Impact of Point-of-Care CD4 Testing on Retention in Care Among HIV-Positive Pregnant and Breastfeeding Women in the Context of Option B+ in Zimbabwe: A Cluster Randomized Controlled Trial

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Introduction: Scale-up of Option B+ in Zimbabwe has increased antiretroviral therapy (ART) coverage but patient loss-to-follow-up remains high; thus, effective strategies to improve retention in care are needed. Evidence for Elimination, a cluster randomized controlled trial, evaluated the impact of point-of-care (POC) CD4 testing with CD4 count-specific adherence counseling on rates of retention among 1150 HIV-positive pregnant women initiating ART in Zimbabwe.

Methods: Thirty-two primary care health facilities were randomized to offer either standard-of-care (SOC) or POC CD4 testing plus CD4-specific counseling to clients (POC Plus). The primary outcome was the proportion of HIV-positive pregnant women retained on ART after 12 months, calculated by cluster-adjusted proportions, unadjusted and adjusted relative risks (RR and aRR, respectively).

Results: Retention in care 12 months after initiation was 50.7% and 54.5% in the POC Plus and SOC arms, respectively (RR 0.93, 95% confidence interval [CI]: 0.78 to 1.11; aRR 0.91, 95% CI: 0.77 to 1.07). Although considered not retained, 9.7% transferred to another facility and 0.2% died. Most women, 95.3% in POC Plus and 92.9% in SOC, initiated ART within 1 month of antenatal booking (RR 1.03, 95% CI: 0.97 to 1.08).

Discussion: Although patient retention was similar in both arms, women in the POC Plus arm were more likely to have received a CD4 test at booking and a repeat CD4 test later in care. CD4 is no longer required for treatment initiation but is still recommended in national guidelines and is of value in clinical management. Further work is needed to identify effective strategies to increase patient retention in ART care.

Key Words: eMTCT, POC CD4, retention, Option B+, Zimbabwe

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INTRODUCTION

An estimated 77,000 children aged 0–14 years were living with HIV in Zimbabwe in 2015,1 most of them infected due to mother-to-child transmission (MTCT) of HIV. In an effort to eliminate MTCT, in 2013, the Zimbabwe Ministry of Health and Child Care (MOHCC) rapidly adopted the WHO-recommended Option B+ to initiate all pregnant and breastfeeding HIV-positive women on lifelong antiretroviral therapy (ART).2 As a result, scale-up of ART has been dramatic; almost all facilities countrywide provide Option B+.3 and in 2015, 84% of HIV-positive pregnant women were either already receiving ART or initiated on ART during pregnancy.4 Estimated MTCT at 6 weeks has fallen from 13% in 2009 to 4% in 2015, but rates increase significantly postpartum, largely due to poor retention.4

Studies comparing retention in Malawi illustrated that women who initiated ART in antenatal care (ANC) under Option B+ were more likely to be lost to follow-up than women who were initiated for their own health (adjusted odds ratio 1.6 to 5.0 of being lost in the first year).5,6 Similarly, in a retrospective cohort analysis of Option B+ in Zimbabwe, ART initiation in pregnant women was found to be high (91%), but at 6 months, only 83% of women were retained in care.7 Poor retention is a program-wide issue, but optimal strategies to improve retention remain unclear. A systematic review of interventions to improve retention in care among pregnant women concluded that stronger evidence on effective interventions is needed.8
Point-of-care (POC) CD4 testing allows patients to receive CD4 results within 15 minutes. In a 2016 meta-analysis, ART initiations were significantly higher among adult patients receiving POC CD4 testing compared with conventional laboratory-based testing (72% vs. 60%).\(^9\) Although pregnant and breastfeeding women no longer require a CD4 count to determine ART eligibility, CD4 testing is still recommended in Zimbabwe to assess patient immunological status and tailor adherence support interventions. POC CD4 has not previously been evaluated among pregnant women as a tool to increase retention in care.

Evidence for Elimination (E4E), a cluster randomized controlled trial (cRCT), evaluated the impact of POC CD4 testing with CD4 count-specific adherence counseling (POC Plus) vs. standard of care (SOC) on retention in care among HIV-positive pregnant women initiating ART in Zimbabwe.

**METHODS**

Details of E4E's methods have been described previously.\(^10\) In brief, E4E was a 2-arm cRCT conducted in 32 primary care clinics providing Option B+ in 3 provinces of Zimbabwe. Sites were chosen based on criteria including performance, size, and staff complement and randomized to either the SOC or POC Plus arm. HIV-positive, ART-naive pregnant women attending their ANC booking were enrolled between January 2014 and June 2015 and followed for 14 months post-ART initiation. The necessary sample size was calculated to be 16 facilities per arm, using a formula\(^11\) that accounted for the study design and assumed \(\alpha = 0.05, 80\%\) power, intracluster correlation coefficient of 0.095, and at least 22 women per facility. The actual intracluster correlation coefficient for women retained in the trial was 0.05, meaning our estimate was conservative. Of the 388 sites in the 3 selected provinces, 59 were eligible for randomization. Sixteen sites were allocated to SOC and 16 to POC Plus. A total of 1,178 HIV-positive women were enrolled, but 28 were excluded primarily for either already having initiated ART or for false pregnancies, leaving 603 and 547 women in the POC and SOC arms, respectively (Fig. 1).

**Description of Intervention**

All facilities providing Option B+ in Zimbabwe follow standardized clinical protocols. Pregnant women with a positive HIV test should receive a baseline CD4 test, initiate ART immediately, and be seen subsequently at 2 weeks, 1 month, and then monthly until the end of breastfeeding.\(^12\) All E4E sites received training in Option B+, as they were among the first sites in the country to implement this policy. Sites were also supported to improve supply chain management for testing and treatment, data management, and data quality. Sites randomized to the SOC arm offered patients the package of services recommended by the MOHCC, including conventional laboratory CD4 testing and same-day ART initiation. The trial team provided ongoing supportive supervision and retraining on technical aspects of Option B+.

Sites randomized to the POC Plus arm were provided with POC CD4 devices, trained on their use, and participated in a quality assurance program throughout the trial period. Health care workers were trained to provide CD4 count-specific counseling using a predefined script that emphasized how ART will maintain high CD4 counts and how low CD4 counts need ART to increase the count and prevent further destruction of the immune system. Unless HIV-positive pregnant women had a CD4 test conducted within the previous 6 months, they were tested using POC CD4 before ART initiation. The E4E team provided continuous supportive supervision including clinical mentoring in Option B+ (also provided to SOC sites), retraining on the use of POC CD4 and CD4-specific counseling, and quality assurance of the POC CD4 instruments themselves.

**Study Outcomes**

The primary study outcome was the proportion of HIV-positive pregnant women retained on ART after 12 months. For the purposes of this analysis, retained on ART was defined as having had an ART refill visit a minimum of 335 days post-ART initiation and on-time attendance for at least 75% of scheduled ART refill visits, up to and including the 12-month visit. A visit was considered on-time if the actual visit occurred before, on, or up to 14 days after the next scheduled visit date. Any woman with a gap in care for greater than 90 days was considered not retained. Deaths and onward transfers were also not considered retained.

Secondary outcomes included the proportion of HIV-positive pregnant women retained on ART after 6 months, the proportion retained after 6 and 12 months stratified by CD4 category (CD4 count of 0–350, 351–500, >500 cells/\(\mu\)L, no CD4 conducted/no result recorded, or CD4 conducted after ANC booking), the proportion initiating ART within 1 month of antenatal booking, and the median time from the first antenatal booking to ART initiation.

**Data Collection and Management**

Patient data were collected prospectively by health workers and recorded in standard facility registers. During routine site visits, research assistants extracted specific data elements on each client and transferred this information onto paper-based case report forms, which were later entered into an electronic database. Data collected included patient demographic information, HIV status at ANC booking, ANC visit dates, ART initiation and review dates, ART regimen, CD4 test dates and results, and delivery dates. Regular quality assurance and quality control checks were completed after each round of data collection that included cross-checking case report forms and looking for implausible values and outliers. In addition to patient data, study site data were collected at baseline including the number of first antenatal bookings per month, facility staffing, and CD4 turnaround time.

**Qualitative Data Collection**

An end-line survey asking open- and close-ended questions on the patient’s knowledge of CD4 count, reason...
for attendance/nonattendance, and status of the HIV-exposed infant was administered, and a blood sample for viral load testing was collected from a convenience sample of mothers whom village and facility health workers were able to contact at the end of the trial period. More detail on the methodology and results can be found in the Supplemental Digital Content 1, http://links.lww.com/QAI/A983.

**Data Analysis**

Baseline facility- and individual-level characteristics were summarized using sample statistics. Significance was tested for HIV and birth follow-up variables using chi-square tests accounting for facility-level clustering. Primary and secondary outcomes were analyzed by univariate and multivariate log-binomial regression using a generalized estimated equation that accounted for the clustering of health facilities, summarized by cluster-adjusted percentages, unadjusted and adjusted relative risks (RR and aRR, respectively), and 95% confidence intervals (CIs). Multivariate analyses adjusted for known individual- and facility-level variables associated with retention; variables such as time since HIV diagnosis that were not associated with retention in this dataset were not included in the models. Sensitivity analyses included examining various criteria for defining retention and per-protocol analyses that excluded women not retained in ANC, transfers, and women not receiving a CD4 count. Statistical analyses were conducted using StataSE 13 (Stata Corporation, College Station, TX).

**Ethics**

The trial was approved by the Medical Research Council of Zimbabwe (reference number: 1659) and the World Health Organization Ethics Review Committee (protocol ID: RPC514). Facility-level consent was granted by the

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**FIGURE 1.** Trial flow diagram for facilities and patients enrolled in E4E.
RESULTS

Table 1 describes baseline facility-level characteristics. Facilities were all rural except one, with approximately equal staffing numbers and median number of first antenatal bookings per month. CD4 test turnaround time at baseline was 9 vs. 7 days for SOC and POC, respectively.

Baseline individual-level characteristics also showed no significant differences between arms. Median maternal age was 27 years (interquartile range: 22–31) in SOC and 26 (interquartile range: 22–31) in POC. In both arms, women had a median gestational age of 21 weeks at antenatal booking and a median parity of 1. Most women were married (72.4% SOC and 73.6% POC), attained a secondary education or higher (510.8% SOC and 55.7% POC), and lived within 10 kilometers of the facility (62.7% SOC and 63.0% POC). Most patients were newly diagnosed as HIV-positive at antenatal booking (80.6% SOC and 76.3% POC), while the remainder came with a previous HIV-positive diagnosis. Most enrolled women were clinically well; 88.7% (SOC) and 88.2% (POC) were WHO HIV stage I or II at diagnosis. Some women were clinically well; 88.7% (SOC) and 88.2% (POC) were WHO HIV stage I or II at diagnosis. Some women were known serodiscordant partnerships, but most had partners of unknown HIV status (79.0% SOC and 74.3% POC).

Significantly more women obtained a CD4 test in the POC arm (92.4% POC vs. 33.8% SOC, \( P < 0.001 \)), and more women received the CD4 test at antenatal booking (85.5% POC and SOC 48.7%) vs. previous (2.9% POC and 10.3% SOC) or after booking (11.7% POC and 41.1% SOC, \( P = 0.001 \)). A repeat CD4 test was conducted for 37.2% vs. 18% of women in POC and SOC, respectively (\( P < 0.001 \)). Just below a quarter of all birth outcomes were unknown; 77.5% (POC) and 73.7% (SOC) were live births, and 4% in both arms were miscarriages or stillbirths. Two women died during follow-up (1 per arm); 10.8% (POC) and 8.6% (SOC) transferred to another facility for care; and 1.8% (POC) and 4.4% (SOC) never initiated; the remainder exited the trial per protocol.

The median time from antenatal booking to ART initiation in both arms was 0 days, and although more women initiated within 1 month of booking in the POC arm (95.5% vs. 92.1%), this difference was not significant. Among women receiving a viral load test (n = 362), 69.9% had an undetectable viral load (<1000 copies).

There was no difference in retention in care 12 months after initiation between the 2 arms in unadjusted or
adjusted models (50.7% POC vs. 54.4% SOC, RR 0.93, 95% CI: 0.78 to 1.11, aRR 0.91, 95% CI: 0.77 to 1.07) (Table 2). There was also no difference between trial arms in sensitivity analyses of alternative retention definitions. Per-protocol analyses also showed no difference. Under the strictest definition, requiring all visits to be on-time, 27.6% (POC) and 29.2% (SOC) of women were retained in care (RR 0.94, 95% CI: 0.70 to 1.27). By contrast, under the most lenient definition, requiring only one visit after the 12-month marker, 61.3% (POC) and 64.6% (SOC) were retained in care (RR 0.95, 95% CI: 0.85 to 1.07).

In both arms, older age (aRR 1.05, 95% CI: 1.01 to 1.09 per 5-year increment of age) and known HIV-positive status (vs. newly diagnosed HIV-positive status, aRR 1.22, 95% CI: 1.08 to 1.37) predicted an increase in retention, whereas poor birth outcome (miscarriage or stillbirth) predicted a decrease in retention (aRR 0.73, 95% CI: 0.54 to 0.99).

Analyses stratified by timing of CD4 count showed the unexpected finding that women who received a CD4 test after their antenatal booking visit had the highest retention, whereas women who had no CD4 test conducted or no CD4 result recorded had the lowest (Fig. 2). Although there were no significant differences in retention between women who had a low vs. medium vs. high CD4 count, retention was lower in all strata in the POC Plus arm in comparison with the SOC arm (aRR 0.72, 95% CI: 0.61 to 0.87).

There was no difference in retention at 6 months (62.7% SOC vs. 59.2% POC; RR 0.95, 95% CI: 0.81 to 1.10). Similar to 12-month retention, retention was lower for the POC Plus arm when the analysis was stratified by timing of the CD4 count testing relative to the ANC booking visit (data not shown).

**DISCUSSION**

In this cRCT, POC CD4 testing plus CD4 counseling among HIV-positive pregnant women did not significantly impact retention. There is no direct evidence explicitly accounting for the lack of impact, but there are several potential explanations. First, while POC CD4 testing increases retention in care before initiating ART, it may not increase retention once patients are on treatment. It is also possible that within the theory of change the interplay of family and/or community-level factors that may weigh on an individual woman’s choices to remain in care was underestimated. The intervention may not have been delivered per protocol and/or with enough intensity, especially the counseling piece, pointing to the need for future studies to do formative work to determine the appropriate intensity required to achieve impact, especially those targeted at achieving behavioral changes. For example, less than half of patients in the POC arm received a repeat CD4 test, and as nurses do not document counseling messages, the trial team was unable to collect information on how often study participants received counseling of CD4 results. Also, it was discovered that some contamination occurred in both directions: women in the SOC arm may have received a POC CD4 test from a rotating POC device, and women in POC arm may have received a SOC CD4 test if POC CD4 devices were broken or temporarily not functional because of power outages. Finally, CD4 counseling messages may not have been understood correctly or not given ample time to observe individual patient behavior modification.

This trial demonstrates the challenge with retaining pregnant and lactating women in care, and on treatment, as only 52.5% of all women were retained after 12 months. POC CD4 did improve access to CD4 monitoring: compared with the SOC arm, 37% more women in the POC arm had a CD4 test at antenatal booking and 35% more had a repeat CD4 test.

Another study in Zimbabwe reported 6-month retention to be 83% compared with the trial’s overall 6-month retention of 60.8%. The criterion used to define retention in this trial (12-month visit plus 75% of all visits being on-time plus no gap in treatment greater than 90 days) was more stringent than the definition used by the Zimbabwe MOHCC (at least one visit after 12 months). The trial definition better assesses women who have stayed in care and adhered to the visit schedule, rather than women only active in care at 12 months but not necessarily in between; women who do not attend consecutive appointments are unlikely to be taking their medication consistently and getting appropriate, continuous care. Although it has been noted that there is no standard definition of retention in care for HIV-positive pregnant women, the unexpected finding that women who received a CD4 test after their antenatal booking visit had the highest retention, whereas women who had no CD4 test conducted or no CD4 result recorded had the lowest (Fig. 2).
A stricter definition is needed because of the importance of maintaining adherence to treatment during the period of MTCT risk. Although few previous studies have compared retention at different levels of CD4 counts, the trial team hypothesized that retention would be lower among women with higher CD4, as these women are more likely to be asymptomatic and feeling relatively healthy. By contrast, a recent study in Rwanda in 2016 showed small but significant increases in 12-month retention of mother–infant pairs as CD4 count rose (aRR 1.02, 95% CI: 1.01 to 1.03). The E4E trial did not observe any difference in retention between women with a low, medium, or high CD4 count; however, it did observe higher retention among women who received a CD4 test and result later in care, and by strata for the SOC vs. POC arm. These findings could have misclassification between strata, especially among women in the SOC arm with missing or undocumented CD4 testing and/or results. It is possible that some women were referred elsewhere for CD4 testing, but the results were not returned to the

### TABLE 2. Unadjusted and Adjusted Risk Ratios for Women Retained in Care After 12 Months

<table>
<thead>
<tr>
<th>Study arm</th>
<th>N</th>
<th>n Retained</th>
<th>% Retained*</th>
<th>Unadjusted RR (CI)</th>
<th>P</th>
<th>Adjusted RR (CI)</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>SOC</td>
<td>547</td>
<td>295</td>
<td>54.5</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>POC Plus</td>
<td>603</td>
<td>304</td>
<td>50.7</td>
<td>0.93 (0.78 to 1.11)</td>
<td>0.426</td>
<td>0.91 (0.77 to 1.07)</td>
<td>0.244</td>
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<tr>
<td>Maternal age at ANC booking†</td>
<td>1150</td>
<td>45.6</td>
<td>1.10 (1.05 to 1.14)</td>
<td>&lt;0.001</td>
<td>1.05 (1.01 to 1.09)</td>
<td>0.021</td>
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<td>HIV status</td>
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<td>Newly diagnosed</td>
<td>901</td>
<td>432</td>
<td>48.3</td>
<td>Reference</td>
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<td>Known HIV-positive</td>
<td>249</td>
<td>167</td>
<td>65.3</td>
<td>1.39 (1.25 to 1.56)</td>
<td>&lt;0.001</td>
<td>1.22 (1.08 to 1.37)</td>
<td>0.001</td>
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<td>Birth outcome</td>
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<td>Live birth</td>
<td>870</td>
<td>546</td>
<td>63.3</td>
<td>Reference</td>
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<td>Miscarriage or stillbirth</td>
<td>50</td>
<td>23</td>
<td>46.4</td>
<td>0.73 (0.54 to 0.98)</td>
<td>0.037</td>
<td>0.73 (0.54 to 0.99)</td>
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<td>230</td>
<td>30</td>
<td>11.9</td>
<td>0.21 (0.14 to 0.30)</td>
<td>&lt;0.001</td>
<td>0.22 (0.13 to 0.35)</td>
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<tr>
<td>No</td>
<td>408</td>
<td>179</td>
<td>41.6</td>
<td>Reference</td>
<td></td>
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<td></td>
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<tr>
<td>Yes</td>
<td>742</td>
<td>420</td>
<td>59.6</td>
<td>1.66 (1.39 to 1.97)</td>
<td>&lt;0.001</td>
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<td>Gestational age at ANC booking</td>
<td>1132</td>
<td>72.9</td>
<td>0.99 (0.98 to 1.00)</td>
<td>&lt;0.001</td>
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<td>Parity</td>
<td>1150</td>
<td>49.3</td>
<td>1.04 (1.00 to 1.08)</td>
<td>&lt;0.001</td>
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<td>Regimen</td>
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<td>TDF/3TC/EFV</td>
<td>1107</td>
<td>593</td>
<td>54.0</td>
<td>Reference</td>
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<tr>
<td>Other/unknown</td>
<td>43</td>
<td>6</td>
<td>18.7</td>
<td>0.24 (0.11 to 0.52)</td>
<td>&lt;0.001</td>
<td></td>
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</tr>
</tbody>
</table>

*Adjusted for clustering. For continuous variables, retention for the median value is listed.
†5-year increments.
3TC, Lamivudine; EFV, Efavirenz; TDF, Tenofovir.

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**FIGURE 2.** Cluster-adjusted percentages of women retained in care for POC and SOC arms, by CD4 category.
original facility, and thus CD4 remain undocumented. Most women in the SOC arm did not have a documented CD4 test; with the roll-out of Option B+, a CD4 result was no longer needed to assess ART eligibility, and it is possible that nurses devalued the importance of CD4 testing and therefore did not prioritize conducting them. In addition, referred patients could have been more motivated, as these women are already displaying health-seeking behavior, and more of these women would have come from the SOC arm, possibly explaining why SOC retention was higher when examined by CD4 strata.

Trial mentors observed that trained nurses were competent in using POC technology appropriately. POC devices also enabled task-shifting, freeing nurses’ time to focus on other responsibilities. However, challenges were experienced when implementing POC devices because transport was not always readily available to send devices for timely maintenance and to assure quick resolution of problems.

The trial attempted to measure the quality of counseling, but clients were not always there on days the mentors conducted site visits; 2 sites received no additional mentoring; among the other 14, only 65 patient–nurse sessions were observed. The mentor’s counseling competency score was subjective and was not correlated with retention (data not shown). Regardless, the difference in retention by the trial arm and CD4 categories that was seen could potentially be explained by inadequate counseling to women receiving a CD4 test.

The trial had several strengths, particularly the randomized controlled trial design meaning that causal interpretations may be drawn from the data. As this trial received special permission to begin Option B+ implementation before the nationwide rollout, the results present up-to-date information on retention in the context of Zimbabwe’s Option B+ program. In addition, E4E was an MOHCC-led implementation research project, and trial-specific activities were conducted by MOHCC staff, making it more feasible to implement these interventions at scale and applying lessons learned in the beginning of Option B+ rollout.

Despite the strong study design and other strengths, this trial had limitations, most importantly that there was no specific measurement of the CD4 counseling and mentorship component, and as such, the quality and consistency of the POC counseling was unknown. Although the qualitative survey suggested that most women had a good understanding of CD4 count, the retention results suggested that there may have been differential behavior based on when a woman received her CD4 test and result, and this could be due to inadequate or insufficient counseling about the importance of maintaining a high CD4 or just a prioritization of ART dispensation over CD4 testing. In addition, nurses who knew that they were part of a trial on retention may have put in additional effort to retain women and received additional supportive supervision from district health officers, even in SOC sites. It is also known that there was some contamination of the intervention, as mentioned above. There may also have been contamination by other partners, in both SOC and POC sites, conducting additional mentoring or related activities outside the trial.

Although no overall difference was observed in retention associated with POC CD4, using POC in health facilities does have benefits such as shorter turnaround times and immediate action on clinical treatment decisions. In this study, POC improved clinical care, as evidenced in the larger number of both baseline and subsequent CD4 tests conducted. There is also potential task-shifting between clinician cadres, which allows more patient–provider time. This trial also provided lessons learned on how to implement and sustainably support POC technology at rural primary care facilities. POC CD4 testing can also be used for patients with in the general ART program (outside of ANC) to establish ART eligibility at the time of enrollment and initiate a greater proportion of eligible patients early on ART. As in other studies, POC devices were found to be feasible and acceptable in a resource-limited setting.

With the scale-up of “Treat All” programs, in which ART is provided to all positive patients, CD4 will no longer be used to determine treatment eligibility, but other types of POC testing may become more important. POC early infant diagnosis testing for HIV-exposed infants will help to expedite treatment initiation for HIV-infected infants, and POC viral load testing may prove crucial for timely patient monitoring and smooth delivery of differential models of care. Evidence will be needed to assess the impact of these new POC technologies on patient treatment and care. Given the persistent problem of low retention in pregnant women and that POC CD4 did not seem to improve retention, further work is needed to identify effective strategies to improve retention among HIV-positive pregnant and lactating women.

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