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Elizabeth Glaser Pediatric AIDS Foundation | *Until no child has AIDS.*

Unitaid/EGPAF Project to Optimize Early Infant HIV Diagnosis through the Introduction of Point-of-Care Testing

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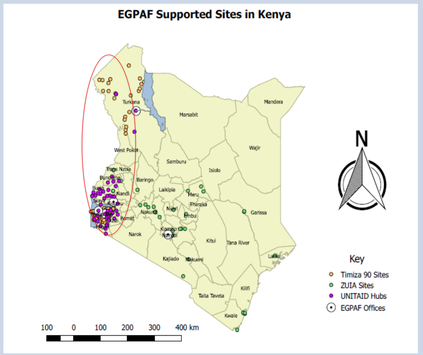


ISSUE

- In 2015, it was estimated that 1.5 million persons were living with HIV in Kenya; Of these, 98,000 were children aged between 0 and 14 years. [1]
- About 900,000 persons (59%) were receiving antiretroviral therapy, including 72% of the HIV-infected children aged between 0 and 14 years and 62% of the HIV-infected adults aged 15 years and above.
- In addition, about 79,000 pregnant women were estimated to be HIV+; only 46% of their infants were tested for HIV by two months of age through DNA PCR.
- Antiretroviral therapy (ART) coverage is sub-optimal due to limited access to diagnosis and delays in return of results to care givers have led to loss to follow up.
- Without treatment, up to 50% of HIV-infected children will die by their second birthday, with a peak mortality at two to three months of age. [2,3,4]
- The goal of the four-year UNITAID/EGPAF POC EID project (2015-2019) is to increase the number of HIV-positive infants whose HIV status is known to facilitate early ART initiation.
- EGPAF will accomplish this by optimizing the existing early infant diagnosis (EID) network through the introduction and scale-up of point-of-care (POC) EID in under-resourced and decentralized facilities in Kenya, while initiating HIV-positive infants on ART through existing EGPAF programs and linkages.

DESCRIPTION

- Under the POC Technical Working Group of the Kenyan Ministry of Health, a criteria for site selection was developed that considered historical testing volumes, low EID uptake (the difference between the number of identified HIV infected women and the number of EID tests conducted within 2 months of age), and turnaround time (TAT) (the time from specimen collection to release of test results from the conventional testing laboratory).
- The criteria yielded 45 hubs that would enable 693 spoke facilities access POC EID testing. To start, three hub and 36 spoke sites were selected for pilot testing.
- The hub-and-spoke model places POC platforms in a centrally located facility “hub”, with smaller health outpost “spokes” delivering samples to hubs for faster diagnoses.
- We compared baseline data on conventional laboratory-based EID with post-intervention data on POC EID testing. Additionally, we evaluated the hub-and-spoke as a model for scale-up of POC EID.

LESSONS LEARNED

- The evaluation has shown that with POC EID almost 100% of caregivers received their test results within the WHO recommended 30 days, up from 18% under conventional testing.
- Results also showed that with POC EID, more caregivers are getting back test results for their infants, sooner.
- The turnaround time between blood sample collection and return of results to the infant’s caregiver has decreased significantly using POC EID. HIV-infected infants are initiated on lifesaving treatment at a younger age which greatly increases their prospect of survival.
- There were no differences in percent results returned between testing and spoke sites.

Conventional Laboratory EID Results for Primary Evaluation Outcomes – Baseline Jul 2015-Mar 2017 at 18 sites in 3 counties

Country (number of conventional tests)	% Results received by Infant Caregiver within 30 days	Median number of days [IQ range] from blood collection to return of results to caregiver	# of HIV-infected infants initiated on ART	Median number of days [IQ range] between receipt of results by caregiver and initiation on treatment of HIV-infected infant
Kenya (n= 540)	**18.3%**	**54 days [31-82]**	**17/24 (71%)**	**0 days [0-2]**

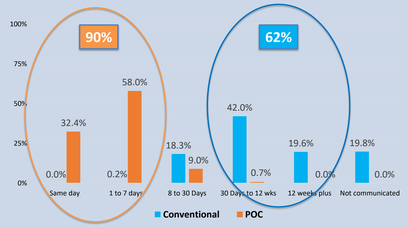
POC EID Results at Pilot Sites for Primary Evaluation Outcomes (Aug 2017 – Jan 2018) at 36 sites in 2 counties

Country (number of POC EID tests)	% Results received by Infant Caregiver within 30 days	Median number of days [IQ range] from blood collection to return of results to caregiver	# of HIV-infected infants initiated on ART	Median number of days [IQ range] between receipt of results by caregiver and initiation on treatment of HIV-infected infant
Kenya (n= 778)	**99.4%**	**2 days [0 – 4]**	**8/8 (100%)**	**0 days [0]**

Comparing EID indicators between Hub and Spoke Sites

Indicator	Hub Sites (n = 3 sites)	Spoke Sites (n = 28 sites)
% of results returned to caregiver	100% (n=311)	100% (n=467)
Median turnaround time [IQ range] from blood sampling to caregiver receipt of results	0 days [0-1]	4 days [2-6]
Median turnaround time [IQ range] from receipt of results to initiation on treatment	0 days [0] (n=1)	0 days [0] (n=7)
% HIV-Infected children initiated on treatment	100% (n=1)	100 % (n=7)

A: Conventional vs POC testing TAT: Sample collection to receipt of results by caregiver



B: POC Hubs vs Spoke testing TAT: Sample collection to receipt of results by caregiver

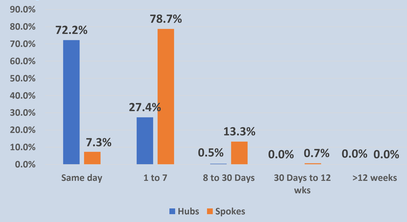


Figure 1. Comparing TAT between conventional and POC EID testing (A) and between hubs and spoke sites (B).

CONCLUSION/RECOMMENDATION.

Routine use of POC EID in sub-Saharan Africa is feasible and may significantly improve key patient outcomes. A hub-and-spoke model can expand access to POC EID, with minimal differences in patient-level outcomes.

Unitaid Innovation in Global Health

HARAMBEE

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