

The Cascade of Care for Early Infant Diagnosis in Zimbabwe

Point of Care HIV Testing at Birth and 6–8 Weeks

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Background: Routine birth testing of HIV-exposed infants (HEI) using point of care (POC) nucleic acid testing may allow for earlier diagnosis and treatment of infants living with HIV, but more data are needed on retention in care for those diagnosed at birth and re-testing for those with a negative HIV birth test.

Methods: POC birth testing (within 48 hours of birth) was offered to all HEI born at 10 public maternities in Zimbabwe from November 2018 to July 2019. Data were abstracted from routine registers, including information on re-testing at 6–8 weeks for infants testing HIV-negative at birth and 6-month retention in care among infants diagnosed with HIV at birth.

Results: Of 2854 eligible HEIs, 2806 (98.3%) received POC HIV birth testing. Thirty-nine infants with HIV were identified (1.4%), and 23 (59%) were started on antiretroviral therapy (ART). Twenty infants (51%) remained on ART at 6 months. Of the 2694 infants who tested negative at birth, 1229 (46.5%) had a documented retest at 6–8 weeks. 7 (0.6%) of those infants tested HIV-positive.

Conclusions: The uptake of POC birth testing was high in study facilities, but low rates of ART initiation after a positive birth test, despite high retention on ART through 6 months, diminish the impact of POC birth testing and must be addressed. Among infants who tested negative at birth, rates of testing at 6–8 weeks of life (46%) were slightly lower than national rates of testing at the same age without a birth test (56%) during the study period. Improving infant HIV testing rates at 6–8 weeks, regardless of birth testing, should be a priority.

Key Words: HIV birth testing, early infant diagnosis, point of care testing, HIV-exposed infants

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Over 1.3 million infants were born to women living with HIV (WLHIV) globally in 2019.¹ In Zimbabwe, over 62,000 infants were born to WLHIV, and 5200 children were diagnosed with HIV. Despite less mother-to-child transmission (MTCT), many infants

are tested too late for treatment to be maximally effective.² Infants who test positive for HIV often face delays in antiretroviral therapy (ART) initiation because of long turnaround times (TAT) for test results and loss-to-follow-up before results are returned.^{3–5} Infants living with HIV who are untreated have a high risk for mortality, up to 10% at 2 months and 30%–40% between 3 and 4 months of age.^{6,7} Early infant diagnosis (EID) of HIV and timely initiation of ART can significantly reduce mortality, limit the establishment of viral reservoirs, reduce HIV disease progression, and improve neurodevelopmental outcomes.^{8,9}

Infants with HIV exposure (HEI) typically receive their first HIV test at 6–8 weeks of life with a nucleic acid test (NAT) to capture in utero, intrapartum and early postpartum infections. Birth testing for HIV, using NAT, allows for earlier diagnosis of infants with HIV acquired in utero. World Health Organization (WHO) testing guidelines in 2021 recommended that, for countries with a high burden of HIV MTCT and robust 6-week testing programs, NAT birth testing be added to existing EID algorithms.⁵ However, long TAT associated with the transport of the sample to central laboratories for NAT-based testing, backlogs at testing facilities, challenges with result return and resulting loss-to-follow-up have made that strategy inefficient, given how few infants receive results and start immediate treatment.^{10,11} Point of care (POC) EID has proven effective in improving clinical outcomes, including increasing the proportion of infants receiving a test result, and shortening the time to ART initiation for those who are diagnosed with HIV; it has also been shown to be acceptable to health care workers, caregivers, and community members.^{11,12} With the increased availability of POC testing platforms, routine birth testing of HEI is not only more feasible but has the potential for significant impact.

In Zimbabwe, 90% of pregnant WLHIV are on lifelong ART, but only 55.7% of HEI received HIV testing within 2 months of life in 2018.¹ In 2017, Zimbabwe adopted a modified version of the WHO 2016 guidelines, offering birth testing for HEI who were designated “high risk” by any of the following criteria: (1) mother’s diagnosis with HIV in labor and delivery, (2) mother’s initiation on ART after 32 weeks gestation, (3) mother’s viral load above 1000 copies/ml, (4) mother’s seroconversion during pregnancy or (5) mother’s nonadherence to ART. However, in a study of WLHIV delivering their infants in Harare, it was found that providers lacked sufficient clinical information to risk-stratify mothers; consequently, only 2% of HEI received HIV testing at birth.¹³ An implementation study, conducted in 2018 to assess the feasibility and acceptability of POC birth testing in public health settings in Zimbabwe, offered birth testing to HEI universally to compare it with the risk-based approach and showed that risk-based birth testing identified only 3 in every 5 infants infected with HIV at birth.¹⁴ That same study found that the mother being diagnosed in labor and delivery, the mother starting ART after 32 weeks of gestation and the mother seroconverting during pregnancy were significantly associated with the infant testing positive for HIV infection at birth.

This analysis uses an expanded dataset from the same implementation study to describe the uptake, testing, follow-up EID testing and treatment cascade of HEI eligible for universal

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HIV birth testing using POC NAT in maternity settings in Zimbabwe.

METHODS

Setting and Study Design

This is an observational, noncomparative single-arm study of POC NAT testing at birth implemented in 10 public hospitals in Zimbabwe. Sites were purposively chosen from 51 health facilities implementing POC EID (for infants 6–8 weeks of age) in Zimbabwe. Study sites were chosen based on the high volume of deliveries by WLHIV and the accessibility of the POC platform to the maternity ward. Of the 10 facilities, 5 were district hospitals, and the others were provincial or general hospitals. The 10 facilities were spread across 9 of the 10 provinces in Zimbabwe.

Study Procedures

All HEI were offered HIV testing at birth using POC NAT, with testing at birth defined as an HIV POC NAT administered within the first 48 hours of life. Mothers who accepted birth testing for their infants were categorized into high or average HIV transmission risk using the national risk assessment tool and offered the test regardless of risk assessment. Health care workers used lancets for heel prick; the capillary blood sample was processed on the m-PIMA HIV 1/2 Detect Abbott POC EID platform or the Cepheid GeneXpert HIV-1 qual POC EID platform, in accordance with manufacturer-provided standard protocols. Test results were documented and returned to the caregiver. If an error or invalid test result occurred, the infant's caregiver was approached for repeat sample collection. Caregivers of infants who tested HIV-negative were counseled to return for testing at 6–8 weeks, as per standard EID recommendations. For infants with a positive POC HIV NAT, a confirmatory sample was collected for POC NAT, and the patient was enrolled in HIV care in accordance with national guidelines. If the confirmatory test was negative, a dried blood spot was run at a central laboratory on a conventional EID platform. Infants with at least one positive NAT were initiated on antiretroviral therapy per Zimbabwe guidelines.

Data Collection

Prospective data were collected on all infants who received POC birth tests and their mothers from November 1, 2018 to July 31, 2019 via Ministry of Health-approved POC EID testing forms. To track infant return for subsequent testing for those testing negative at birth, the study team maintained a list of these infants and the name and location of the clinic where each caregiver planned to bring the infant for follow-up testing. At 12 weeks after birth, the study team reviewed the Opportunistic Infection/ART (OI/ART) patient registers and infant diagnosis clinic registers for the 10 study sites and any additional site identified by the caregiver in the HEI register to determine if a 6–8 week follow-up test was performed. Information on HIV enrollment and treatment for infants with positive HIV NATs was abstracted from the OI/ART booklet.

Statistical Analysis

All data were entered into Microsoft Excel. Calculations were carried out with STATA version 15.0. Data analyzed included the number of infants eligible for birth testing, percentage of infants tested, percent of test results reaching the caregiver on the same day, HIV positivity yield, percentage of infected infants initiated on treatment and proportion who returned for 6–8-week testing.

Ethical Considerations

Written informed consent was obtained from all mothers of HEI for birth testing and data collection. Less than 2% of women invited to participate declined. If consent was declined, birth testing for infants was still offered according to national guidelines. The study protocol was reviewed and approved by the Research Council of Zimbabwe, the Medical Research Council of Zimbabwe (A/2343) and Advarra IRB based in the United States. This study is registered in ClinicalTrials.gov (NCT04206241).

RESULTS

Testing Uptake, Results and Turnaround Time

Of the 2854 infants born to WLHIV during the study period, 98.3% (n = 2806) received a POC HIV birth NAT (Fig. 1). Among the 2806 infants tested, 96% had a negative HIV NAT (n = 2694), 1.4% had a positive (n = 39) test and 2.6% (n = 73) had a test result with an internal quality control (IQC) failure that required further testing and were excluded from analysis. One infant with 2 test results from birth, 1 positive and 1 negative, was censored from the data set and not included in subsequent analysis. These numbers differ from earlier data reported from the same implementation program at 10 sites in Zimbabwe due to 3 cases that were excluded in this study due to the high likelihood of being duplicates.¹⁴

Of the 2806 infants tested, 91% (n = 2605) of their results were received by caregivers, with 93% (n = 2423) of the received results reaching the caregiver on the same day as testing. However, 86.4% of all completed testing were received by the caregiver on the same day.

ART Initiation and Retention in Care Among Infants Testing Positive at Birth

In total, 39 infants with HIV were identified, of whom 59% (23/39) were known to have started on ART. Six infants were documented as not starting treatment because of low birth weight, with plans to initiate ART once the infant weighed more than 3 kg. ART initiation data for 10 of the infants who tested positive at birth were unavailable (Fig. 1), as were data about these infants at 6 weeks. Univariate analysis revealed no differences in available infant (birth weight) or maternal characteristics (risk screening status) between those infants initiated on ART (23/39) and those lacking documentation of ART initiation (10/39). Information regarding TAT for each caregiver-infant pair was not available, though receipt of all HIV-positive results by caregivers (39/39) was documented.

One infant who had been initiated on ART died during the study period. Of the 22 infants initiated on ART who survived, 20 were still on treatment at 6 months of age (Fig. 2). Data regarding viral suppression of infants at 6 months were beyond the scope of this study.

Re-testing at Age Six to Eight Weeks of Infants Testing Negative at Birth

Of infants who tested negative at birth, 45.6% (1229/2694) returned for a repeat test at age 6–8 weeks. At that time, 0.6% of the infants (7/1229) had a positive HIV NAT, 97.5% (1198/1229) tested negative and 2% (24/1229) had missing results. Information regarding ART initiation of the infants who tested positive at age 6–8 weeks was unavailable.

DISCUSSION

This observational study of POC EID for birth testing in routine settings in Zimbabwe demonstrates 3 primary findings: a high rate of uptake of POC birth testing among eligible HEI,

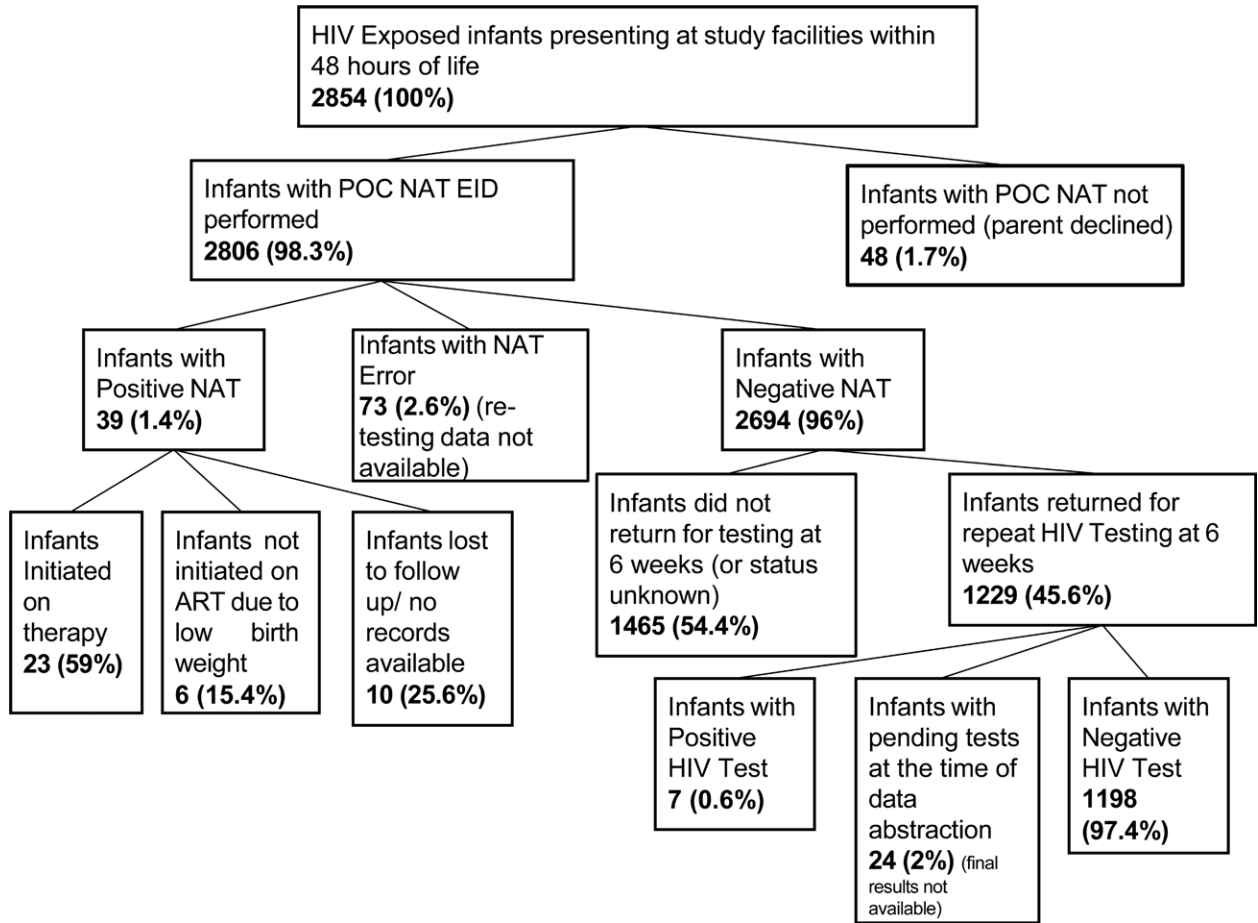


FIGURE 1. Study enrollment.

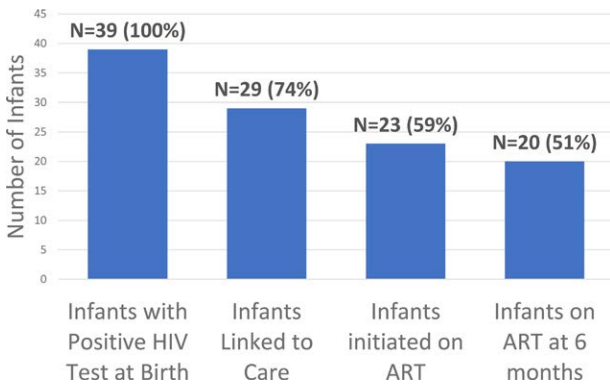


FIGURE 2. Zimbabwe EID cascade of care birth testing.

inadequate initiation of ART among infants testing positive at birth, and high continuation of treatment for those initiating treatment at birth.

Receipt of results was also rapid, with 93% of results available to the infant caregiver on the same day. The low rate of IQC failures shows that operators were able to successfully utilize the POC EID platform. The high rate of uptake and low IQC failures suggest that HIV testing at birth using a POC platform is a feasible practice in decentralized maternities in Zimbabwe. Similarly high rates of uptake and low IQC failures have been reported in the other EID birth testing

settings.¹⁵⁻¹⁸ Our findings are consistent with other studies of POC birth testing, both in terms of acceptability and feasibility.¹⁷ An implementation study in South Africa, instituting POC testing for both maternal viral loads and EID, highlighted the need for increased personnel and resources to scale up coverage and ensure result return.¹⁹ In South Africa, mothers and health care workers vastly preferred POC birth testing to conventional birth testing.²⁰ Feasibility studies in Eswatini and Kenya using POC birth testing demonstrated high levels of test uptake (76% and 68% of eligible infants, respectively), fast turnaround times and near-universal receipt of results by caregivers (100% and 98%, respectively).^{15,21,22}

Initiation of ART for infants who tested positive at birth documented in this study was inadequate (59%). Incomplete data may have led to an underestimation of the proportion of infants initiated on ART. Nonetheless, additional resources beyond initial diagnostic testing are needed to ensure that birth testing leads to improved infant health outcomes. In pilot studies in South Africa, 100% of infants who tested positive for HIV at birth with POC testing initiated ART, but investigators from both studies highlighted the increased resources necessary to link infants to care.^{21,23} These were single-center studies, whereas our data are from the implementation of routine birth testing across 10 facilities, which may have impacted both accurate record-keeping for infant follow-up and the ability to focus resources on initiating ART for every infant who tested HIV-positive at birth.

Among infants with HIV diagnosed at birth who were initiated on ART, retention in care was high, comparable to retention in

care for other children living with HIV, and higher than retention in care of infants identified as having HIV at birth using conventional testing.^{3,15,19,20,24} In a 2022 randomized control trial comparing POC and central lab-based EID among HEI in Zambia, though not at birth, POC testing reduced delays in diagnosis and ART initiation, but both groups experienced high levels of care interruptions, virologic failures, and mortality at 12 months.²⁵

Recent model-based cost-effectiveness studies show investing in POC technology will be more cost-efficient for EID efforts than scaling up preexisting laboratory-based testing methods.²⁶ POC EID is most cost-effective in settings with low rates of formal prevention of mother to child transmission coverage, long TAT for central laboratory testing, and where POC platforms can be used in multiple clinical contexts.²⁷ Frank et al²⁸ modeled POC testing in Zimbabwe specifically and noted that transitioning to POC testing, rather than central laboratory testing, would be cost-effective and improve outcomes for infants living with HIV. None of these studies addressed the use of POC for birth testing specifically; further work is needed in this area.

This study also investigated retention in care for infants testing HIV-negative at birth. Of these, at least 46% had a subsequent test within the recommended timeframe. This proportion is likely an underestimate, as we were unable to track HEI who received an HIV test outside of the 10 study facilities or the facilities where caregivers stated they would return for follow-up. National data for Zimbabwe in 2019 suggest that the proportion of 6–8-week HIV testing is 56% for all HIV-exposed infants.²⁹ Outreach to mother-child pairs who were lost to follow-up resulted in higher rates of subsequent testing in studies in South Africa and Zimbabwe.^{30,31}

South Africa modified its testing guidelines in 2015 to include routine birth NAT (but not necessarily POC testing) for HEI and delayed postnatal testing from age 6 to 10 weeks. Early implementation studies showed high uptake of testing at birth but difficulty linking infants with positive results to care using current staffing models and lower than expected rates of re-testing at age 10 weeks.^{20,30,32,33} Dunning et al³⁴ reported infants who received birth testing were 40% less likely to return for testing at 6–10 weeks. However, South Africa has high rates of testing at 6–10 weeks at baseline—over 80% of HEIs receive postnatal testing. A modeling study comparing various testing algorithms showed that testing at birth and 6 weeks maximized life expectancy for HEI, but only if more than 60% of infants who tested negative at birth were retained in care through follow-up testing.³⁵

The lower rate of return for 10-week testing in South Africa contrasts with other sites piloting routine birth testing of HEI. A recent feasibility study of routine POC birth testing for HEI in Eswatini showed comparable rates of 6–8-week testing after implementation of routine birth testing—91% of exposed infants were tested pre-intervention, compared with 96% post-intervention.²¹ Notably, that study used national testing data, which likely provided a more accurate account of re-testing among those tested at birth. A pilot study of routine birth testing at 4 hospitals in Kenya showed that infants with negative birth tests were more likely to present for repeat testing at age 6–8 weeks than those not tested at birth; accompanying qualitative data suggested that caregivers found the negative result at birth to be motivating for continued engagement in care.^{36,37} Meggi et al³⁸ studied the addition of POC birth testing to Mozambique's guidelines of testing HEI at 4–6 weeks and noted a 16% increase in the number of infants with HIV identified, suggesting that the addition of birth testing may capture infants who might otherwise go untested.

Further study is needed to determine if there are identifiable factors to identify infants at risk for not completing testing at 6–8 weeks, which in turn would allow for targeted outreach or prioritized 6–8 week testing for those at highest risk of transmission. Maternal

factors such as age, HIV disclosure status, disease status as well as infant factors including birth weight or sex, should be explored as possible predictors; these data were not analyzed in our study. Robust randomized trials comparing the addition of POC birth testing among HEI in addition to POC testing at 6–10 weeks versus POC testing at 6–10 weeks alone, examining time to ART initiation, retention in care, and morbidity and mortality of HEI are needed.

Strengths and Limitations

This study relied on routine program and national laboratory system data for information about mothers and HEI. Missing data and recording errors are common in routinely collected data. Information about infants with HIV infection was often incomplete in registers. For infants lost to follow-up, our study did not systematically assess the reasons why infants were not retained in care at study sites or if those infants received care at sites other than study sites or those identified by mothers at discharge after delivery. The lack of a comparator arm is another limitation in this study, as it is not possible to directly compare the benefits of POC birth testing over the current standard of care.

The selection of 10 maternities may have introduced bias into the study, given possible important differences in hospital maternities interested in implementing POC birth testing and choosing to work with Elizabeth Glaser Pediatrics AIDS Foundation compared with other facilities. However, the feasibility and high rates of uptake of birth testing are similar to other sites where POC EID testing has been studied, and the 10 included sites represent a range of hospital types and geographic settings, which suggests this finding may be generalizable beyond these maternities.

The small number of infants testing positive at 6–8 weeks made it difficult to assess maternal risk factors leading to the conversion from a negative test at birth to a positive test at 6–8 weeks. This is an area that requires further study, as it may lead to more targeted outreach at 6–8 weeks for infants at high risk.

Zimbabwe made significant improvements in EID, with over 95% of HEI now reported as receiving an HIV test within the first 2 months of life in 2021.¹ Follow-up data regarding ART initiation and retention in care in the setting of improved EID are not yet available. Improvements in EID may have increased the relevance of routine birth testing in Zimbabwe, as WHO recommends the addition of birth testing only in the setting of robust EID.⁵

CONCLUSION

This study shows that POC birth testing of HEI is feasible in public maternities in Zimbabwe, with a high uptake of universal birth testing (>98%), and is likely feasible in other countries with high HIV prevalence. However, receiving an earlier diagnosis does not guarantee initiation of treatment, and outreach and retention in care for infants diagnosed at birth must be strengthened if POC birth testing is to improve outcomes for HEI. Early diagnosis and initiation of ART in infants with HIV are essential; universal POC birth testing for HEI should be further explored as a strategy to engage vulnerable infants in care as early as possible.

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