 32 results for standard EID PCR where results were returned to MDH, 15/32 results were lost/ not returned

Sensitivity and Specificity

Sensitivity and specificity of Xpert HIV and HIV antibody tests in comparison to PCR

	Xpert HIV	HIV antibody tests Determine/Unigold
Sensitivity	(15/15) 100% (95% CI: 78.2 - 100%)	(10/13) 76.9% (95% CI 42.3-95.0%)
Specificity	(585/585) 100% (95% CI: 99.4 - 100%)	(485/486) 99.8% (95% CI 98.9 -100%)
Positive predictive Value (PPV)	(15/15) 100% (95% CI: 78.2 - 100%)	(10/11) 90.9% (95% CI 58.7-99.8%)
Negative predictive Value (NPV)	(585/585) 100% (95% CI: 99.4 - 100%)	(485/488) 99.4% (95% CI 98.2 -99.9%)

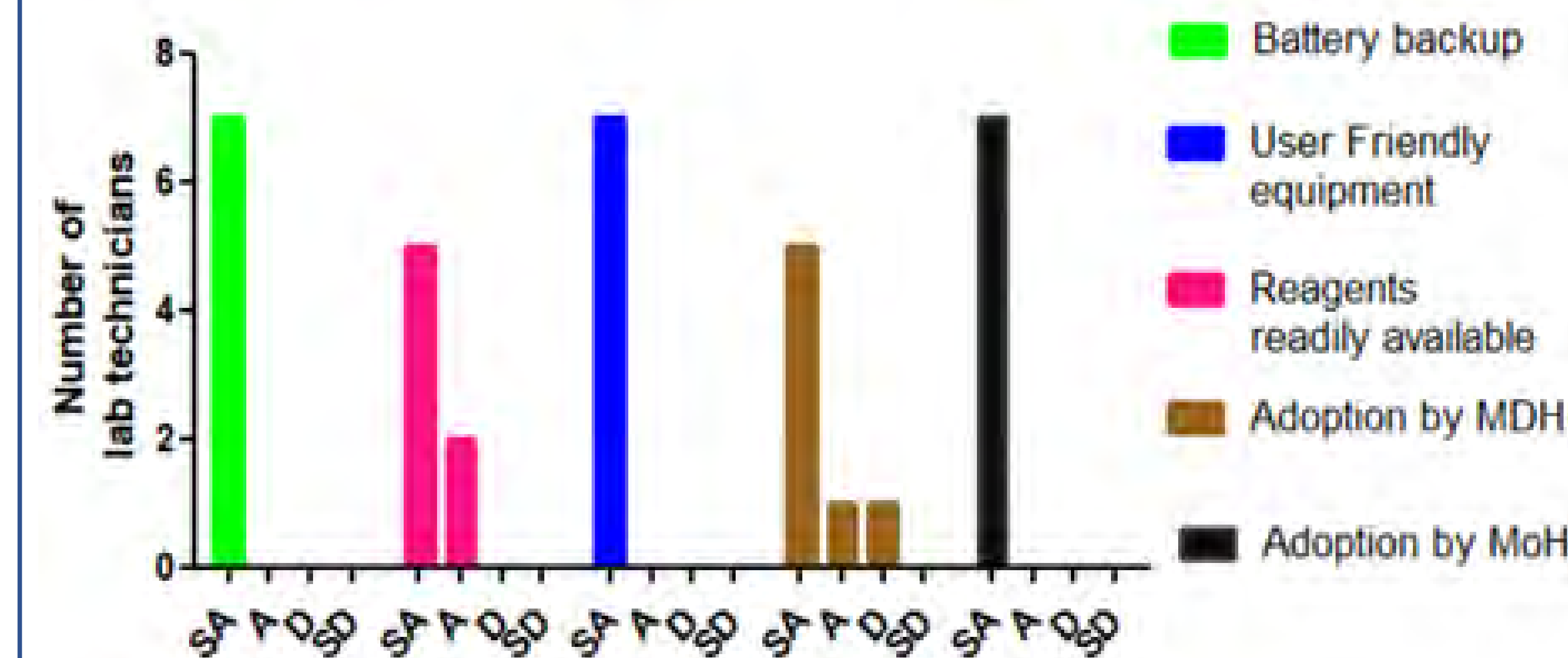
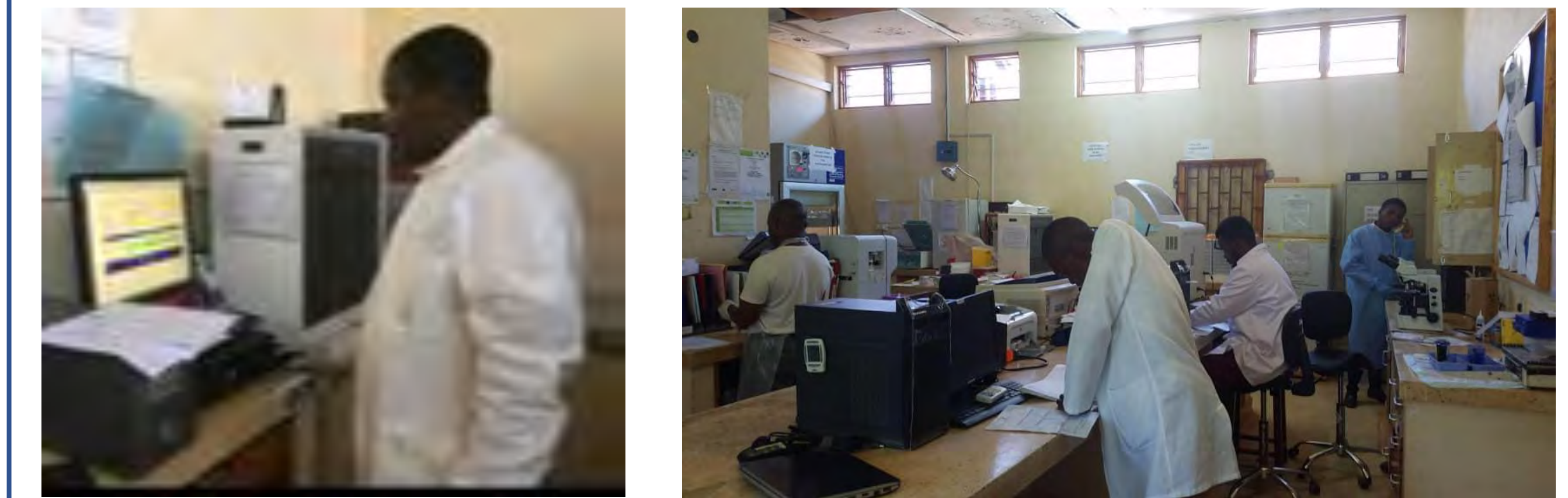
Linkage to HIV care

- 15/600 diagnosed HIV positive
- 85% of HIV positive >1 year old started antiretroviral therapy within 1 day

Acceptability

- Xpert HIV was accepted by 60 caregivers and 5 nurses
- 100% response rate by caregivers and nurses

Usability of Xpert HIV



Usability of Xpert HIV by laboratory technicians

SA-Strongly agree, A- Agree, D – Disagree, SD- Strongly Disagree

MoH - Ministry of Health, MDH - Mulanje District Hospital

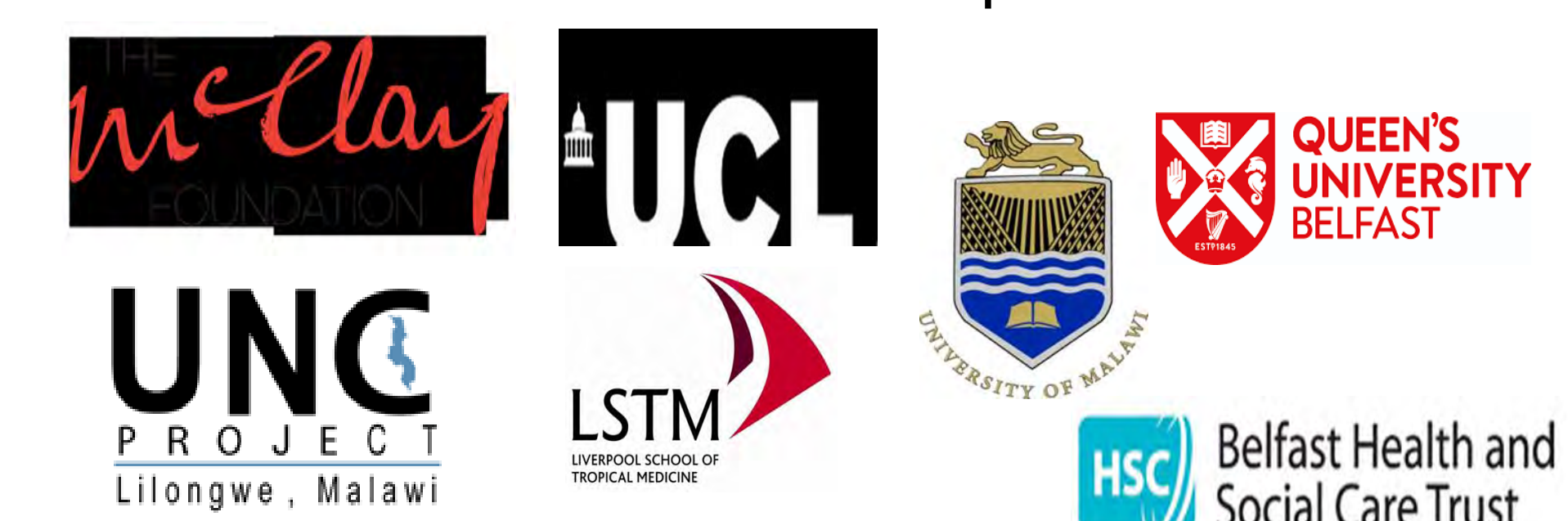
CONCLUSION

Xpert HIV:

- Performance - highly sensitive and specific as per WHO ASSURED standards.
 - TAT is approximately 5 hours.
 - Acceptable to caregivers and nursing staff .
 - Easy to use by laboratory technicians suggesting that its use is acceptable to both, caregivers and healthcare providers in Mulanje, Malawi.
- These preliminary results may suggest that implementing Xpert HIV could significantly improve EID, decrease loss to follow-up, thereby decreasing morbidity and improving linkage to HIV care.
- There is need for cost-effectiveness analyses before scale up of Xpert HIV.

Acknowledgements

Study participants, Mulanje District Hospital and Queen Elizabeth Central Hospital teams



References

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