

Implementing Point-of-Care CD4 Testing for HIV-Positive Women and Their Families in Maternal and Child Health Settings: Early Lessons



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About the Elizabeth Glaser Pediatric AIDS Foundation Zimbabwe Program

Since 2001, EGPAF has been working to provide and support comprehensive PMTCT services in pursuit of the Zimbabwe Ministry of Health and Child Welfare’s goal to “**promote delivery of comprehensive, high-quality PMTCT services that are integrated and linked to treatment, care, and support.**” This support has been funded primarily by the U.S. President’s Emergency Plan for AIDS Relief through the U.S. Agency for International Development and by the UK Department for International Development. In 2010, EGPAF was awarded a five-year grant by The Children’s Investment Fund Foundation, which significantly boosted EGPAF’s capacity in 2011 to rapidly scale up and expand the provision of high-quality comprehensive PMTCT services in line with the World Health Organization 2010 PMTCT guidelines, including the deployment of point-of-care CD4 analyzers at maternal and child health facilities as described in this document.





BACKGROUND

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) Zimbabwe country program has been supporting the Ministry of Health and Child Welfare (MOHCW) to implement and strengthen its national prevention of mother-to-child HIV transmission (PMTCT) program since 2001. With national adoption of the 2010 World Health Organization (WHO) PMTCT guidelines (Option A) in 2010, the program began to look for ways to effectively increase antiretroviral therapy (ART) initiation in family and child health (FCH) clinics,* where health care workers often consist of nurses and/or midwives with varying levels of education and training. Increasing ART initiation among pregnant and postnatal women who are eligible for treatment is seen by the MOHCW and its implementing partners as an essential component of Zimbabwe's national PMTCT strategy, the goal of which is to reduce the rate of mother-to-child HIV transmission nationally to less than 5% by 2015.

Traditionally, women testing HIV-positive in FCH settings in Zimbabwe are referred to the opportunistic infections / ART clinic, where they are scheduled for CD4 testing. It can take two to three weeks or more to be tested, and it takes more time for results to be returned from the laboratory. As a result, many treatment-eligible women are never initiated on ART or are initiated late because they either did not return for CD4 testing or never received their test results. These challenges are even more pronounced in rural areas where women must travel long distances to a health facility.¹ Another barrier to ART initiation in FCH settings is the lack of an explicit national policy in Zimbabwe allowing nurses to initiate ART. While some provinces have made this a priority, nurses in settings where this practice has not been actively supported often do not feel comfortable proceeding without formal guidance.

With the support of public and private donor funding aimed at helping Zimbabwe achieve its national goal of virtual elimination of new HIV infections in children by 2015 and keeping mothers alive, EGPAF provided a total of 50 point-of-care (POC) CD4 analyzers to the MOHCW in April 2011. The machines were deployed to 50 high-volume FCH facilities with the specific aim of increasing HIV-positive pregnant and postnatal women's access to CD4 testing so that they could be more easily assessed for ART eligibility. A second deployment of 104 analyzers occurred in May–June 2012, and deployment of additional analyzers will be considered based on the results of these initial experiences. This program brief describes some of the early lessons emerging from the implementation of POC CD4 testing at select EGPAF-supported health facilities.

¹In Zimbabwe, maternal and child health clinics are referred to as family and child health clinics.

POC CD4 TESTING AND PMTCT

Determining the CD4 T-lymphocyte count of people living with HIV is critical for accurately determining their eligibility for long-term ART. Timely initiation of ART is especially crucial for HIV-positive pregnant and breastfeeding women, who run a higher risk of transmitting HIV to their infants when their CD4 counts are reduced.² Current WHO PMTCT guidelines recommend that all HIV-positive pregnant and lactating women with CD4 counts of less than 350 cells/mm³, regardless of clinical staging, be initiated on ART to protect their own health and reduce the risk of mother-to-child transmission of HIV.³ Yet while an estimated 38% of all pregnant women living with HIV in low- and middle-income countries in 2010 were eligible to receive ART (based on modeled estimates), only 34% of eligible women received it.⁴

Evaluation of ART eligibility can prove extremely challenging in resource-limited settings, where access to laboratory-based CD4 analysis is limited and overburdened laboratory technicians can take weeks to months to work through a backlog of samples streaming in from several facilities. Recently, POC diagnostic technology has begun to expand access to CD4 testing, even in settings with frequent power outages and no trained laboratory technicians. Field testing of POC CD4 analyzers operated by nurses in primary health facilities has yielded promising results, with accuracy comparable to that of laboratory-based diagnostics.⁵ Introduction of POC CD4 testing at antenatal care (ANC) sites, even in the most remote settings, now makes it possible to determine a pregnant woman's eligibility for ART on the same day that she receives an HIV test so that she can be counseled on long-term treatment adherence on the same day and initiated on ART soon after, protecting her health and the health of her infant.

THE PIMA CD4 ANALYZER

The Pima POC CD4 analyzer (Alere Technologies; Jena, Germany) is a portable device weighing roughly 2.5 kg that comes with a canvas carrying case for mobile operation. The test system consists of a disposable test cartridge containing dried reagents (which can be stored at room temperature) and the Pima analyzer (see Figure 1). A low sample volume of approximately 25 μ L capillary or venous whole blood is collected in the test cartridge, which is then capped and inserted into the analyzer (see Figure 2). During the course of processing the test, data are recorded, analyzed, and interpreted using software embedded within the machine. On completion of the test, the cartridge is removed and a test result is displayed.⁶ It takes approximately 20 minutes to test a single sample.

The analyzer's simplicity of use allows nonlaboratory staff to operate the machine after completion of a one-day training course. A 2010 study demonstrated that the Pima analyzer performed acceptably compared to the laboratory-based Becton Dickinson FACSCalibur platform (BD Biosciences; San Jose, California) in Zimbabwe health facilities.⁵ In addition, the machine can be battery operated, with an approximate eight-hour battery life when fully charged, which makes it ideal for use in settings with inconsistent power supplies or for outreach (i.e., community-based) testing.



Figure 1. Pima CD4 analyzer



Figure 2. Cartridge being inserted into the analyzer

EARLY RESULTS OF POC CD4 ANALYZER DEPLOYMENT

ART Eligibility Screening and Initiation

The MOHCW, in cooperation with EGPAF, deployed Pima POC CD4 analyzers to 50 health facilities seeing a high volume of PMTCT clients in June 2011 following health worker training on use of the machines and related data-collection tools (e.g., POC register, test summary sheets).^{*} Early results have been promising. An increase of more than 100% was observed in the total number of HIV-positive pregnant women screened for ART eligibility in ANC settings nationally (through both POC and laboratory-based testing) following deployment of the POC analyzers, from 4,485 during the April to June 2011 quarter to 9,107 during the July to September 2011 quarter. As of March 2012, POC CD4 testing already accounted for 20% of all CD4 tests provided to pregnant women at 1,354 EGPAF-supported sites nationally. These statistics demonstrate the promising potential of POC testing to dramatically increase CD4 testing uptake in ANC settings as it is further rolled out across the country.

STUDY SHOWS POINT-OF-CARE CD4 TESTING LEADS TO INCREASED ANTIRETROVIRAL THERAPY INITIATION IN ELIGIBLE PREGNANT WOMEN⁷

To assess the early impact of POC CD4 analyzer deployment on ART eligibility screening and treatment initiation among HIV-positive pregnant women, the Elizabeth Glaser Pediatric AIDS Foundation performed a quasi-experimental before-and-after study looking at quarterly summaries of CD4 register data collected at antenatal care sites before (October 2010–June 2011) and after (July 2011–March 2012) POC analyzer deployment at 43 of the 50 initial deployment sites.

Before the introduction of the POC analyzers, 617 (51%) of 1,210 HIV-positive pregnant women received CD4 testing at the 43 sites, compared to 890 (81%) of 1,100 pregnant women after deployment of the analyzers. There was a significant difference between the proportion of women receiving CD4 testing before and after the introduction of the POC analyzers ($P=0.023$) and between the proportion of pregnant women initiated on ART (9% before versus 25% after [$P=0.001$]) (see Figure 3).

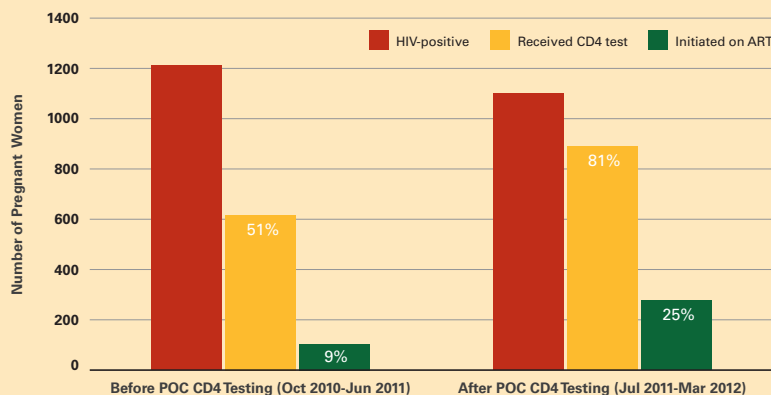
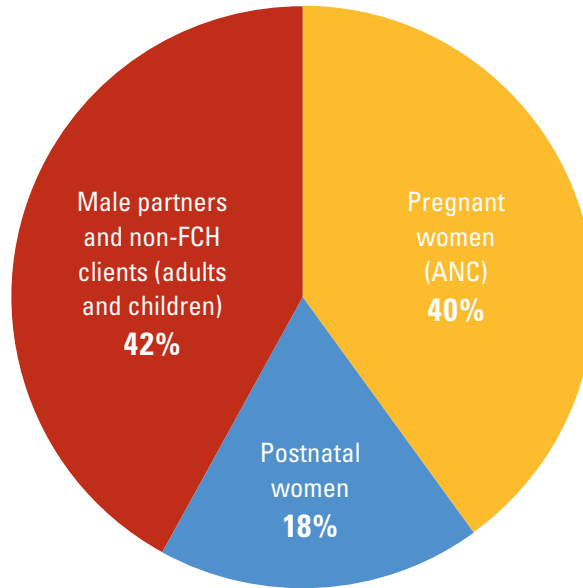


Figure 3. CD4 testing and ART initiation among HIV-positive pregnant women before and after POC CD4 analyzer deployment at 43 sites

⁷Pima point-of-care CD4 analyzers were evaluated and endorsed for use by the Zimbabwe National Reference Laboratory in 2009.

Figure 4. Delivery of point-of-care CD4 testing by client type (n=9,771) at 49 sites (July 2011–March 2012)



ANC=antenatal care; FCH=family and child health

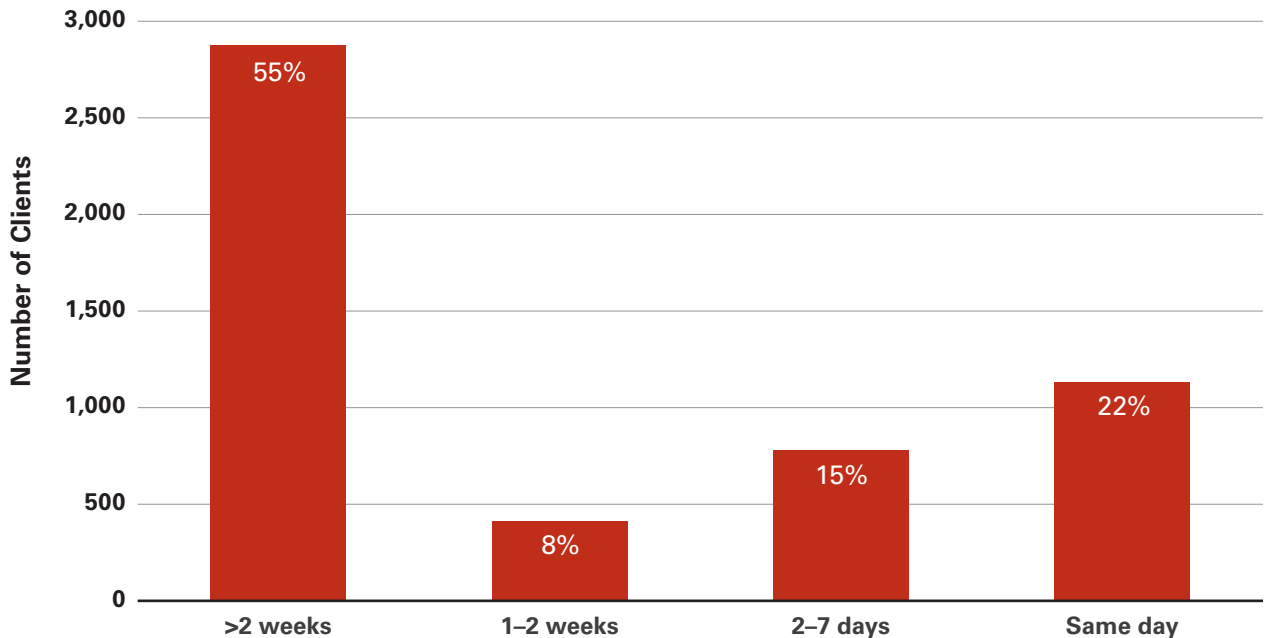
Delivery of CD4 testing at the initial 50 FCH facilities receiving EGPAF-supported POC CD4 analyzers has been continually monitored by the MOHCW and EGPAF since the June 2011 deployment. Between July 2011 and March 2012, a total of 6,117 FCH clients at 49 sites^{*} received POC CD4 testing. This included 3,943 HIV-positive pregnant women tested in ANC, as well as 1,747 postnatal women and 427 male partners of FCH clients.[†] An additional 1,853 non-FCH clients attending ART clinics at the same facilities received POC testing during this time period, highlighting the important secondary use of the analyzers as backup testing mechanisms for clients from other departments in cases where there is a backlog or breakdown of a laboratory-based CD4 test system, or at sites where such systems are not in place (see Figure 4 for a breakdown of clients receiving POC testing by type).

“Pregnant and postnatal women no longer have to visit the ART clinic for CD4 testing. CD4 testing and delivery of results can now occur the same day as rapid [HIV] testing, right here in the FCH clinic.”
— Nurse at Guruve District Hospital

^{*} Data not available from one site due to the absence of an EGPAF-supported PMTCT focal person.

[†] Data on male partner testing not collected during the July–September 2011 reporting period.

Figure 5. Interval between provision of initial HIV test and point-of-care CD4 test among both FCH and non-FCH clients (n=5,194) at 49 sites (October 2011–March 2012)

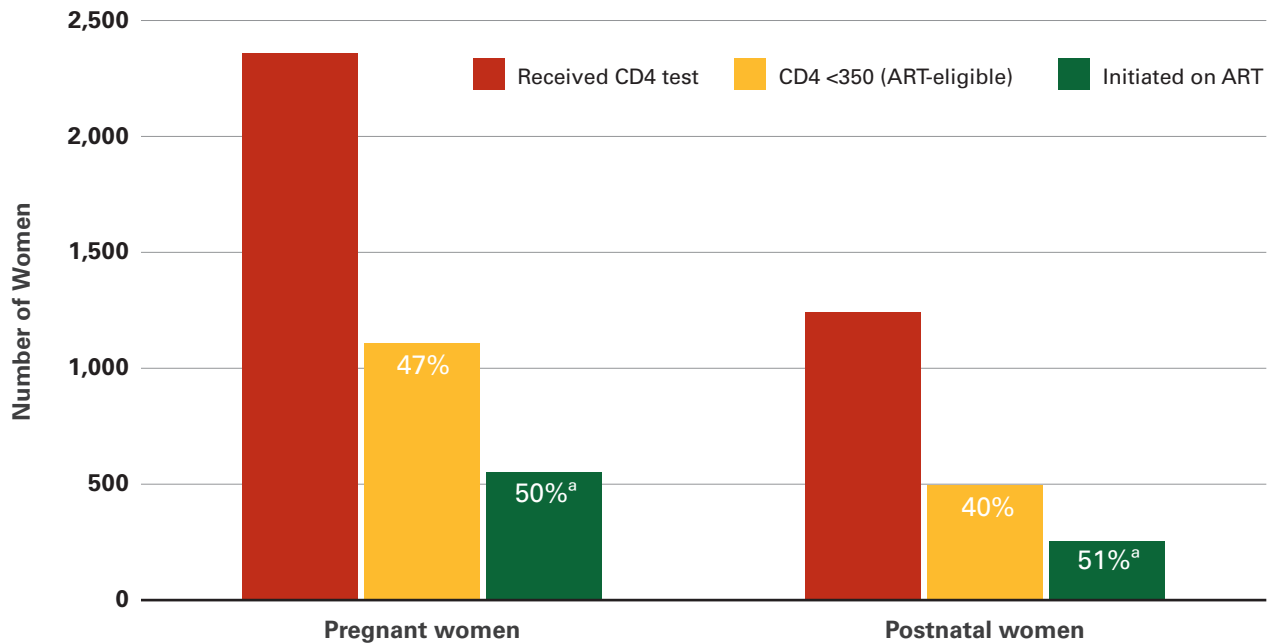


Note: Figures were calculated from a subset of all point-of-care CD4 tests conducted (5,194/6,395) for which timing data were available.

While CD4 testing ideally occurs on the same day as a client’s initial HIV test, early results from POC CD4 deployment sites show that this is often not the case. Between October 2011 and March 2012,⁷ slightly more than half (55%) of POC CD4 tests performed on both FCH and non-FCH clients were conducted more than two weeks after the client’s initial HIV test; just 22% of CD4 tests were performed on the same day as HIV testing (see Figure 5). While the reasons for delayed CD4 testing have not been formally assessed, these findings underline the importance of systematically identifying and addressing all potential barriers to delivering same-day HIV and CD4 testing.

⁷ Data on timing of CD4 testing not collected during the July–September 2011 reporting period.

Figure 6. CD4 testing and ART initiation among HIV-positive pregnant and postnatal women (n=6,006) at 49 sites (October 2011–March 2012)



^a Proportion of eligible women initiated on ART.

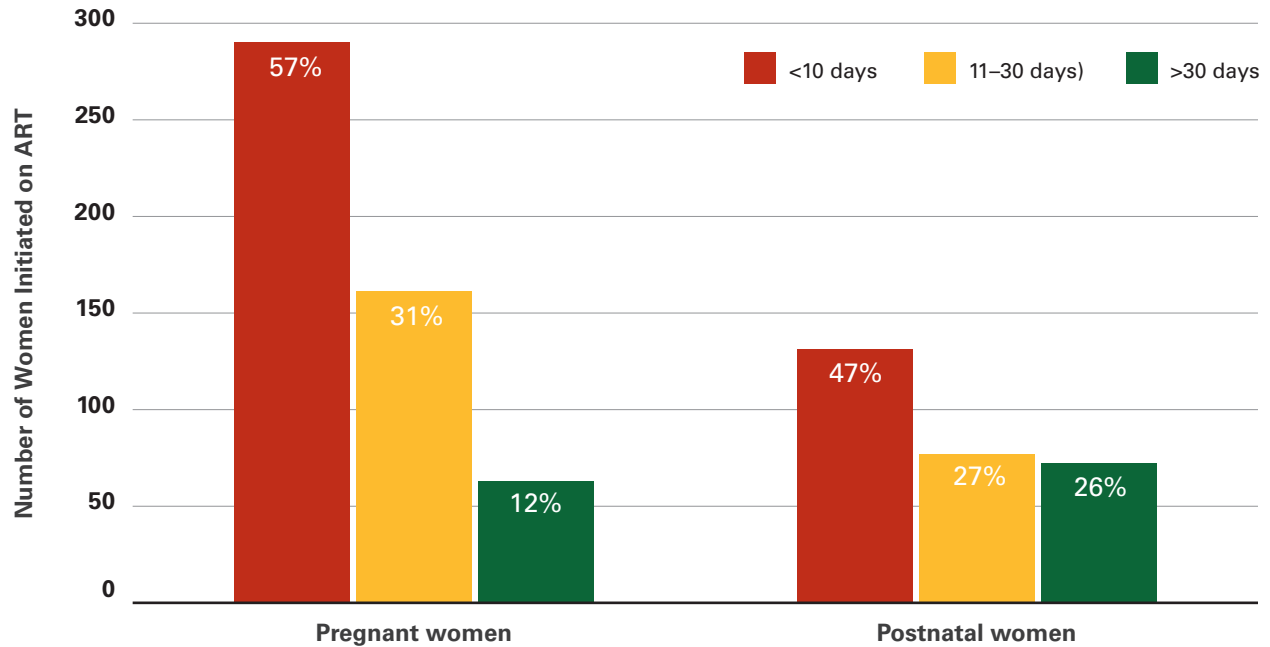
Between October 2011 and March 2012,* 47% of 2,358 HIV-positive pregnant women receiving POC testing in ANC were found to be eligible for ART; of those eligible, 50% were initiated on ART. Among the 1,239 postnatal women receiving POC testing during the same period, 40% were found to be eligible and 51% of those eligible were initiated on ART (see Figure 6). While these figures are encouraging compared to an observed baseline rate of treatment initiation among pregnant women of 9% at a subset of deployment sites prior to POC CD4 introduction (see related sidebar on page 5), they also demonstrate that determining a woman’s treatment eligibility does not guarantee she will be initiated on ART.

Early data also show that work is needed to ensure timely ART initiation for all eligible women. Of the 514 pregnant women initiated on ART in ANC between October 2011 and March 2012,† just more than half (57%) were initiated less than 10 days after receipt of a CD4 test; this figure was 47% among postnatal women (see Figure 7). To date, nurse-led ART initiation has been introduced at select sites in the country to support roll-out of ART initiation in FCH settings, but it is not yet a widespread practice. Further roll-out of this and other interventions designed to address barriers to ART initiation among pregnant and postnatal women will be critical to providing all eligible women with timely access to treatment as POC CD4 testing is introduced at additional facilities.

* Data on ART eligibility by client type not available for the July–September 2011 reporting period.

† Data on timing of ART initiation not available for the July–September 2011 reporting period.

Figure 7. Time interval between point-of-care CD4 testing and antiretroviral therapy initiation among treatment-eligible pregnant and postnatal women (n=794) at 49 sites (October 2011–March 2012)



Note: Data on timing of ART initiation were available for a subset of all women initiated on ART during this time period (794/805).

POC CD4 Analyzer Operation

The deployment of POC CD4 count machines has not been without challenges. Service interruption has been noted at some sites, mainly due to machine breakdowns and rotation of staff trained on POC CD4 testing to other sites. As noted previously, the demand for POC CD4 tests goes beyond women attending FCH clinics to include their children and male partners, as well as other HIV-positive adults and children receiving HIV care at the same facilities. Use of POC CD4 machines for these other populations has in some cases resulted in underestimation of needed CD4 testing commodities. EGPAF, as a member of the POC subcommittee of the Zimbabwe PMTCT Partnership Forum, has continued to advocate for donors and other partners to support the procurement of additional Pima cartridges and related supplies to meet the needs of these additional clients.

During the distribution of POC CD4 count machines, it was noted that some rural health centers use solar power and hence require inverters and adaptors to charge the POC CD4 analyzer batteries when not in use. EGPAF is now in the process of procuring inverters for this purpose. In one district, a health facility successfully collected funds from community members for the purchase of a solar panel to charge the EGPAF-provided CD4 analyzer, representing an encouraging sign of community-level support for CD4 testing.

EARLY EXPERIENCES FROM MASHONALAND CENTRAL PROVINCE

In order to gain a deeper understanding of early lessons emerging from the use of POC CD4 analyzers, EGPAF staff conducted an informal survey of four facilities (two district hospitals and two rural health centers) in February 2012 in Mashonaland Central Province. All four sites had received the Pima analyzers from EGPAF in July 2011 as part of the first round of deployment (a second deployment of 104 analyzers occurred in May–June 2012). This section outlines the key findings from these site visits. It should be noted that the findings cited here are in no way representative of all sites receiving POC CD4 analyzers but are presented with the aim of providing a snapshot of experiences at a few sites to highlight issues arising from the introduction of POC CD4 testing.

Machine Operation

Staff at all four sites remarked on the analyzer's ease of use, with no major difficulties reported in the running of tests or quality control measures. Instances of machine errors were limited, and when reported were due to expiring cartridges, operator error (e.g., not removing cartridges promptly), or machine defects (errors ceased after machine repairs). All operators surveyed were nurses or nurse-midwives who had received a one-day EGPAF-supported formal training provided by the Pima analyzer vendor, Medsure.

Access to CD4 Testing

Analyzers at all sites surveyed were located in the FCH clinics. Patient flow was similar at each clinic, with pregnant women sent for CD4 testing immediately after receipt of a positive HIV rapid test. Despite the availability of POC CD4 analyzers, however, most sites reported challenges in ensuring that all women received CD4 testing on the same day as their HIV-positive diagnoses. In some cases, women testing HIV-positive were reported to have left the clinics immediately after their post-test counseling sessions, despite instructions given by the counselors to wait for a CD4 test. All sites surveyed reported also using the machines for male partners, as well as postnatal women for up to two years, both for initial treatment eligibility assessment and treatment monitoring.

ART Initiation in FCH Settings

All sites reported offering ART initiation in the FCH clinics, with this process greatly facilitated by the presence of POC analyzers. If a newly diagnosed pregnant woman is found to be eligible for ART, she is given antiretroviral prophylaxis on the same day and is instructed to return to the facility for ART adherence counseling. Delivery of adherence counseling varied by facility but generally consisted of two to three individual counseling sessions given over one to two weeks. On completion of the required sessions, a woman can be initiated on ART. This was reported to be an improvement over previous practices, wherein women were referred to the ART clinic, making it difficult for FCH clinic staff to determine whether women they had referred had actually been initiated on ART since client type was not recorded in the ART clinic register.

Documentation of CD4 Testing

All sites maintained records on those receiving CD4 testing, with some sites using an improvised POC register while others used the EGPAF-provided POC log sheet. At all sites, data from the POC register or log sheet, including client type and CD4 count, were summarized at the end of each month and entered into the MOHCW PMTCT monthly return form, which was then sent on to the MOHCW Health Information Office for entry into the MOHCW monitoring and evaluation system. Some health workers had devised a system in which CD4 counts less than 350 cells/mm³ were entered into the POC register in red ink for easy identification of treatment-eligible clients.

LESSONS LEARNED

The following key lessons have been learned by EGPAF Zimbabwe during its early experiences rolling out POC CD4 testing at 50 FCH facilities:

- ◆ POC CD4 deployment should be combined with other complementary interventions to address all key barriers to CD4 testing and ART uptake among pregnant and postnatal women.
- ◆ ART initiation may remain suboptimal after introduction of POC CD4 analyzers in the absence of nurse-led ART initiation (especially where no physician is on staff).
- ◆ Consumption of POC testing commodities should be closely monitored and estimated rates of consumption adjusted to account for testing of non-FCH clients, especially in settings with no laboratory-based CD4 system.
- ◆ Training for machine operators should include information about how to address common machine error codes and proper documentation of results in the POC register.
- ◆ Rotation of staff trained on POC analyzer operation should be minimized or anticipated to ensure that at least one trained provider is always present to perform CD4 testing.
- ◆ Clients may be more cooperative with HIV treatment plans if health workers explain, in simple language, the meaning of their CD4 results; as CD4 counts increase with treatment, communicating this to clients can support improved adherence.
- ◆ For facilities with on-site laboratories, laboratory staff should be oriented on POC analyzer operation and informed of the evidence that supports the validity of POC results so that they are not disputed.

CONCLUSION

Introduction of POC CD4 testing in FCH settings shows great promise as an approach to increase timely access to ART among HIV-positive pregnant and postnatal women, their partners, and their families. At the same time, these early experiences highlight the challenges associated with reaching all HIV-positive women with CD4 testing as soon as their HIV status is determined and with ensuring that all women found to be eligible for treatment receive timely initiation on ART. As EGPAF supports further roll-out of POC CD4 testing in Zimbabwe, it will work closely with the MOHCW and other implementing partners to simultaneously address these and other challenges associated with delivery of CD4 testing and ART initiation. Innovative technologies such as the Pima POC CD4 analyzer, while not a panacea, are powerful tools for addressing complex public health challenges when combined with proven complementary interventions such as nurse-led ART initiation, among others. By using all methods available to strengthen the provision of PMTCT services nationally, Zimbabwe is well on its way to achieving its goal of eliminating new HIV infections in children while supporting the long-term health of all people living with HIV.

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