Lebele Mathato with her daughter, Nyakallo, and lay counsellor, Sefoli Mabafokeng at a 6-week check-up in Lesotho. [EGPAF Lesotho]

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

Issue Brief
Point-of-Care Early Infant HIV Diagnosis

Doing more, faster: Preliminary results from the routine use of point-of-care early infant HIV diagnosis in six sub-Saharan African countries

> *"Everyone knows that the problem here is the period of time that elapses between collecting and transferring blood samples to laboratories, but also the time it takes to collect results and send them back to health centres". Key Stakeholder, Cameroon (2016)*

In 2015, more than 1.2 million babies were born to mothers living with HIV in 21 countries.[1] While the World Health Organization (WHO) recommends that all HIV-exposed infants receive a virologic test for HIV within two months of birth, only 50% were tested and, of those, only 50% received results, with weeks or months passing before caregivers knew the test outcome. Of those HIV-infected infants who did receive their results, only half were placed on treatment (Figure 1).[2,3,4] Without treatment, up to 50% of HIV-infected children will die by their second birthday, with a peak mortality at 2 to 3 months of age.[5,6,7]

To improve health and to save lives, HIV-infected infants must be diagnosed early, rapidly and efficiently, and immediately initiated on treatment. Yet, current current early infant diagnosis (EID) systems in resource-limited countries are challenged at multiple levels of the cascade.
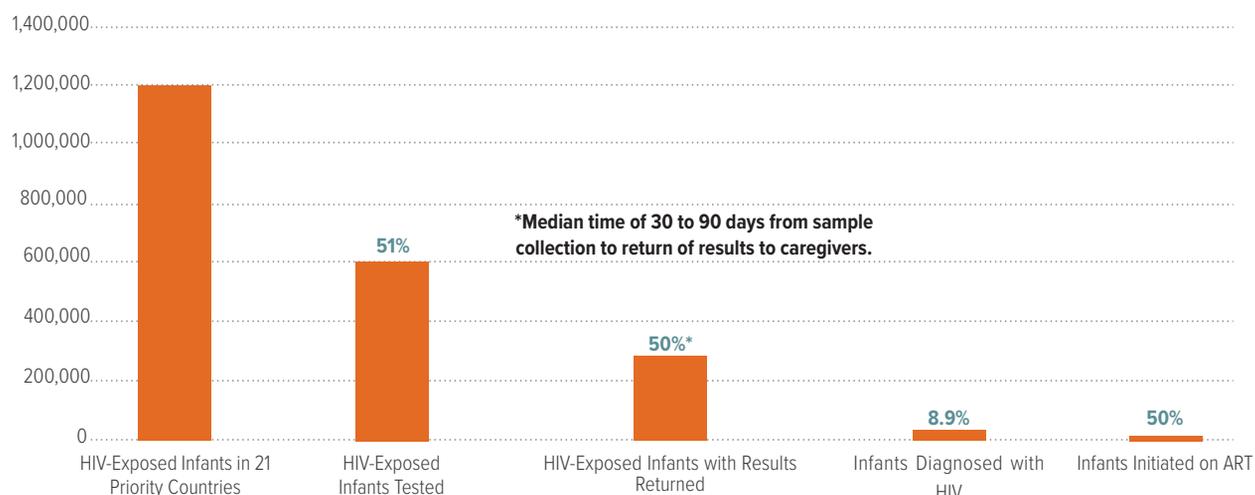

Median time of 30 to 90 days from sample collection to return of results to caregivers.

Figure 1. Cascade of early infant diagnosis through treatment, global, 2016[1]

New-to-market, point-of-care early infant diagnosis (POC EID) technology can help address these challenges and ensure HIV-exposed infants are tested on-site, or at nearby sites. Point-of-care testing platforms are easy to use in a variety of service delivery settings, and do not require trained laboratory technicians to operate. This technology allows for a greater number of HIV-infected infants to be rapidly enrolled on lifesaving antiretroviral treatment.

> *"Even if they follow PMTCT protocols, mothers still worry about the HIV status of the baby, so to wait a long time for the mother to get the results is really hard,"* said Sefoli Mabafokeng, a lay counselor in Lesotho. *"The machine is doing a fantastic job. It fills the gaps in early infant diagnosis."*

Since 2015, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), through funding and support from Unitaid, is working to initiate more HIV-infected infants on life-saving treatment early and fast by integrating POC EID into the current EID system in nine high-prevalence countries: Cameroon, Côte d'Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Swaziland, Zambia, and Zimbabwe.

POC EID placement

Working side-by-side with each country's ministry of health and key stakeholders, the project is employing multiple approaches and models to optimize national EID networks according to unique needs, implementation context and priorities. POC EID placement models aim to increase access to EID testing in underserved areas, and to decrease turnaround time in high-volume and/or decentralized facilities. In eight of the nine project countries, a "hub-and-spoke" model has been applied to increase both access to EID and decrease turnaround time in underserved and decentralized areas. A "hub and spoke" model (see Figure 3) places POC platforms ina centrally located facility "hub", with smaller health outposts "spokes" delivering samples for faster diagnoses to these hubs (alleviating national laboratories of EID sample processing). Countries are also using stand-alone sites which only process samples collected at their own facility (see Figure 2).
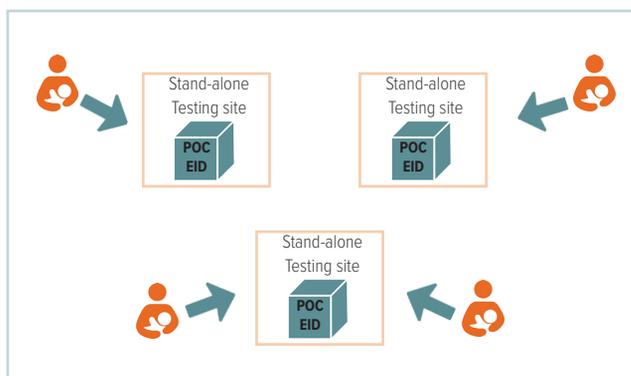

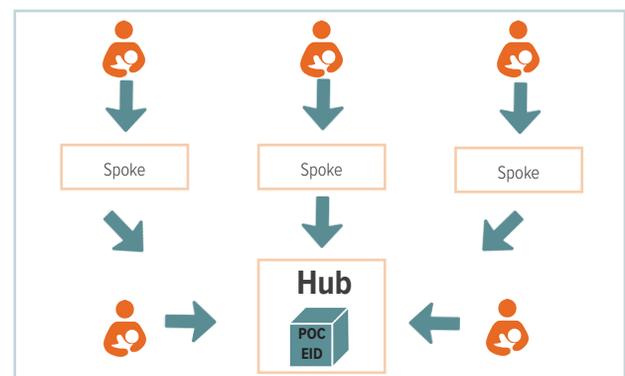Figure 2. Stand-alone testing sites (without spokes): process tests collected from clients directly

Figure 3. Testing samples collected at spoke sites; processing samples at hubs

Evaluating the effect of POC EID: Preliminary results from six countries

To understand the effect of POC EID, EGPAF is conducting a pre-and post-intervention evaluation. Pre-intervention, baseline data from infants tested using conventional, laboratory-based EID was collected in 2016 and 2017 from a sub-set of intervention sites, prior to introducing POC technology. Baseline data is compared with POC EID data on key service delivery indicators. Pilot findings from six intervention countries are summarized below.

Comparison of pre- and post-intervention data

Methodology

Pre-intervention data on conventional EID testing were collected in 73 health facilities, representing a sub-set of project intervention sites across Cameroon, Côte d'Ivoire, Lesotho, Rwanda, Swaziland, and Zimbabwe. In each facility, patient data for a sample of 30 infants born to mothers living with HIV tested using conventional EID were abstracted from patient registers. In total, 2,210 records were abstracted.

To collect post-intervention data, a POC EID test request form was introduced as part of routine service delivery. All key data on POC performance, including the time and date of blood sample collection, specimen processing, return of results to caregiver, and initiation of treatment are collected in one form.

By including multiple phases of the testing process cascade on one form, bottlenecks preventing the rapid return of results and initiation of treatment can be identified. Data collected from these forms were used for post-intervention analyses and compared to pre-intervention data, stratifying by testing vs. spoke site locations. As of June 15, 2017, data have been analyzed across 95 sites, including 28 testing sites and 67 spoke sites. Almost 2,800 tests have been run on 2,646 infants. For all positive test results, a second POC EID test was conducted with a new blood sample in order to confirm the positive result.

Preliminary results

With POC EID, almost 100% of caregivers received results, up from 77.4% under conventional testing (see Table 1). The median turnaround time between blood sample collection and return of results to the infant's caregiver has also decreased from 53 days at baseline to 0 days post-intervention; 67% of tests were returned on the same day and 92.8% were returned within 7 days. More caregivers received test results for their infants, sooner. The post-intervention data also shows that among children testing HIV-positive using POC EID, a larger proportion were initiated on treatment. Furthermore, because the turnaround time from sample collection to return of results was greatly reduced with POC EID, HIV-infected infants were initiated on lifesaving treatment at a younger age, greatly increasing their prospects of survival.

Table 1. Pre- and post-intervention data: key findings*

	Pre-intervention data (baseline)	Post-intervention data
Number of infants tested	2,210	2,646
Percentage of results returned to caregiver	77.4%	99.6%
Median turnaround time from blood sampling to caregiver receipt of results	53 days (range 2-438 days)	0 days (range: 0-98 days)
Median turnaround time from receipt of results to initiation on treatment	0 days (range: 0-75 days)	0 days (range: 0-28 days)
Number of infants tested who were diagnosed as HIV-positive	69	145
Percentage of newly identified children living with HIV initiated on treatment	72.4%	86.8%

Data for Mozambique, Kenya and Zambia are forthcoming.

Table 2 presents post-intervention findings disaggregated between testing and spoke sites. Preliminary results are promising, suggesting that a hub and spoke model can be feasibly used to further expand access to EID testing. Almost 100% of results were received by caregivers across both models, and the median turnaround time between sample collection and return of results to caregiver was 0 days in both.

Table 2: Testing site vs. spoke site

	Testing sites (n= 28)	Spoke sites (n= 67)
Percentage of results returned to caregiver	99.5%	99.9%
Median turnaround time from blood sampling to caregiver receipt of results	0 days (range: 0-33 days)	2 days (range: 0-98 days)
Median turnaround time from receipt of results to initiation on treatment	0 days (range: 0-28 days)	0 days (range: 0-7 days)
Percentage of newly identified children living with HIV initiated on treatment	88.5%	80.6%

Cost Analysis

The price of diagnostic technologies for EID – both conventional and POC – is a key consideration for national programs, other implementers and funders. Currently, the individual test price is higher for POC EID than for conventional EID. However, it is important to not only consider the cost of the test itself, but also to include other costs, such as service and maintenance costs, and to look at the cost per test result received. The cost per test result received may be considered a closer measure of the true value of a diagnostic, as any results not received by a caregiver cannot impact clinical decision-making, which can be considered a waste of scarce human, financial and material resources that are used to collect and analyze a blood sample but not deliver a test result. Thus, the cost per test result returned to caregivers was estimated using the pre- and post-intervention data and estimates a total cost of ownership, which considers a more comprehensive estimate of operating costs of EID technologies.[8]

When the price of testing commodities is combined with the comprehensive operating costs of delivering EID testing services, as well as the rate of result return (77.4% under conventional as per baseline data, as compared to nearly 100% for POC EID), the cost per test result received are estimated to be approximately $19-39 and $21-33 USD for conventional and POC, respectively.

Conclusions and recommendations based on preliminary pilot phase results

Initial data from routine use of POC EID show that introduction of POC technologies into national EID networks is improving patient outcomes and may reduce HIV-related pediatric mortality. Through POC EID, almost 100% of test results are reaching caregivers, and almost 15% more infants tested with POC are initiated on treatment, as compared to infants tested through conventional EID. These data support continued use of implementation methods applied.

Initial cost analyses using estimates from The Global Fund of total costs of ownership suggest that POC and conventional EID are nearly equivalent for cost per result received by caregivers. As demand for POC EID increases, lower prices may be negotiated and POC EID may become even more cost-effective (see EGPAF issue brief titled *At What Price? Cost Considerations for Integrating Point-Of-Care EID into National Diagnostic Networks*).

When caregivers and clinicians get tests results sooner, they can make patient care decisions faster and save infants' lives. Early results are encouraging, suggesting that there are significant benefits to incorporating POC into the existing EID network. National programs, funders and other implementers should consider introducing or expanding of the use of POC EID testing.

Follow POC EID results online, in real time

EGPAF developed an interactive data dashboard, using Microsoft Power BI, to summarize and display key POC EID findings across the nine project countries. Project data is regularly uploaded to the dashboard, allowing for real-time monitoring of key metrics and indicators. View the POC EID data dashboard online at:

http://www.pedaids.org/pocdashboard.

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For more information, please contact the EGPAF Unitaid Project Team: unitaid.POCEID@pedaids.org