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Lessons learned from integrating point-of-care testing technologies for early infant diagnosis of HIV into the national laboratory systems of nine Sub-Saharan African Countries

Introduction

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Lessons Learned Framework

Infants infected with HIV during pregnancy or childbirth are at high risk of early illness and death due to their immature immune systems. Without antiretroviral therapy (ART), up to 30% of HIV-infected children will die before their first birthday, with a peak mortality risk at just 8 to 12 weeks of age.^{i,ii,iii} For this reason, the World Health Organization (WHO) recommends that all HIV-exposed infants have a virological test for HIV within 4 to 6 weeks of birth; that caregivers receive their child's test results within 30 days; and that infants with an initial positive test result are immediately started on treatment^{iv} However, in 2015, fewer than 50% of HIV-exposed infants had a virological test by two months of age in the nine African countries with centralized laboratory-based testing where the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) collected baseline data. Among those tested, only 15% received their test results within 30 days. For those who received their results and were HIV-positive, only 62% started treatment within 60 days of blood sample collection.

Through funding and support from Unitaid, EGPAF leveraged its presence and experience in pediatric diagnosis, care, and treatment in nine African countries to integrate point-of-care early infant diagnosis of HIV (POC EID) into national laboratory systems. The countries were **Cameroon, Côte d'Ivoire, Eswatini, Kenya, Lesotho, Mozambique, Rwanda, Zambia and Zimbabwe**. Across the nine countries, the routine use of POC testing technologies aimed to achieve national targets for pediatric HIV testing, care, and treatment by reducing gaps in EID services, with the specific objectives to:



FIGURE 1: Focus countries for point-of-care EID introduction

- Increase access to EID test results for HIV-exposed infants;
- Reduce turnaround time (TAT) from blood sample collection to return of test results to caregivers;
- Increase the proportion of test results returned to caregivers;
- Improve timely initiation of ART among HIV-positive infants; and
- Reduce infant morbidity and mortality.

To achieve those objectives, EGPAF collaborated with national ministries of health in the nine focus countries to apply a phased implementation approach over a four-year period, which was both data-driven and sustainable. The phases included: preparation; early implementation; progressive site enrolment; routine testing and monitoring; and transitioning. Throughout all phases, EGPAF collected and routinely analysed data and information for use not only in communications and advocacy to promote

acceptance and uptake of the new technology, but also to inform the continuous quality improvement of each phase of POC EID activities. The initiative demonstrated that innovative POC technologies consistently deliver a larger proportion of test results, faster, allowing for the rapid diagnosis of more HIV-positive infants, and the initiation of ART at a younger age as compared to centralized lab-based testing.¹

An after action review of the approach concluded that activities within six key input areas were critical to achieving the expected outcomes. Those input areas are:

1. Leadership, governance, planning and monitoring;
2. Site and product selection, site capacity assessments and upgrades, and national approval of products;
3. Site enrolment, orientation, training and competency assessments;
4. Site monitoring, support, and post-market surveillance;
5. Quantification, procurement, supply chain and waste management; and
6. Quality Assurance, data systems and connectivity.

This series of lessons learned modules captures key knowledge under each of the above input areas that can be used by implementers, including national program managers and international health program

implementing partners, who will be supporting the introduction or scale up of POC EID. For each input area, the modules suggest good practices that worked well, and report on poor practices, activities, or approaches, that did not work well and should be avoided in the future. Finally, each module provides recommendations as well as a set of guidance documents, tools, and references that can be used to support the introduction or scale-up POC EID in a country.

Process of Developing the Modules

EGPAF followed a four-step process to develop each module. The approach drew heavily from WHO guidance for identifying and documenting best practices in family planning programs as well as the process for developing the WHO compendium of lessons from transforming health services delivery.^{v,vi}

The steps for each module included:

- Step 1: Structured interviews with key informants and document review
- Step 2: Drafting of the module
- Step 3: Review of the module by country implementation leads in all nine project countries to validate the contents
- Step 4: Incorporation of reviewer feedback and finalization, including compiling referenced resources, guidance and tools to include as an appendix to each module

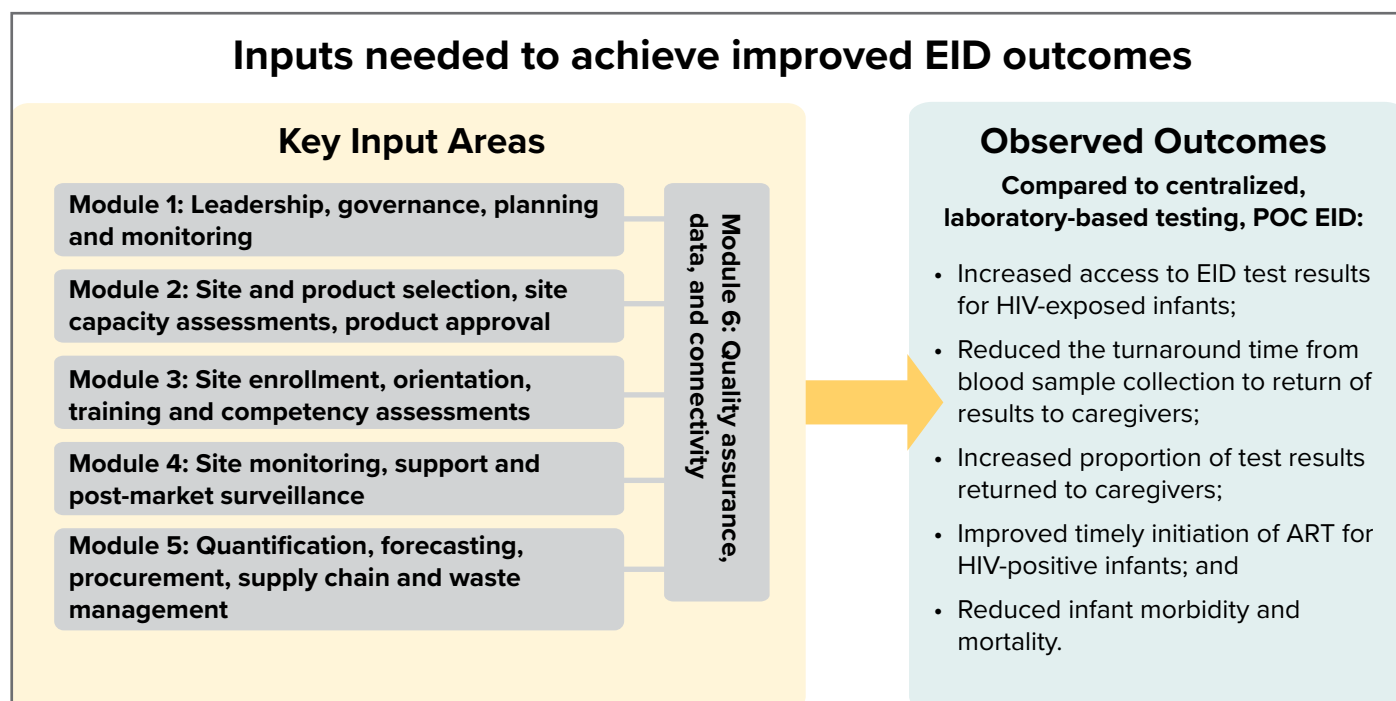


FIGURE 2: Lessons learned framework

¹ Bianchi F. et al. (April 2019) Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries. *Lancet HIV* ([https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(19\)30033-5/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(19)30033-5/fulltext))

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