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EXPANDING ACCESS TO POINT-OF-CARE EARLY INFANT DIAGNOSIS: IMPLEMENTATION APPROACHES AND TESTING STRATEGIES

Ending paediatric AIDS and achieving the Super-Fast-Track targets for paediatric HIV requires intensified efforts to rapidly identify and treat HIV-positive infants and young children. In 2017, only 51 per cent of all HIV-exposed infants were tested for HIV within the recommended first two months of life, and only 52 per cent of children living with HIV received life-saving antiretroviral therapy (ART).¹ Without access to timely diagnosis and treatment, up to 30 per cent of HIV-infected children will die by their first birthday, and 50 per cent will die by their second birthday.²

A game changer in global efforts to end paediatric AIDS, point-of-care early infant diagnosis (POC EID) is an innovative technology that allows for the rapid return of HIV test results to caregivers and timely initiation of ART and care³ for the youngest and most vulnerable children. The World Health Organization recommends that turnaround time from specimen collection to results returned to a caregiver should never exceed four weeks.⁴ While POC EID can return results on the same day and/or clinic visit, the turnaround time for test results using conventional

laboratory-based EID often exceeds 50 days.⁵ By reducing turnaround time for test results, POC EID has been shown to speed up treatment initiation and dramatically increase the number of infants on ART.⁶

Since 2015, Unitaid has committed more than US \$150 million to catalyse the introduction and integration of affordable POC EID technologies into national diagnostic programmes. In collaboration with implementing partners—the African Society for Laboratory Medicine (ASLM), Clinton Health Access Initiative (CHAI), Elizabeth Glaser Paediatric AIDS Foundation (EGPAF) and UNICEF—POC EID is being introduced and scaled up across 15 countries in Africa. The countries include Cameroon, Côte d'Ivoire, the Democratic Republic of the Congo, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Rwanda, Senegal, Uganda, the United Republic of Tanzania, Zambia and Zimbabwe. While these countries are at different stages of implementation, experience has demonstrated that POC EID can be effectively deployed using a range of approaches and service delivery models.

Strategic placement of POC EID technologies

When introducing POC EID technologies, national governments and stakeholders will need to determine which facilities may benefit most from the introduction of POC testing, which available POC device may be best for the site, and which testing strategies are most fit for purpose and country context. To increase access to timely EID testing and maximize patient impact, placement strategies for POC EID technologies should be developed within the broader context of laboratory network mapping and optimization efforts.

In most settings, a mix of placement and testing strategies will be needed to increase access to testing, expand HIV case finding, and optimize platform utilization. Two key placement strategies currently being utilized include deploying POC EID technologies at stand-alone sites; and deploying POC EID technologies through hub-and-

spoke networks (discussed further below). In addition, two testing strategies have evolved during POC EID implementation: testing samples from multiple entry points (i.e., maternal, newborn and child health clinics, nutrition units, paediatric wards, etc.) and multi-disease testing (e.g., HIV, tuberculosis (TB)) on the same platform (see Figure 1). Each placement strategy may be mixed with testing strategies to best address the local health system and epidemiologic context.

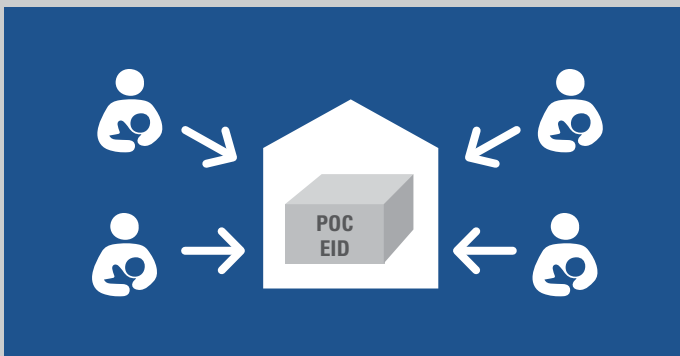
Expanding access to POC EID in both PMTCT and non-PMTCT entry points

Given that only 51 per cent of all HIV-exposed infants in 2017 were tested for HIV within the recommended first two months of life, expanding access to POC EID both through PMTCT programmes as well as non-PMTCT entry points is critical for identifying HIV-exposed and HIV-positive infants that are falling through the cracks.

Figure 1
Placement and testing strategies for POC EID technologies

STAND-ALONE SITES

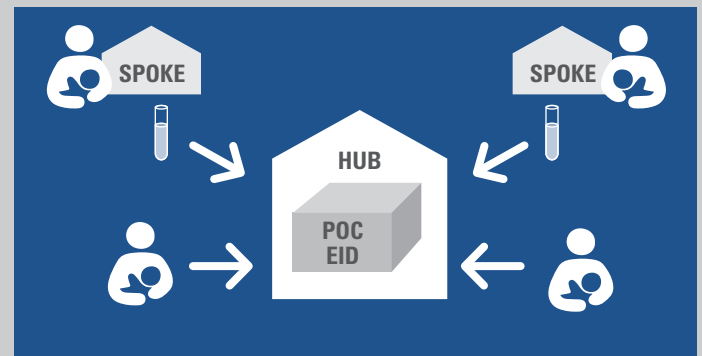
Receive samples directly from clients and perform POC EID tests on site.



In this model, caregivers bring the infant to the facility, where tests are run on site. This could include, for example, placing the device in a maternal, newborn and child health clinic to test HIV-exposed infants at their routine check-up four to six weeks after birth. This strategy is suitable for high-volume sites that provide testing to a large population of HIV-exposed infants.

HUB-AND-SPOKE NETWORKS

Hub sites provide testing for patients at that site and for spoke sites. Nearby spoke sites send samples to the hub sites for testing.



In this model, a device is placed at one facility ('the hub'), and samples are sent from multiple nearby facilities ('the spokes'). Hub-and-spoke networks are particularly suitable for sites with low prevention of mother-to-child transmission (PMTCT) registrations and EID testing volumes (less than one test per day). Importantly, short-haul hub-and-spoke EID extends the reach of POC devices to cover more HIV-exposed infants because samples can be transported and tested daily, achieving very short and predictable turnaround times (one to two days). In planning a short-haul hub-and-spoke network, it is important to carefully consider the availability or feasibility of effective sample transport and rapid result return (e.g., by using SMS printers) to ensure that the benefit of POC testing is not lost.

Although PMTCT programmes have grown to cover 80 per cent of HIV-positive pregnant women globally (1.1 million), there were still 180,000 new childhood HIV infections and an estimated 280,000 mother-infant pairs who did not receive PMTCT in 2017. Without antiretroviral treatment for pregnant and breastfeeding mothers, mother-to-child transmission rates range between 15 per cent and 45 per cent (depending on the presence and duration of breastfeeding),⁷ suggesting that a sizable proportion of new HIV infections are among infants not enrolled in PMTCT. In addition, according to 2018 estimates from the Joint United Nations Programme on HIV/AIDS (UNAIDS), an estimated 47 per cent of new paediatric infections occur postnatally during the breastfeeding period.⁸ This is likely shaped by various factors including, but not limited to, challenges with ART adherence among breastfeeding mothers in the post-partum period,⁹ as well as undiagnosed HIV acquisition among women during pregnancy and the breastfeeding period.¹⁰

Expanding access to POC EID both through PMTCT programmes and alternate entry points is thus crucial for closing the paediatric HIV testing and treatment gap, and for uncovering HIV-positive infants who might otherwise be missed through conventional EID screening. In particular, there is growing evidence that expanding access to POC EID through entry points such as inpatient paediatric wards and nutrition clinics offers important opportunities to identify missed HIV-positive infants and

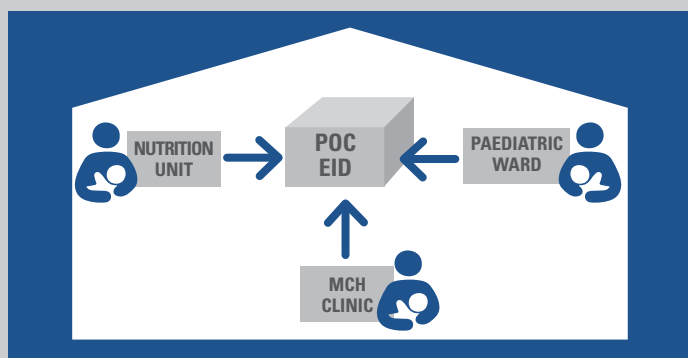
Expanding access to POC EID through both PMTCT programmes and alternate entry points is crucial for closing the paediatric HIV testing and treatment gap.

Figure 1 (continued)

Placement and testing strategies for POC EID technologies

MULTIPLE-ENTRY-POINT SITES

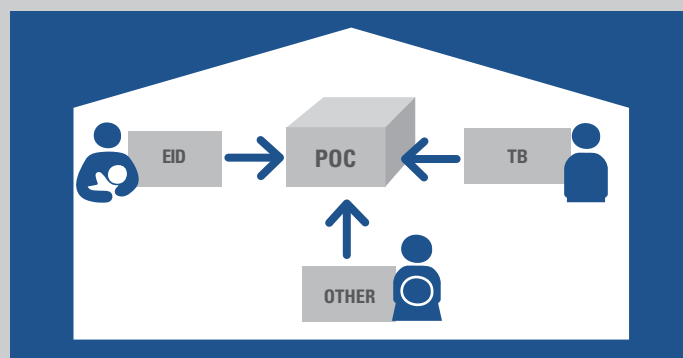
Stand-alone or hub testing sites receive samples from different units or wards within the same health facility.



In this approach, a device is used to test samples from multiple wards or clinics within the same facility. For example, a device may be placed in the laboratory at a regional or district hospital, with samples coming from different clinics and/or wards, such as maternal, newborn and child health clinics as well as paediatric wards and nutrition units.

INTEGRATED TESTING SITES

A device has the capacity to process different types of POC tests (e.g., EID, TB, other).



In this model, POC devices with multiplexing capacity can be used to run different tests, such as EID, viral load monitoring, and TB diagnosis and resistance testing. Integrated testing allows a site to increase device utilization while serving a variety of patient populations. For example, utilization rates on existing Cepheid GeneXpert devices initially installed for TB diagnosis and resistance testing are often low in many countries. TB-EID integration on such devices offers the opportunity to cost-effectively scale up POC EID. This strategy is particularly useful in contexts where the EID test burden is low and unlikely to compete with TB testing needs on these devices.

rapidly link them to treatment. A systematic review and meta-analysis which examined the diagnostic yield of HIV testing in paediatric populations in four contexts— inpatient paediatric settings, paediatric outpatient settings, nutrition centres and immunization clinics—found particularly high paediatric HIV prevalence in inpatient wards (21.1 per cent) and nutrition centres (13.1 per cent).¹¹ A recent study assessing HIV prevalence in infants receiving care at various primary health-care service facility entry points (PMTCT, immunization, inpatient, nutrition, outpatient and community outreach services) in Uganda found similar results. Across the various entry points, nutrition and inpatient testing combined identified the majority of HIV-positive infants (68 per cent).¹² Moreover, within entry points such as nutrition centres

and inpatient paediatric wards, where HIV-exposed infants are often ill and/or at the facility for a brief period, POC EID means that these infants can be quickly diagnosed and, if HIV-positive, initiated on treatment before they are discharged.

Lastly, to reduce the number of new paediatric infections, additional efforts are needed to increase the number of mothers receiving PMTCT care. Maternal re-testing and support for ART adherence during pregnancy and the postpartum breastfeeding period are also urgently needed. With increased investment, accelerated scale-up and the strategic integration of POC EID technologies into national diagnostic systems, an AIDS-free generation can be achieved.



AN AIDS-FREE
GENERATION
CAN BE ACHIEVED.

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