PILOT IMPLEMENTATION OF POINT OF CARE EARLY INFANT HIV DIAGNOSIS IN KENYA

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The HIV and AIDS Burden in Kenya

- In 2016, 1.5 million persons were living with HIV in Kenya
  - About 79,000 pregnant women were HIV-positive
- Kenya has one of the most advanced conventional early infant diagnosis (EID) systems in sub-Saharan Africa
  - Dedicated and regular long-haul hub-and-spoke sample transport
  - Early adopter of dried blood spot testing
  - Eight conventional labs for EID testing
  - National EID dashboard used for immediate return of results to clinics
  - Significant site-level support provided to track and contact lost to follow-up mother/infant pairs
Gaps in EID Services

Despite these investments, some gaps still exist:

- Only 46% of HIV-exposed infants (HEI) are tested by two months of age.
- 20% HIV-infected infants remain uninitiated due to limited timely diagnosis and delays in return of results to caregivers due in part to specimen transportation to national labs.
- Peak infant mortality at 6-8 weeks of age → approximately 20% of perinatally HIV-infected infants will die.

Unitaid/EGPAF point-of-care (POC) EID Project (2015-2019) aims to increase the number of HEI tested and facilitate timely antiretroviral therapy (ART) initiation by bringing testing closer to the patients through introduction and scale-up of POC EID in under-resourced and decentralized facilities.
Study Objectives

- We evaluated the effect of POC EID on key service delivery indicators as compared to pre-intervention, conventional EID in purposively selected project sites.
- The evaluation also aimed to assess the hub and spoke as a model for scale-up of POC EID in Kenya.

Rational:
POC diagnosis equipment placed at health facilities may provide an opportunity to reduce turnaround time (TAT) of EID results by eliminating the need to transport samples over long distances. By reducing the TAT between sample collection and return of results to the caregiver, health care workers and caregivers can make clinical decisions for the infants, sooner.
Evaluation Methods

- Pre-post intervention design.
- Pre-intervention conventional EID data were collected retrospectively from registers across a purposively sampled sub-set of sites.
- Post-intervention data for specimens processed between August 2017 and January 2018 were collected prospectively using a POC EID testing form.
- Median TAT, % results received by caregiver, and % infants initiated on ART were compared between conventional and POC EID.
- Prospective data compared between POC hubs and spoke sites.

Lessons from pilot phase will inform expansion to other counties in a phased approach over 2018.

Scale:
- 10 counties
- Estimated 45 POC EID platforms and up to 41,000 tests
Results From Pilot Phase
## POC EID Results at Pilot Sites for Primary Evaluation Outcomes (Aug 2017 – Jan 2018, 39 sites, two counties)

<table>
<thead>
<tr>
<th>Country (number of POC EID tests)</th>
<th>% Results received by infant caregiver within 30 days</th>
<th>Median number of days [IQ range] from blood collection to return of results to caregiver *</th>
<th># of HIV-infected infants initiated on ART</th>
<th>Median number of days [IQ range] between receipt of results by caregiver and initiation on treatment of HIV-infected infant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya (n= 778)</td>
<td>99.3%</td>
<td>2 days [0 – 4]</td>
<td>8/8 (100%)</td>
<td>0 days [0]</td>
</tr>
</tbody>
</table>

*Tests for which no date for caregiver result return was recorded were censored and not included in calculation of turnaround time.*
Conventional vs. POC testing TAT distribution: Sample collection to receipt of results by caregiver within WHO-recommended 30 days

- Same Day: Conventional 99%, POC 32.2%
- 1-7 Days: Conventional 68.3%, POC 0.4%
- 8-30 Days: Conventional 10.4%, POC 20.9%
- >1 Month: Conventional 0.0%, POC 0.6%
- Not Communicated: Conventional 0.0%, POC 0.0%
### Comparing Hub and Spoke Sites

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Hub Sites (n = 3 sites)</th>
<th>Spoke Sites (n = 28 sites)</th>
</tr>
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<tbody>
<tr>
<td>% of results returned to caregiver</td>
<td>100% (n=311)</td>
<td>100% (n=467)</td>
</tr>
<tr>
<td>Median TAT from blood sampling to caregiver receipt of results</td>
<td>0 days [IQ range: 0-1]</td>
<td>4 days [IQ range: 0-5]</td>
</tr>
<tr>
<td>Median TAT from receipt of results to initiation on treatment</td>
<td>0 days (n=1)</td>
<td>0 days [0-3] (n=7)</td>
</tr>
<tr>
<td>% HIV-infected children initiated on treatment</td>
<td>100% (n=1)</td>
<td>100 % (n=7)</td>
</tr>
</tbody>
</table>
Conclusions

- When tested using the POC model, almost 80% more caregivers are getting their infant’s test results back within 30 days from blood sample collection.

- POC EID has resulted in faster TAT from sample collection to receipt of result by caregiver; from 52 median days with conventional testing, to 2 median days with POC.

- Almost 41% more HIV-infected infants were initiated on ART after testing with POC EID.

- Results are comparable between hub and spoke sites. The hub-and-spoke model can make EID testing more accessible.

- EID is a time-bound intervention that requires rapid clinical decision making
  - Worth considering the integration of POC EID into current EID network.
Thank you

This project is made possible thanks to Unitaid’s support. Unitaid accelerates access to innovation so that critical health products can reach the people who most need them.