Elizabeth Glaser Pediatric AIDS Foundation / **Unitaid** Innovation in Global Health

Issue Brief

Catalyzing Expanded Access to Early Testing, Care, and Treatment for HIV-exposed Infants in Kenya

Kenya is among four countries (including Nigeria, South Africa and Mozambique) with the highest HIV disease burden in Africa. As of 2015, approximately 1.5 million people, including estimated 98,000 children under the age of 15 years, were living with HIV infection in Kenya[1]. HIV prevalence has remained stable at almost 6% over the last five years, with geographical variation ranging from 0.4% to 26% depending on the region.[2] The mother-to-child HIV transmission rate stands at 6.1%.

Without treatment, up to 50% of HIV-infected children die before their second birthday, with a peak mortality at 2 to 3 months of age. Despite a relatively high pediatric treatment coverage rate - 77% of children living with HIV receiving antiretroviral therapy (ART) - the HIV-associated mortality rate among Kenyan children remains high at 14%.[2] Access to early infant HIV diagnosis (EID) screening is key to identifying HIV-positive infants as early as possible and immediately initiating them on lifesaving treatment. While currently up to 68% of HIV-exposed infants in Kenya have access to conventional laboratory-based EID, initiation of ART for HIV-infected infants is frequently delayed due to the long turnaround times (30-60 days currently in Kenya) from sample collection to return of results to providers and caregivers.[3]

The Elizabeth Glaser Pediatric AIDS Foundation in Kenya (EGPAF-Kenya), with funding from Unitaid, is integrating new-to-market, point-of-care (POC) technologies for EID into the existing national EID network. POC testing platforms are easy to use in a variety of health care entry points as they do not require trained laboratory technicians to operate. This POC technology, which does not require moving the sample to the central laboratory, allows HIV-exposed infants to be screened on-site at the facility and receive the test results the same day. Those infants with positive test results and newly identified HIV infection can be immediately started on ART.

The project will adopt the hub-and-spoke model currently used by the conventional laboratory for sample transportation by placing POC platforms in hub sites which will support the testing of additional samples from nearby surrounding spoke sites (regularly sending samples to the hub sites for POC EID testing via the already-existing sample transportation network).

Goal and Targets of POC EID in Kenya

Through the incorporation of POC EID into the national diagnostic network in Kenya, EGPAF aims to increase the number of infants whose HIV status is known and to significantly increase the number of infants living with HIV who are initiated on lifesaving treatment. To reach this goal, EGPAF is focusing on achieving the following targets by the end of 2019:

- Perform approximately 43,000 POC EID tests.

- Reduce turnaround time between sample collection and results receipt by caregiver from the

current 30-60 days to zero days at POC testing sites (stand-along and hub sites) and to less than five days at POC spoke sites;

- Reduce the time/period between a positive HIV test and start-up of ART in infants living with HIV to less than 14 days;

- At a current vertical HIV transmission rate of 6.1%, detect an estimated 2,405 infants living with HIV; and

- Ensure that at least 2,221 newly identified infants (90% of identified infants) are linked to treatment by the end of the project.

Strategic Project Site Selection in Kenya

To achieve these targets, EGPAF jointly undertook a site selection process with the Ministry of Health (MOH) in order to strategically place POC platforms. Using criteria developed by Kenya's nationally-delegated POC Technical Working Group, project sites were selected based on a two-step approach of considering historical test volumes and test-to-results receipt turnaround time. EID uptake is defined as the proportion of eligible HIV-exposed infants with completed EID testing by 2 months of age; and turnaround time is defined as time from specimen collection to release of test results to the caregiver. The first step was to prioritize the counties with high HIV burden followed by mapping out the health facilities within the high-burden counties. Determination of sites to receive POC devices was based on review of 2015 site-level data from 1,148 health facilities from the national EID database. A majority of selected sites are already serving as hub sites (sample referral sites for surrounding smaller health facilities) in the current EID sample networking.

Phased Introduction and Expansion of POC EID Testing

Working hand-in-hand with the MOH and other stakeholders, EGPAF has been working to:

- Ensure that conditions for use of POC EID are met;

- Procure POC technology for EID;

- Place POC platforms in selected health facilities under the direction of the MOH and according to the national EID network plans;

- Generate and share lessons learned through routine project monitoring and formal evaluation studies with the World Health Organization and other partners (Kenya will be one of the sites for a POC EID impact study); and

- Develop and implement transition plans, to ensure sustainability of this work within each supported setting.

EGPAF supported the enrolment of the first three POC EID hub sites in Homabay and Turkana counties in August 2017. The three hubs supported a total of 36 spokes. All sites were closely monitored and supported from August 2017 through January 2018 to ensure that all aspects of POC EID were functioning effectively prior to expanding to additional sites. Upon completion of the pilot, the remaining hub and spoke sites will be enrolled with the last site expected to be enrolled in December 2018. Currently, the project is in the scale-up phase with 10 additional hub and 157 spoke sites enrolled in early 2018.

Evaluating the Effect of POC EID to Date on Key Service Delivery Indicators

To understand the effect of POC EID, EGPAF has conducted a pre- and post-intervention evaluation comparing data on key service delivery indicators. Baseline data on 540 infants tested using conventional, laboratory-based EID were collected in 2017 from a sub-set of intervention sites, prior to introducing POC technology. Across 18 baseline sites, a sample of 30 consecutive EID tests of infants born to mothers living with HIV were collected. To collect post-intervention data, a POC EID test request form was introduced in all intervention sites in Kenya, as part of routine service delivery. The POC EID test request form allows the project to collect the date the blood sample is collected, results are received by the caregiver and for HIV-infected infants, the date of treatment initiation. Post-intervention data were analyzed and compared to pre-intervention data, stratifying by testing sites and spoke sites.

Between August 2, 2017 and April 30, 2018, data for POC EID tests conducted across 139 sites, including 13 hub sites and 126 spoke sites were analyzed. During this period, 2,412 tests were conducted on 2,365 infants using POC. Forty four infants tested HIV-positive. Table 1 below shows the pre- and post-intervention results. POC EID resulted in impressive increases in caregivers who receive EID results within 30 days and percentage of HIV-infected infants initiated on HIV treatment.

Table 1. Pre-intervention (July 2015 to March 2017) and post-intervention (August 2017 to April 2018) data: results for key service delivery indicators

	Conventional EID Data (n = 540 tests)	POC EID Data (n = 2412 tests)
Number of infants tested	540	2,365
Percent of results returned to caregiver within 30 days	18.3%	99.6%
Median turnaround time from blood sample collection to caregiver receipt of results	52 days [IQ Range: 31-82]	1 day [IQ Range: 0-4]
Median turnaround time from receipt of results to initiation on treatment	0 days [IQ Range: 0-2]	0 days [IQ Range: 0-1]
Percent of newly identified HIV-infected infants initiated on treatment	71%	100%
Median turnaround time from blood sample collection to ART initiation for infants identified as HIV-infected	43 days [IQ Range: 31-71]	2 days [IQ Range: 0-5]

Preliminary results are promising, suggesting that a hub-and-spoke model can effectively expand access to EID testing (see Table 2). Almost 100% of results were received by caregivers within a median of 0 days at hub and 2 days at spoke sites, and the median turnaround time between receipts of results by caregivers to initiation on treatment was comparable.

Table 2: Comparison of hub and spoke sites

	Hub Sites (n = 13)	Spoke Sites (n = 126)
Number of infants tested	909	1456
Number of tests	933	1479
Number (percent) of results returned to caregiver	933 (100%)	1479 (100%)
Median turnaround time from blood sample collection to caregiver receipt of results	0 days [IQ Range: 0-1]	2 day [IQ Range: 0-5]
Median turnaround time from receipt of results to initiation on treatment	0 days [IQ Range: 0]	0 days [IQ Range: 0]
Number (percent) of newly identified HIV-infected infants initiated on treatment	12 (100%)	32 (100%)

Lessons Learned

Kenya has invested heavily in improving the conventional EID system with dedicated and regular long-haul hub-and-spoke sample transport, early adoption of DBS as a sample type, eight conventional labs for EID testing and a national EID dashboard used for immediate return of results to clinics. However, despite these improvements in conventional testing turnaround time, there are still delays in delivery of samples to the testing labs and getting back the results to the caregivers. Initial data from routine use of POC EID in Kenya show that introduction of POC technologies into the national EID network improve patient outcomes. Through POC EID, more infants and their caregivers are receiving their results faster: 80% more results reached caregivers within 30 days from blood sample collection when tested using POC EID; and almost 30% more infants were initiated on treatment as compared to infants identified as HIV-infected through conventional EID. Furthermore, data from early routine use of POC EID show that there is very little difference in key service delivery indicators between testing and spoke sites, making the hub-and-spoke model a viable option to optimize EID. The success of POC EID has also benefited from acceptance and buy-in from health care workers and also on the synergies between the lab and PMTCT programs.

When caregivers and clinicians get test results sooner, they can make patient care decisions faster and save infants' lives. Early implementation results are very encouraging, suggesting that there are significant benefits to incorporating POC into the existing EID network. National programs, funders, and other implementers should consider further scale-up of this technology.

PHOTO: ERIC BOND/EGPAF, 2016

References

[1] Joint United Nations on HIV and AIDS Programme (UNAIDS). Prevention Gap Report 2016. http://www.unaids.org/en/resources/documents/2016/prevention-gap.

[2] National AIDS Control Council. Kenya AIDS Response Progress Report. 2016 http://nacc.or.ke/wp-content/uploads/2016/11/Kenya-AIDS-Progress-Report_web.pdf.

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