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: Results from the routine use of innovative point-of-care technologies for early infant diagnosis in eight sub-Saharan African countries

"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."

In 2015, more than 1.2 million babies were born to mothers living with HIV in 21 countries.[1] To improve health and save lives, HIV-infected infants must be diagnosed early and immediately initiated on treatment. Yet, current early infant HIV diagnosis (EID) systems in resource-limited settings are challenged at multiple levels of the cascade. 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 across nine African countries where EGPAF collected baseline data on conventional EID testing. Among those tested, only 15% received test results within 30 days, as recommended by WHO.[2] Of those infants who received their results and were diagnosed with HIV, only 62% were placed on treatment within 60 days of blood sample collection (Figure 1).[3] 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.[4,5,6]

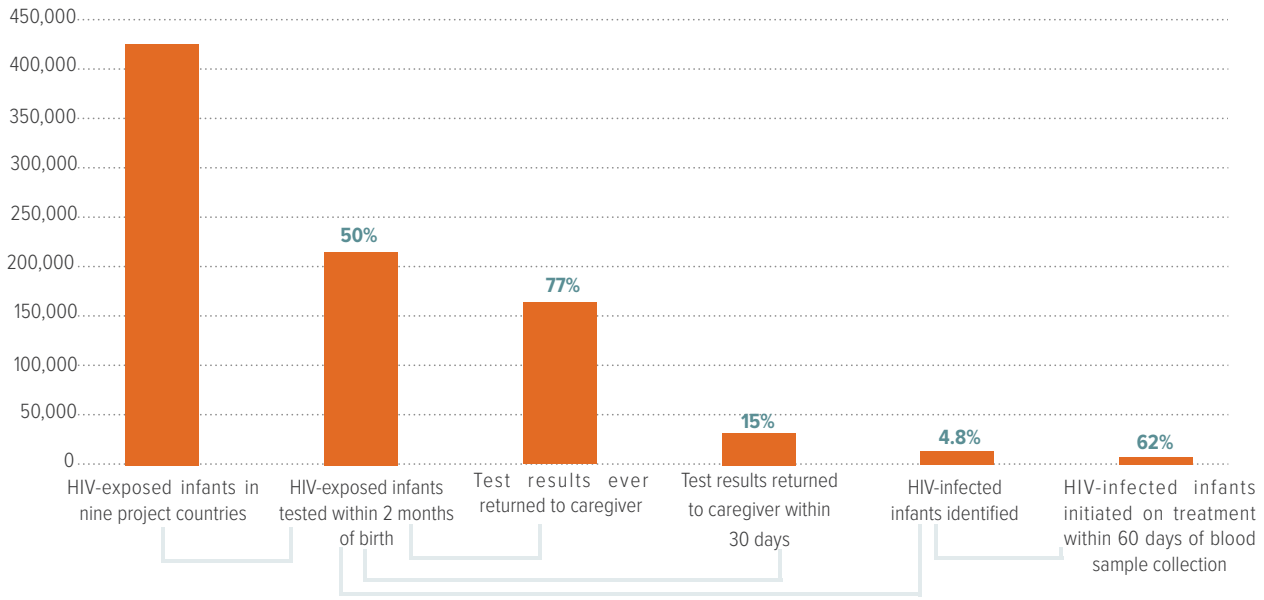

Figure 1. Cascade of EID through initiation of treatment, across nine African countries, 2017[3]

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New-to-market, point-of-care (POC) EID technology can help address these challenges and ensure that HIV-exposed infants are tested on-site, or at nearby sites, rather than at central labs. POC testing platforms are easy to use in a variety of service delivery settings, and do not require specialized laboratory technicians to operate. This technology returns a greater number of test results to caregivers and allows infants diagnosed as HIV positive to be rapidly enrolled on antiretroviral treatment (ART).

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

> *"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 send the test results back to health centers." Program Manager, Cameroon (2016)*

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. The hub-and-spoke model (see Figure 2) places POC platforms in a centrally located facility "hub", with smaller health outpost "spokes" delivering samples for faster diagnoses to these hubs. Countries are also using stand-alone sites, such as high-volume facilities, that only process samples collected at their own facility (see Figure 3).

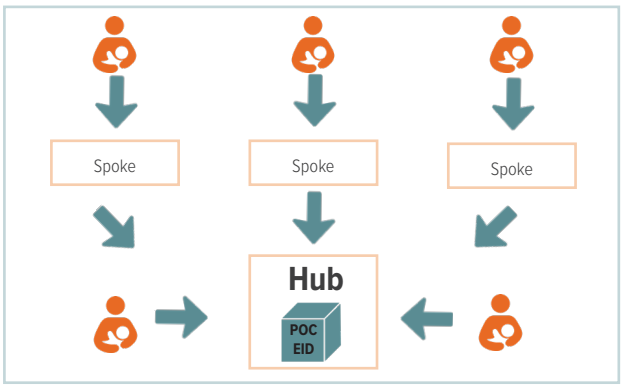

Figure 2. Hub-and-spoke model: Blood samples collected at spoke sites and processed at hub sites

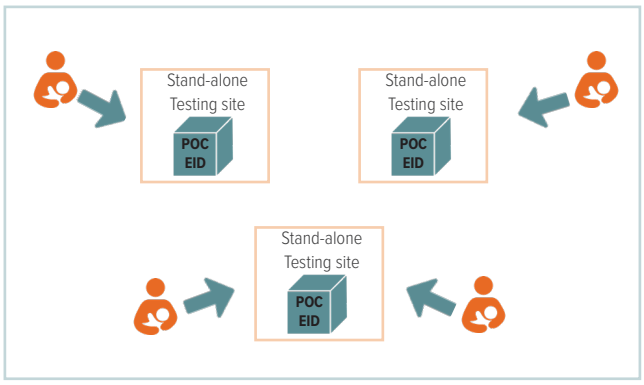

Figure 3. Stand-alone testing sites (without spokes): Blood samples collected from clients and processed directly on site

Evaluating the effect of POC EID

To understand the effect of POC EID, EGPAF conducted a pre- and post-intervention evaluation comparing data on key service delivery indicators. Baseline data on infants tested using conventional, laboratory-based EID were collected in 2016 and 2017 from a sub-set of intervention sites in nine project countries, prior to introducing POC technology. Baseline data were then compared with data collected during the implementation of POC EID in eight countries. The findings are summarized below.

Comparison of pre- and post-intervention data

Pre-intervention data on conventional EID testing were collected from patient registers for 2,867 infants across 102 selected health facilities in the nine project countries. In each facility, data were collected for a sample of 30 consecutive conventional EID tests of infants born to mothers living with HIV.

To collect post-intervention data, a POC EID test request form was introduced in all but one project country as part of routine service delivery. Post-intervention data were analyzed from all project countries, except Zambia, and compared to pre-intervention data, stratifying by testing sites and spoke sites. Zambia data were not included, because POC EID testing started in June 2018, after the cut-off date for this analysis.

Between December 1, 2016 and March 31, 2018, 26,313 POC EID tests were conducted across 538 project sites, including 155 testing sites and 383 spoke sites. Table 1 below shows the pre- and post-intervention

results. POC EID resulted in impressive increases in caregivers who received EID results within 30 days and in the percentage of HIV-infected infants initiated on HIV treatment.

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

	Pre-intervention data (conventional) (102 sites)	Post-intervention data (POC EID) (538 sites)
Number of infants tested who received a valid outcome (either negative or positive)	2,867	25,102
Number of tests conducted with a valid outcome (either negative or positive)	2,891	26,313
Percent of results returned to caregiver within 30 days from blood sample collection	19.7%	98.3%
Median turnaround time from blood sample collection to caregiver receipt of results	55 days (IQR: 31-77)	0 days (IQR: 0-1)
Percent of newly-identified, HIV-infected infants initiated on treatment within 60 days of blood sample collection	41.3%	91. 7%
Median turnaround time from blood sample collection to ART initiation for infants identified as HIV-infected	50 days (IQR: 31.5-69.5)	0 days (IQR: 0-2)

Table 2 presents post-intervention findings disaggregated by testing and spoke sites. Results are promising, suggesting that a hub-and-spoke model can effectively expand access to EID testing. More than 95% of results were received by caregivers within 30 days across both testing and spoke sites, and the median turnaround time between sample collection and return of results to caregiver was comparable. Over 90% of HIV-positive infants in both testing and spoke sites were initiated on treatment within 60 days from blood sample collection.

Table 2: Comparison of testing and spoke sites

	Testing sites (sites=155)	Spoke sites (sites=383)
Number infants tested	17,720	7,442
Number of tests conducted	18,586	7,727
Percentage of results returned to caregiver within 30 days	99.4%	95.7%
Median turnaround time from blood sample collection to caregiver receipt of results	0 days (IQR: 0-0)	2 days (IQR: 1-6)
Median turnaround time from receipt of results to initiation on treatment	0 days (IQR: 0-1)	0 days (IQR: 0-1)
Percent of newly-identified, HIV-infected infants initiated on treatment within 60 days of blood sample collection	91.1%	93.5%

Cost and cost-effectiveness

The price of diagnostic technologies is a key consideration for national programs, implementers, and funders. Currently, the individual test price for POC EID is higher than conventional, laboratory-based EID. However, it is important to consider not only the price of the test itself, but also other costs, such as service and maintenance costs, and to factor in the proportion of test results returned to the caregiver. The cost per test result received is a closer measure of the true value of a diagnostic. Any result not received by a caregiver cannot impact clinical decision making, which can be considered a waste of the scarce human, financial, and material resources used to collect and analyze a blood sample, but not deliver a test result.

Using The Global Fund's total cost of ownership (TCO) calculations, and EGPAF's pre- and post-intervention data for the proportion of results returned to caregivers, the estimated cost per test result returned is similar under the two approaches: approximately $20-$41 for conventional, and $21-$33 USD for POC.[7] Cost-effectiveness estimates using the CEPAC simulation model factor in the costs of linking children to lifelong HIV care and ART, and the resulting dramatic improvements in their long-term survival.[8] The CEPAC model shows that POC EID improved survival and life expectancy and was cost-effective compared to conventional EID, with an incremental cost-effectiveness ratio (ICER) of an additional $630 per year of life saved for POC EID when compared to conventional EID in Zimbabwe (see Figure 4). POC EID remained cost-effective across a wide range of inputs, including when assuming that conventional EID would return up to 95% of results within 1 month.

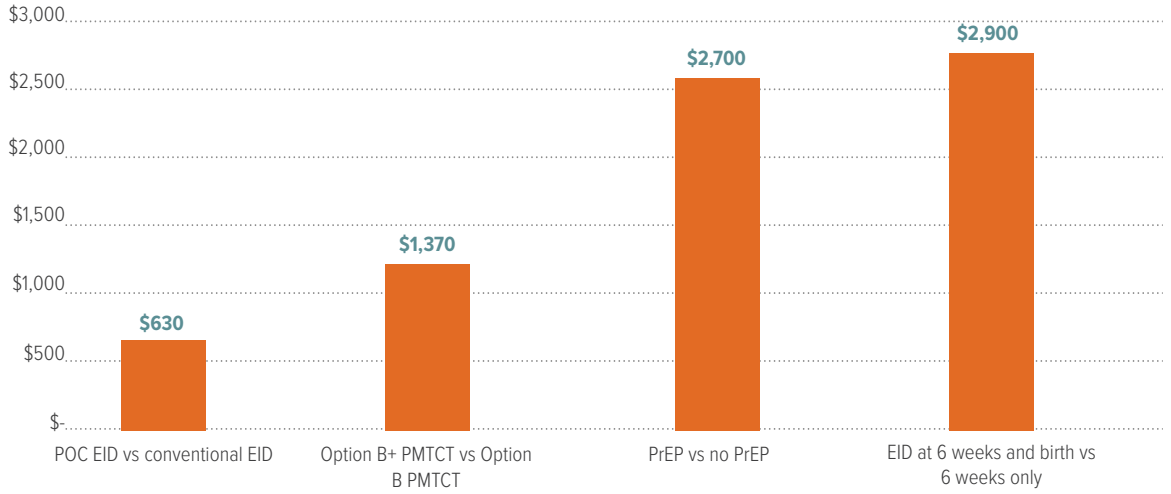

Figure 4: Comparison of ICERs (additional $ per year of life saved) across different types of HIV interventions in southern Africa

Conclusions and recommendations based on early routine use of POC EID

Data from routine use of POC EID show that introduction of POC technologies into national EID networks is improving patient outcomes. Through POC EID, more caregivers are receiving their infant's results faster: almost five times more results reached caregivers within 30 days of blood sample collection when tested using POC EID and 50% more infants were initiated on treatment within 60 days of blood sample collection, using POC as compared to conventional EID. Furthermore, 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 POC EID.

Cost effectiveness analyses demonstrate that POC EID is cost effective. As demand for POC EID increases, lower prices may be negotiated and the POC EID cost per result returned may become even more attractive.

When caregivers and clinicians get test results sooner, they can make patient care decisions faster and save infants' lives. There are significant clinical and cost-effectiveness benefits to incorporating POC into the existing EID network. National programs, funders, and other implementers should consider introducing or expanding 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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