Innovations in the women-centered continuum of care: Perspectives from Malawi

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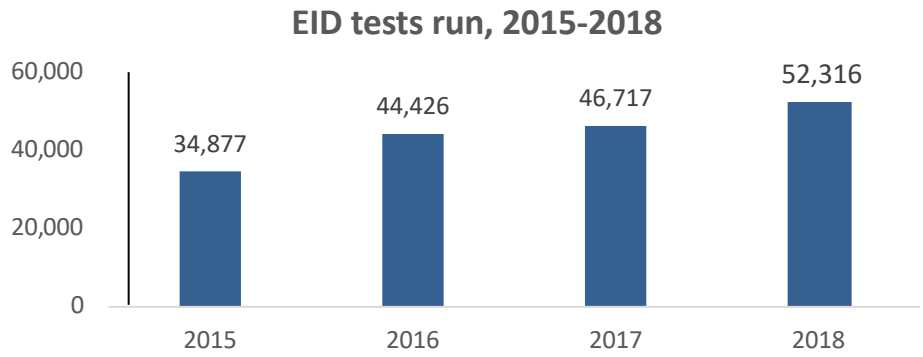
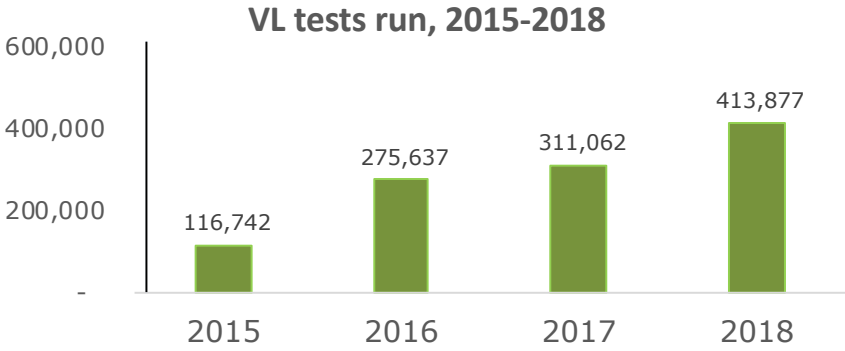
Molecular testing volumes for TB and HIV in Malawi have increased dramatically from 2015-2018 as programs continue to scale up

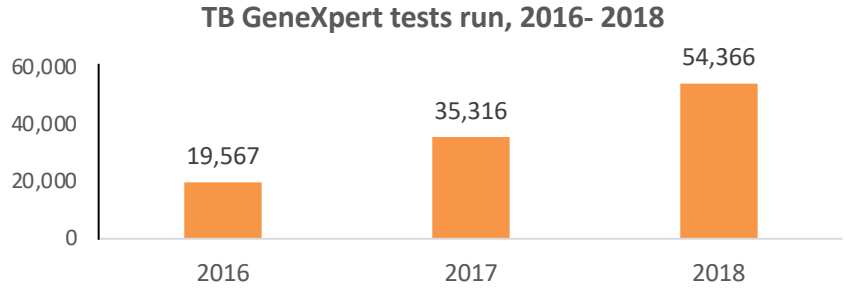
EID volumes increased 50% since 2015, reaching 52,000 in 2018



VL volumes increased 254% since 2015, to >413,000 tests in 2018

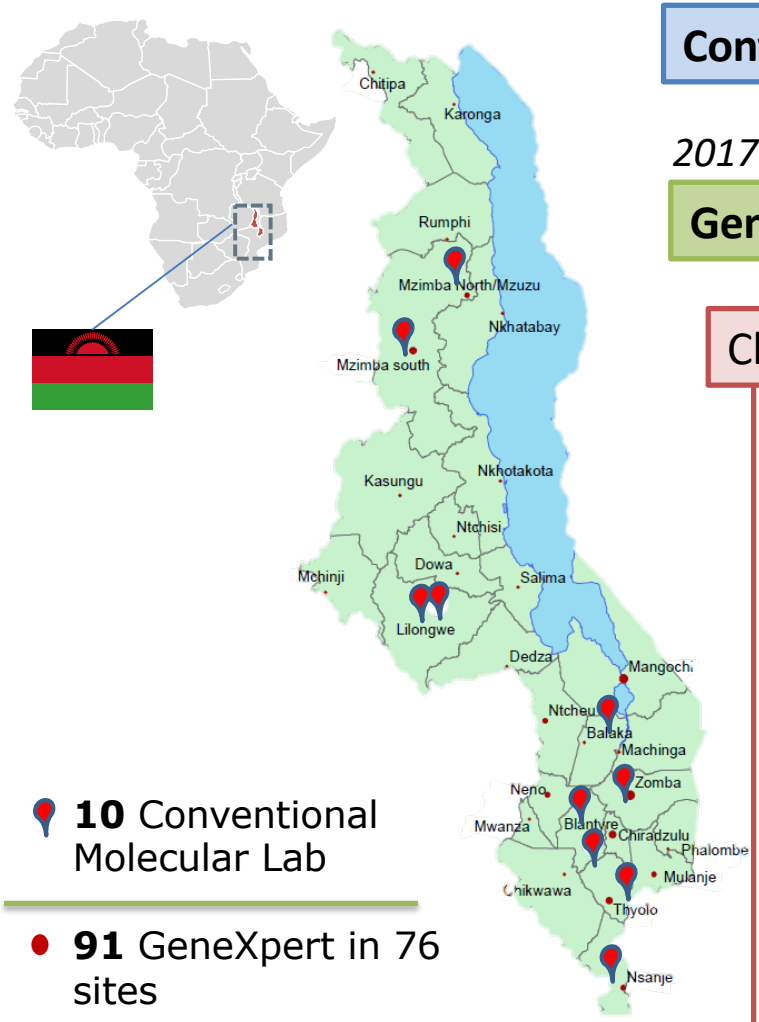


TB volumes on GeneXpert increased 177% from 2016-2018, reaching 54,000 in 2018



Source: Malawi National LIMS data, NTP data

The conventional laboratory network was being fully utilized but not adequately serving patients while GeneXpert devices overall were typically underutilized



10 Conventional Molecular Lab

91 GeneXpert in 76 sites

2017 HIV Viral Load and EID Conventional Testing Capacity[1]

Conventional Device utilization: 96%

2017 Overall GeneXpert Testing Capacity

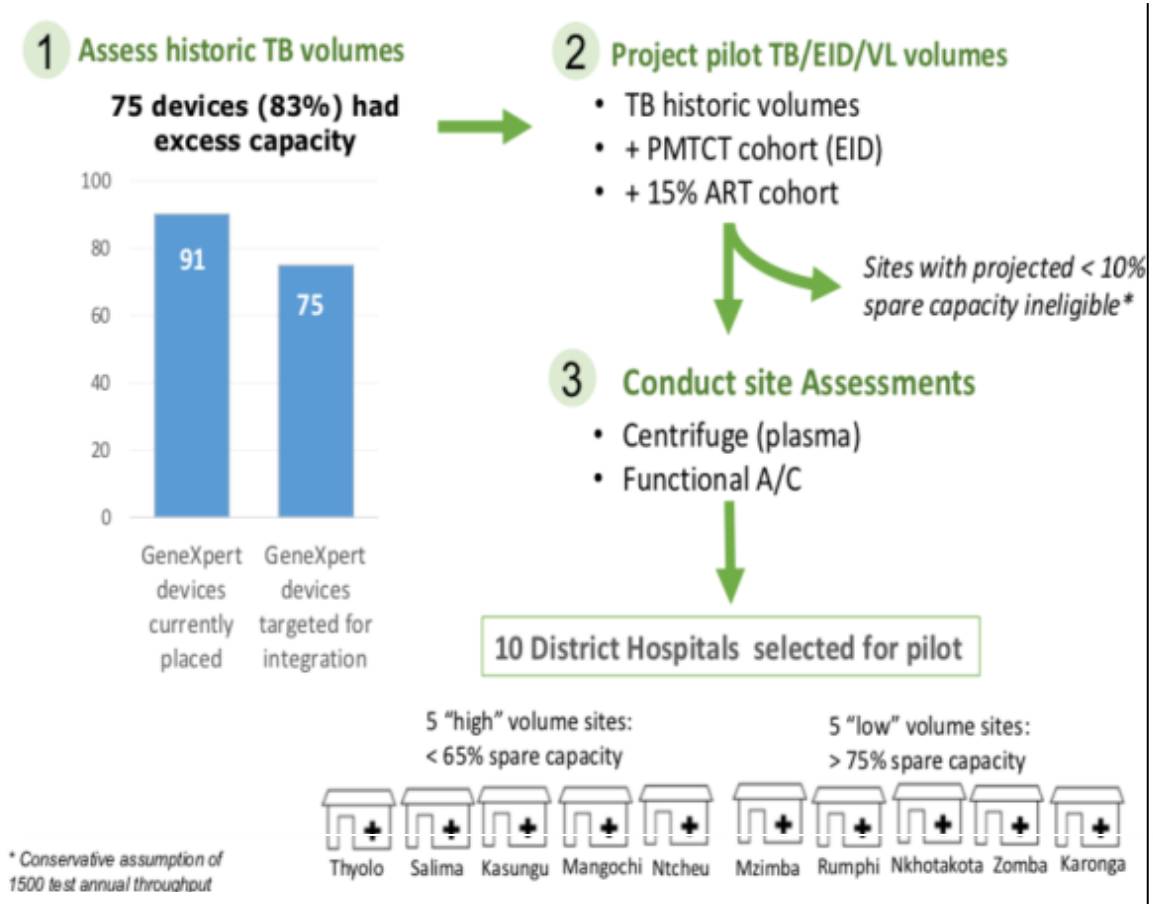
GeneXpert utilization: 28%

Challenges

1. **Long result turnaround time**[2]
   - **22 days** from EID sample collection to result dispatch to clinic
   - **35 days** for VL sample collection to result printing
2. **Low ART Initiation/clinical action rates**
   - **65%** ART initiation for peds patients
   - **37%** 2nd VL sample collected of patients with elevated VL
3. **Long time for ART initiation/clinical action**
   - **40 days** from sample collection to ART initiation for HIV+ infants
   - **30 days** time to clinical action after 2nd VL

Source: [1]Towards Viral Load Scale up plan 2019-2022, Oct 2018; [2]Malawi MoH Integrated HIV program report Q4 2017

An initial pilot in 2017 evaluated expanding the use of GeneXpert devices to include EID and VL monitoring in 10 District Hospital



Testing Mix on POC GX

VL

- **Targeted VL:** PLHIV suspected of immunological or clinical failure
- **Confirmatory VL:** PLHIV with previous documentation of elevated VL, followed by 3 months of enhanced adherence counseling

EID

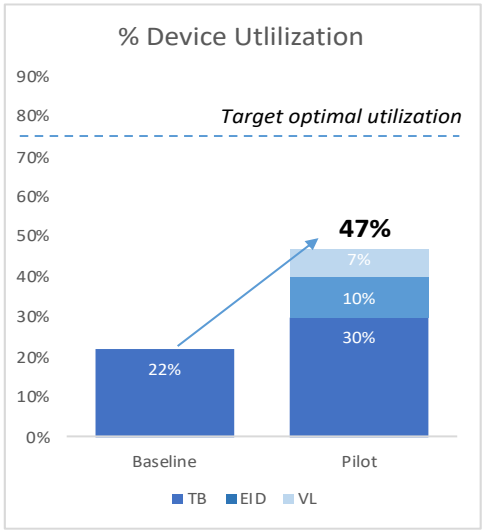
- All HIV-exposed infants (HEI) eligible for EID according to national algorithm
- *DBS sample collection only*

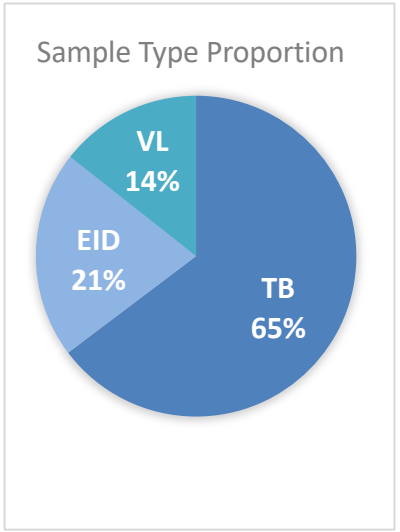
TB

- Patients suspected of drug-resistant TB, PLHIV, Presumptive TB cases (urban intervention)
- Children < 5 years

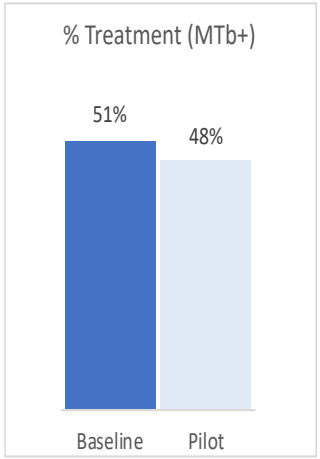
The pilot successfully demonstrated the operational feasibility and positive impact of integrated testing on the GeneXpert

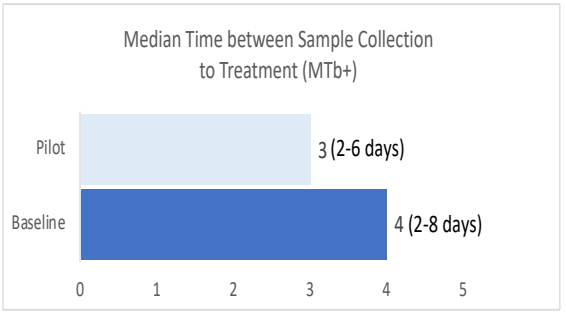
- **Integrated multi-disease testing <u>did not</u> overwhelm device capacity**
  - Utilization did not exceed 70% across the 10 pilot sites
  - Despite the addition of EID and VL, **65% of all Xpert testing was for TB**





- **TB service delivery was <u>not</u> negatively impacted**
  - Time to result return and proportion of MTb+ patients that initiated treatment stayed the same before and after integration

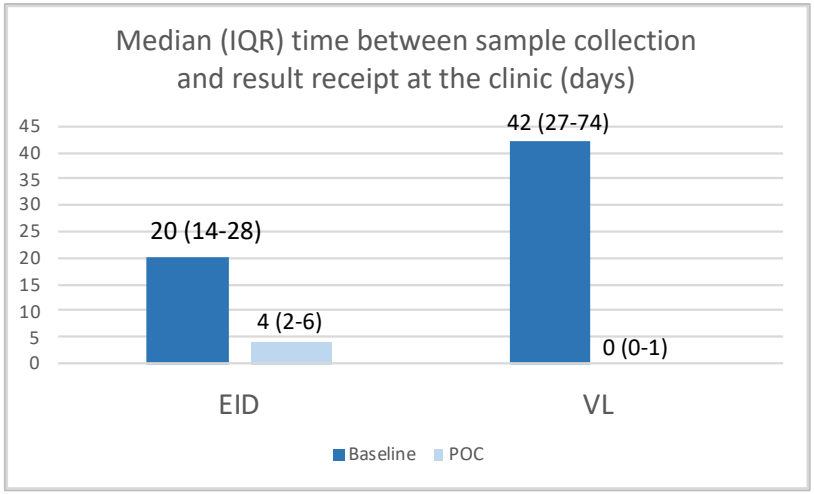




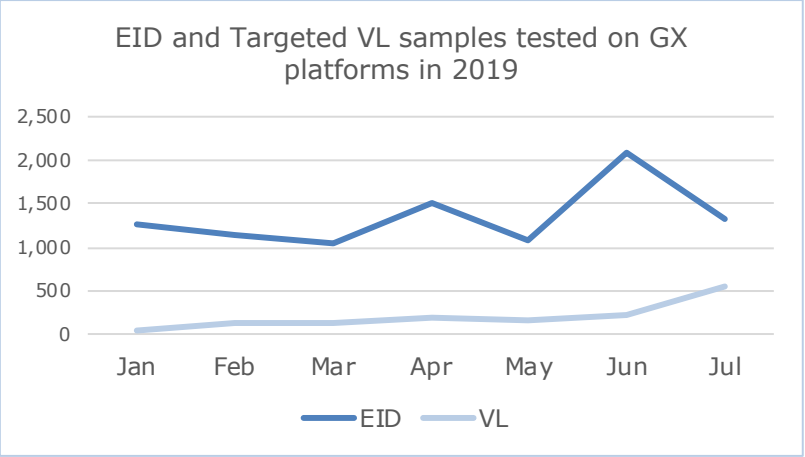
Source: Integrated TB-HIV testing on GeneXpert is feasible, enables increased device utilization and does not negatively impact TB services: implementation experience in Malawi and Zimbabwe, Oral Poster ASLM 2018

The pilot demonstrated positive patient impact and has informed the scale up of integrated POC testing to 43 sites

- **HIV patients <u>did</u> experience the benefits of POC testing, including:**
  - Faster result turnaround times
  - Increased proportion of patients receiving results
  - Increased proportion of patients receiving appropriate clinical management (HIV+ infants, PLHIV on ART with elevated VL)



- **POC EID and Targeted VL now running at 43 sites on GX platforms**
  - Between January and July 2019 over 10,800 EID and VL samples have been tested on GX platforms
  - 9,461 EID samples
  - 1,362 Targeted VL samples



To address the high prevalence of cervical cancer, Malawi has begun investigating the use of GX platforms for primary HPV screening

- Malawi has the highest age-standardized incidence and mortality of cervical cancer
  - Incidence: 75.9 per 100,000 women[†]
  - Mortality: 49.8 per 100,000 women[†]
- Women living with HIV (WLHIV) are at higher risk of HPV infection and progression to cervical cancer compared to those without HIV[‡]
- Screening coverage for cervical cancer in Malawi is 27%, with all screening done with VIA
- MoHP and CHAI is conducting a 5-site study to understand which service delivery models are most feasible and acceptable for offering HPV testing to screen WLHIV for cervical cancer

Objectives:

- To describe the uptake of GX-based HPV testing for WLHIV, max enrollment of 15,000 WLHIV
- To describe linkage to VIA and treatment for HPV+ WLHIV and the feasibility of same day test-triage-treat for HPV+ WLHIV with small pre-cancerous lesions (i.e. eligible for on-site cryotherapy)
- To document patient and HCW opinion on HPV screening and treatment programs across different service delivery models

Sources: [†]Ferlay J, et al (2014). GLOBOCAN 2012 v1.1, Cancer Incidence and Mortality Worldwide: IARC Cancer Base No. 11. Lyon: International Agency for Research on Cancer. [‡]Denslow, S.A. et al (2014) Incidence and progression of cervical lesions in women with HIV: a systematic global review. International Journal of STD & AIDS, Vol. 25(3) 163–177