EID testing in Malawi has expanded, but challenges persist, leading to leaky cascade

**Progress in the EID program** (8% HIV prevalence rate in pregnant women\(^1\))
1. Testing volume increased from 25,079 in 2012 to 38,504 in 2014\(^2\)
2. Testing coverage increased from 15% in Q4 2011 to 38% in Q4 2014\(^3\)

**Challenges**
1. **Poor uptake of timely first PCR**: Only 36% of HEI are tested at 6-8 weeks of age.\(^4\)
2. **Long TAT**: Median time between sample collection and dispatch of the result is 19 days; 75% of results are dispatched between 14 and 29 days after sample collection.\(^1\)
3. **Poor Linkage to ART**: Only 44% of HIV-infected infants are confirmed to be initiated onto treatment.\(^4\)
4. **Leaky Cascade**: During Q2 2015 LTFU in the 2 month, 12 month, and 24 month age cohorts were 6%, 20%, and 39%, respectively. Only 48% of the total 24 month age cohort had a known HIV status.\(^1\)

**EID Program Snapshot, Q2 2015**

- ~55% of expected HEI
- ~36% of results returned within 2 months
- ~57% of samples returned to facilities
- ~48% of infected infants initiated

<table>
<thead>
<tr>
<th>Number of Expected HIV-Exposed Infants</th>
<th>Number of DNA-PCR Samples Collected and Recorded</th>
<th>Number of EID Results Received at Sites</th>
<th>Number of EID Results Communicated to Mothers</th>
<th>Number of Positive EID Results</th>
<th>Number of HIV-Infected Infants &lt;12 Mo. Initiated on ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>14,500</td>
<td>7,992</td>
<td>2,871</td>
<td>1,624</td>
<td>181</td>
<td>87</td>
</tr>
</tbody>
</table>

Source: 1National VL and EID Monitoring Update Q2 2015, 2LIMS data, 3DNA PCR testing in 2 month cohort, 4Integrated HIV Program Reports Q4 2013 – Q3 2014,
The MOH has approved a POC EID pilot to inform decision making on national implementation

Rationale for Adoption of POC EID

- Early diagnosis and early linkage to treatment for HIV-infected infants are critical for Malawi to achieve UNAIDS 90-90-90 targets for its pediatric population
- POC EID has the potential to provide accelerated, or same-day, diagnosis and facilitate same-day treatment initiation for HIV-infected infants
- POC EID will complement established national conventional EID network

Selection of Alere Q

- HIV-1 and HIV-2 detection results in <1 hour
- Suitable for use in laboratory and non-laboratory environments at all levels of health system
- Suitable for use by non-laboratory operators

POC EID Pilot Objective

- To assess the operational characteristics of device to inform an optimal national deployment strategy if decision to scale up is made.

Estimated Pilot Timeline: October 2015 to January 2016
POC EID is placed at three levels of the health system with different device placement strategies.

Factors influencing POC EID placement include:

- **High burden**: HIV prevalence among women >10% at each site
- **High volume**: High EID volumes maximize patient impact based on 2014 LIMS data
- **Strong buy-in**: Sites expressed interest in implementing POC EID
- **Patient / clinic flow**: Facility-specific patient / clinic flow informed device placement strategies

### Device placement strategies within a facility

- **Testing at various entry points**: Device in a common lab
- **In-patient testing**: Device in pediatrics ward
- **Testing from mother-infant-pair (MIP) clinic**: Device in MIP clinic
- **Testing all HEIs in peripheral low volume sites**: Device shared between 2 primary HCs or networked with peripheral sites
Early observations from the pilot can inform future site selection and deployment strategies

**Key Question:** Within a high-volume site, which location maximizes EID access for HEI?

**Observation:** Lab model (Mzuzu Central Hospital) receiving patients from ART clinic, in-patient wards, and the health centre 5 kms down the road.

**Key Question:** How can a district hospital optimally handle on-site and referral patients using POC EID? Is device throughput a concern?

**Observation:** Clinicians have commented that they would prefer if more than one sample could run at a time to reduce waiting times to manage fluctuating patient volumes.

**Key Question:** How can device throughput be maximized in a network of low-volume primary health centres?

**Observation:** HEIs concentrated on a particular day of the week, hence patient volumes fluctuate drastically. MIPs asked to come back the next day for EID sample collection and results to manage peak days, and sharing of the device and patient referral from networked sites aimed at increasing overall device utilization.
Pilot preliminary findings and lessons learned during first 30 days

<table>
<thead>
<tr>
<th>Total POC EID tests</th>
<th>Total HIV positive results</th>
<th>Impact on LTFU/ ART Initiation</th>
</tr>
</thead>
</table>
| 193                 | 11                        | • 10 infants initiated onsite on the same day of testing following receipt of HIV-positive result on Alere Q  
|                     | (5.7%)                    | • 1 infant sent to referral facility for ART initiation |

**Advantages of POC EID**
1. Clinicians find POC EID convenient
2. Operators find device user-friendly
3. Mothers are happy to wait for the same-day results

**Opportunities for Improvement**
1. Deployment strategy may need to consider how to handle peaks and valleys in patient volumes – average daily patient volume may not be an appropriate criteria to use at some sites
2. Better SOPs are needed to support operators in interpreting results and error codes to minimize device downtime
3. Higher than expected error code occurrence has increased patient waiting times
Zikomo!