



Lessons Learned from Implementation of Integrated Point-of-Care Testing for HIV Early Infant Diagnosis and Viral Load Monitoring in Malawi; a model for limited resource settings.



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BACKGROUND

Malawi has approximately 1.1 million people living with HIV. HIV viral load (VL) is a quantitative nucleic acid test (NAT) and is the gold standard for monitoring treatment adherence and success.^{1,2}

In addition, an estimated 40,000 infants are born to HIV positive mothers annually in Malawi³. These HIV exposed infants require a qualitative NAT that detects the presence of the HIV virus in their blood, and it is called an HIV early infant diagnosis (EID) test.

HIV EID and VL testing in Malawi has traditionally been conducted on molecular conventional platforms at centrally located laboratories in urban areas. However, centralized testing faces several limitations in resource-limited settings like Malawi. It uses complex equipment, requires uninterrupted power supply, relies on cold chain for reagents, and has high up-front costs including limited human resources. Sample/results sorting at district hubs and backlogs in centralized laboratories contribute to delays in return of results.⁴

These delays result in long turnaround times or missing results. Patients travel long distances and bear high transportation costs to check results or get a sample redrawn. Delayed EID results have also been associated with loss-to-follow up of HIV exposed infants.⁵

LESSONS LEARNED

- Introduction of POC testing decongested molecular laboratories and partially helped address a shortfall in laboratory personnel.
- Stakeholder engagement at each stage of implementation ensured sustainability of the integration.
- Supervision and mentorship ensured quality POC testing; testing errors on GeneXpert and mPima were usually high soon after training but declined after mentorship.
- Timely technical support and routine service and maintenance to devices also contributed to the success.
- Data management was crucial to ensure timely data visibility at the central level. Routine data on indicators such as TATs, rates of ART initiation and device functionality were used for decision making through-out the implementation
- POC testing saved resources by leverage on existing infrastructure. Minimal upfront costs were incurred.

References:
 (1). UNAIDS. HIV and AIDS Estimates. 2020. (2). Ministry of Health. Integrated HIV Program Report January-March; 2021.
 (3). Ministry of Health. HIV Spectrum Estimates; 2021. (4). Vojnov L, Markby J, Boeke C, Harris L, Ford N, Peter T (2016) POC CD4 Testing Improves Linkage to HIV Care and Timeliness of ART Initiation in a Public Health Approach: A Systematic Review and Meta-Analysis. PLoS ONE 11(5): e0155
 (5). Govindasamy D, Ford N, Kranzer K (2012) Risk factors, barriers and facilitators for linkage to antiretroviral therapy care

(6). Significant Patient Impact Observed Upon Implementation of Point-of-Care Early Infant Diagnosis Technologies in an Observational Study in Malawi. <https://pubmed.ncbi.nlm.nih.gov/29490026/>
 (7). Feasibility and impact of near-point-of-care integrated tuberculosis/HIV testing in Malawi and Zimbabwe <https://pubmed.ncbi.nlm.nih.gov/34310372/>

INTERVENTION DESCRIPTION

Malawi has successfully rolled out integration of HIV EID and targeted V) testing on Point of Care (POCs) devices, a shift from testing on large equipment at centralized laboratories. This has led to significant reduction in test results turn-around time and ART initiation from 56 days and 38 days to just 1 day for mPima EID and GeneXpert VL respectively, and 3 days for GeneXpert EID. The proportion of infants initiated on ART within two months of birth has also improved by more than 50%. Introduction of POC EID and targeted VL took place in two phases following successful feasibility studies conducted between 2015 and 2017.^{6,7}

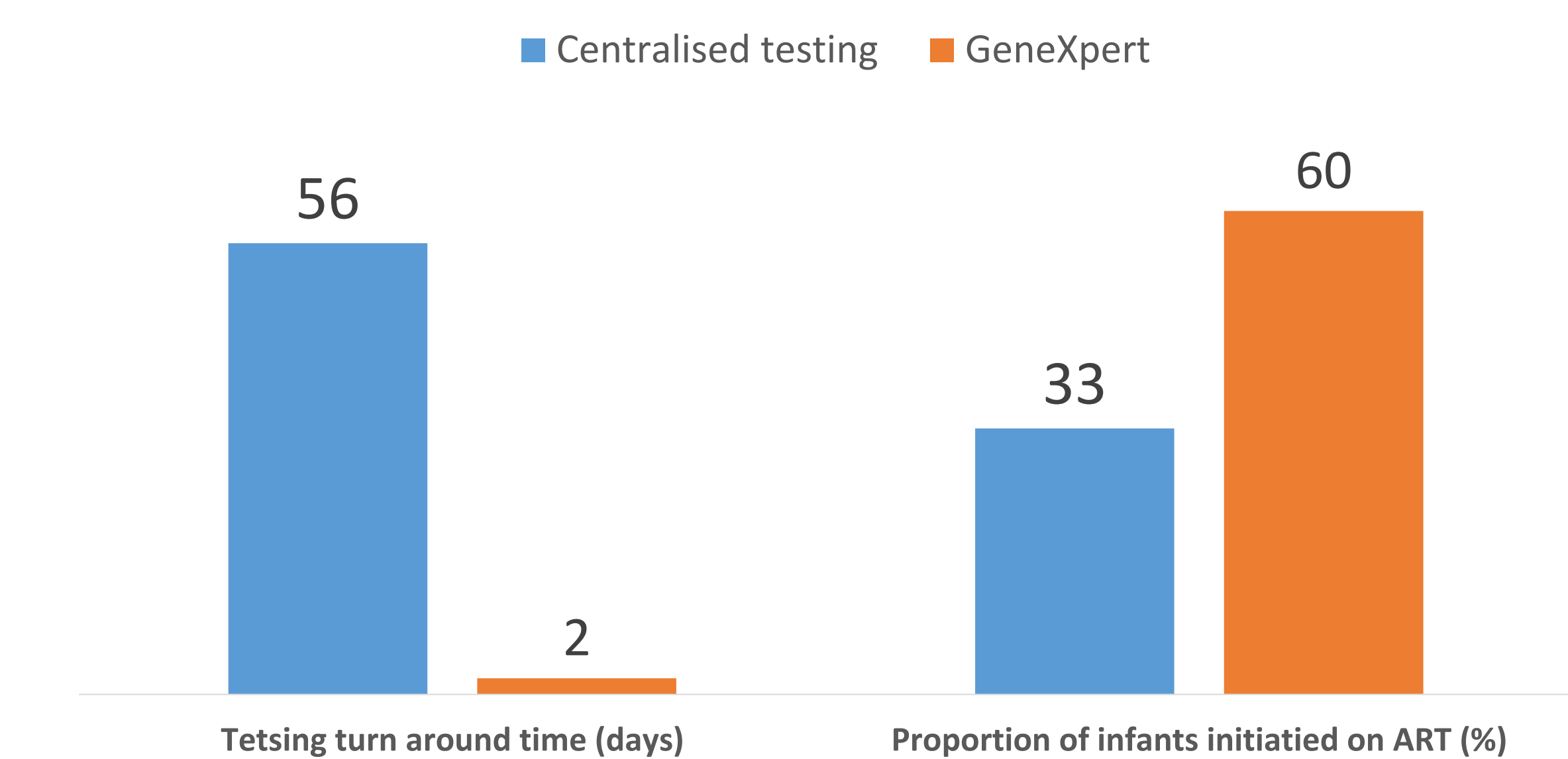
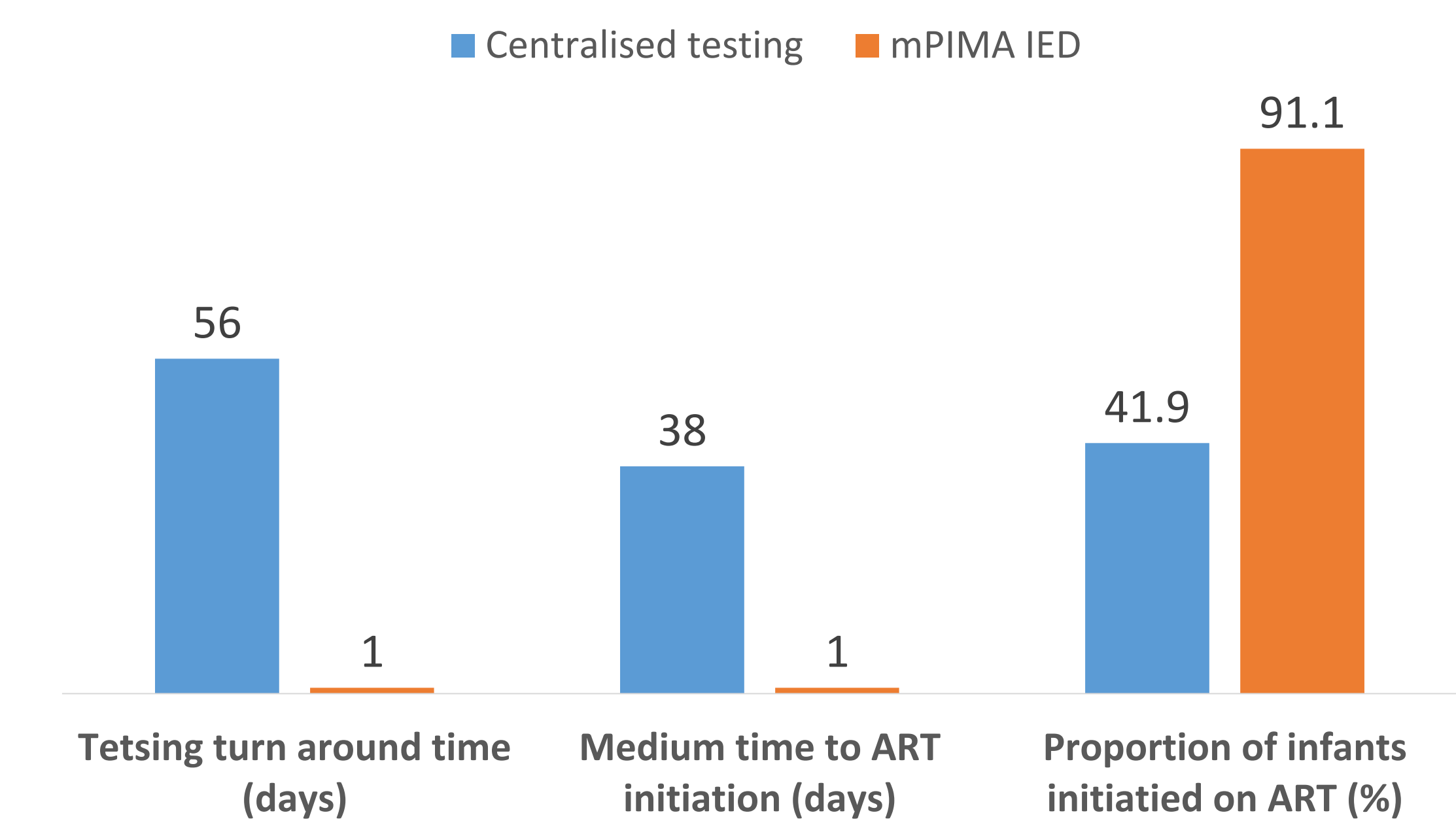
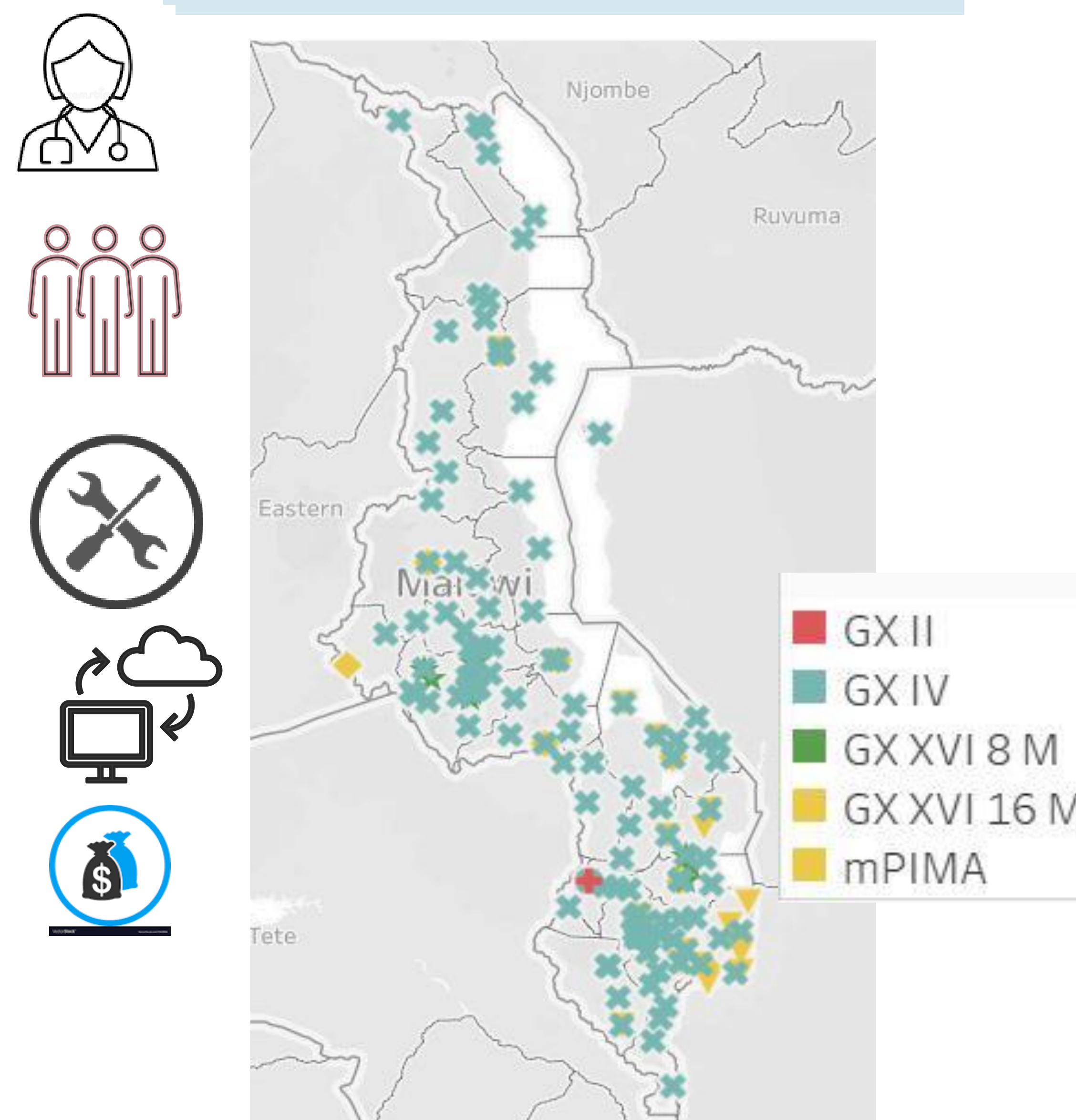
GeneXperts are already widespread across the country for TB diagnosis.

Phase 1: EID testing on Abbott mPima

Phase 2: EID and VL testing on GeneXperts



Distribution of POC devices across the country



CONCLUSION

POC EID and VL have significantly improved patient care in Malawi. They reduced the turnaround time of returning results to patients. The short turnaround time allowed healthcare workers to make quick and informed decisions about patient care.

POC EID and VL are now part of Malawi's HIV care package. The Ministry of Health is now managing the implementation of POC EID and VL testing.

Governments across similar contexts would benefit from following Malawi's lead in using POC EID and targeted VL to improve patient care.

Acknowledgements:

Ministry of Health, Lilongwe, Malawi.

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