



# Point-of-Care Early Infant Diagnosis of HIV

## The challenge with early infant diagnosis of HIV

Over 1.2 million newborns are exposed to HIV each year, with more than 65% in sub-Saharan Africa.<sup>1,2</sup> If left untreated, infants infected with HIV during pregnancy or childbirth have a high risk of dying before their first birthday.<sup>3,4,5</sup> For this reason, the World Health Organization (WHO) recommends that all HIV-exposed newborns receive a virological nucleic acid test (NAT) within four to six weeks of birth with immediate return of results. Infants who are HIV-infected should start treatment without delay.<sup>6</sup> Access to early infant diagnosis (EID) has steadily increased in recent years, but it varies significantly by region. By 2022, an estimated 63% of HIV-exposed infants globally received a virological test by two months of age. Coverage for EID testing rose to around 83% in eastern and southern Africa, but only to 23% in western and central Africa.<sup>7</sup> Because of delays in obtaining results and further losses in the testing-to-treatment cascade, only 30% of perinatally infected infants are linked to services and started on antiretroviral therapy (ART) in a timely manner.<sup>8</sup>

## Integrating point-of-care EID testing into national diagnostic networks

Innovative point-of-care (POC) EID technologies can increase access to testing for HIV-exposed newborns and accelerate diagnosis and linkage to treatment for infants living with HIV.<sup>9,10</sup> From August 2015 through July 2019, with funding from Unitaid, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) collaborated with ministries of health (MOHs) in nine African countries (Cameroon, Côte d'Ivoire, Eswatini, Kenya, Lesotho, Mozambique, Rwanda, Zambia, and Zimbabwe) to demonstrate the feasibility, effectiveness, affordability, and scalability of POC EID testing (see Figure 1 Theory of Change).

EGPAF introduced POC EID through a phased approach that included preparation, early implementation, progressive sites enrollment, routine testing and monitoring, and transitioning. Throughout all phases, EGPAF collected and analyzed data and information. This was used for communication and advocacy to promote acceptance and

**Goal:** Increase the number of HIV-exposed infants whose HIV status is known and improve early initiation on treatment through the integration of point-of-care (POC) testing into national diagnostic networks.

Activities	Outputs	Outcomes	Impact
<ul style="list-style-type: none"> <li>Engage key stakeholders, including civil society organizations, to increase awareness of and demand for POC EID</li> <li>Develop national plans to integrate POC EID into clinical services and diagnostic networks</li> <li>Negotiate volume-based procurement agreements with manufacturers</li> <li>Obtain POC EID commodities and integrate them into quantification, procurement, and supply chain systems</li> <li>Develop or adapt programmatic and training tools for POC EID testing</li> <li>Orient program managers and train and mentor clinical and laboratory staff to conduct POC EID testing</li> <li>Create and implement national connectivity, post-market surveillance, and quality-assurance plans</li> <li>Monitor progress/evaluate impact</li> <li>Develop transition and sustainability plans for each country</li> </ul>	<ul style="list-style-type: none"> <li>POC EID integrated into relevant national policies, strategies, guidelines, plans, and systems</li> <li>Signed agreements with manufacturers for improved pricing, service, and maintenance</li> <li>Platforms delivered, installed, and operating at project sites in accordance with manufacturer agreements</li> <li>Program, laboratory and clinical staff oriented and trained to support and operate POC EID</li> <li>Infants tested using POC EID in accordance with national guidelines</li> <li>Monitoring and evaluation results shared with key stakeholders</li> <li>Relevant stakeholders formally agree on a transition plan</li> </ul>	<ul style="list-style-type: none"> <li>Increased number and percent of HIV-exposed infants tested by two months of age</li> <li>Reduced turnaround time from blood sample collection to return of test results to caregivers</li> <li>Increased proportion of test results returned to caregivers</li> <li>Improved timely initiation of ART among HIV-positive infants</li> <li>Demonstrated cost-effectiveness of POC EID technology</li> <li>Resources committed by MOHs and donors to sustain and scale up POC EID in project countries</li> <li>Increased financial savings and health systems efficiencies attributable to POC EID</li> </ul>	<ul style="list-style-type: none"> <li>Reduced morbidity and mortality among HIV-exposed infants</li> </ul>

**Assumptions:** Sufficient number of women enrolled in prevention of mother-to-child transmission (PMTCT). Caregivers bring infants to test. POC instruments are functioning and can meet testing demand. Reliable and timely data is available. Increased access to POC testing over time.

**Contextual factors:** Funding is available. Platform and tests prices remain accessible and stable. MOHs continue to support POC testing and expansion.

Figure 1. Theory of change for POC EID

uptake of the new technology and to inform continuous quality improvement of each phase of activities. To increase access to and use of POC EID, eight of the nine project countries established local hub-and-spoke networks. In each case, hub health care facilities used POC instruments to test infants from nearby spoke clinics using short-distance referrals or sample transport.

## The results: A game changer for early diagnosis and treatment of infants living with HIV

The four-year project demonstrated that innovative POC technologies can be integrated into national diagnostic networks. This allows for timely and rapid diagnosis and treatment among infants living with HIV compared to centralized lab-based testing. Key outcomes included:

- With the introduction of POC EID at project sites:<sup>11</sup>
  - The median turnaround time from collecting blood samples to returning test results was zero days (0-1) compared to centralized lab-based testing the median was 55 days (31–77).
  - The proportion of test results returned to caregivers within 30 days increased from 19% to 98%.
  - The proportion of infants with HIV who started ART within 60 days of sample collection increased from 43% to 92%.
- The market share of POC EID reached 35% across the nine project countries, and overall EID coverage grew by nearly 10%.<sup>12</sup>
- Clinical personnel appreciated POC EID and integrated POC testing into clinic workflows<sup>13, 14, 15</sup>
- The cost per test result returned within 30 days decreased from \$131 (\$96–\$165) under lab-based testing to \$38 (\$33–\$43) using POC EID.<sup>16</sup>
- Compared to centralized lab-based EID, POC EID improved survival by 7.4 % in the first three months of life and was cost-effective.<sup>17</sup>
- All project countries created MOH-led plans for continued POC EID testing and scale up, and secured funding to implement those plans.
- The project generated health systems savings and efficiencies of over \$9 million and saved an estimated 26,569 years of life.<sup>18</sup>

## Lessons learned and recommendations for sustaining and scaling up POC EID

Strategies to increase POC instrument utilization included creating hub-and-spoke networks, leveraging existing near point-of-care platforms for EID testing, and processing several types of tests on the same instrument (i.e., multiplexing).

- To sustain implementation and enable scale up of POC EID, the following areas need to be prioritized:
  - national-level coordination and guidance
  - diagnostic network optimization
  - strengthening information and quality assurance systems
  - building capacity in the procurement and effective use of POC EID diagnostics.

In practice, this includes:

- Supporting national technical working groups to sustain and further expand the use of POC EID within national diagnostic networks,
- Adapting EID guidelines and algorithms to reflect the use of POC EID as part of the larger EID and laboratory system,
- Developing and/or refining placement and scale-up strategies that optimize diagnostic networks to achieve a cost-effective balance between improved access to and optimal use of POC EID,
- Adapting and rolling out training, training tools, standard operating procedures, and job aids for both laboratory and clinical personnel,
- Providing site monitoring and mentorship to support the rapid uptake and appropriate use of POC EID,
- strengthening national capacity for quantification, forecasting and management of POC EID commodities,
- Integrate POC EID into national lab quality assurance systems, including introducing or expanding connectivity solutions and integrating those solutions into national information systems.

Developed and refined strategies, training packages, job aids, and tools to support introduction and scale up of POC EID are available. The materials have been integrated into the following toolkits:

- *EGPAF Program Tools: Integrating Point-of-Care Testing Technologies for Early Infant Diagnosis of HIV into National Diagnostic Networks* (<https://www.pedaids.org/resource/lessons-learned-from-integrating-point-of-care-testing-technologies-for-early-infant-diagnosis-of-hiv/>)
- *UNICEF HIV Point-of-Care Diagnostics Toolkit* (<https://www.childrenandaids.org/poc-toolkit-page>)

## Endnotes

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