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PIMA Point of Care CD4+ Cell Count Machines in Remote MNCH Settings: Lessons Learned from Seven Districts in Zimbabwe

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ABSTRACT: An evaluation was commissioned to generate evidence on the impact of PIMA point-of-care CD4+ count machines in maternal and new-born child health settings in Zimbabwe; document best practices, lessons learned, challenges, and recommendations related to scale up of this new technology. A mixed methodology approach that included 31 in-depth interviews with stakeholders involved in procurement, distribution, and use of the POC machines was employed. Additionally, data was also abstracted from 207 patient records from 35 sites with the PIMA POC CD4+ count machines and 10 other comparative sites without the machine. A clearer training strategy was found to be necessary. The average time taken to initiate clients on antiretroviral treatment (ART) was substantially less, 15 days (IQR-1-149) for sites with a PIMA POC machine as compared to 32.7 days (IQR-1-192) at sites with no PIMA POC machine. There was general satisfaction because of the presence of the PIMA POC CD4+ count machine at sites that also initiated ART.

KEY WORDS: PIMA, CD4+, MNCH settings, point of care, lessons learnt

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Introduction

In Zimbabwe, HIV remains one of the leading causes of mortality among pregnant women, with an estimated Antenatal Care (ANC) HIV prevalence of 15% reported in 2012.[1] These statistics clearly indicate the high HIV prevalence amongst women of child bearing age, which results in a high number of children infected through mother to child transmission. The new World Health Organization (WHO) strategy to eliminate this type of transmission of HIV by 2015 can only be achieved by the provision of a comprehensive maternal newborn and child health (MNCH) services to over 90% of the women in the child-bearing age.[2]

In Zimbabwe, all pregnant women attending ANC are required to undergo routine opt–out HIV counseling and testing (HCT) and other related laboratory investigations. The proportion of those that were assessed for ART eligibility using CD4+ cell count test increased from 54% in 2011 to 60% in 2012 due to the increased availability of POC CD4+ count machines.[3] According to the WHO, between 30–40% of HIV infected pregnant women have a CD4+ count of less than or equal to 350 cells and are eligible for ART.[2] This subgroup of pregnant women is potentially a 'high transmitter' of HIV to their exposed babies, contributing almost 75% of all new HIV infections through mother to child transmission (MTCT).[4] Without access to CD4+ cell testing, an HIV-positive pregnant woman may be clinically assessed (WHO clinical staging for HIV) as not yet needing treatment, when in fact her CD4+ count would show that she requires treatment.[5]

It is therefore evident that some ART eligible HIV-positive pregnant women who attended ANC missed the opportunity to be on ART during pregnancy as they did not have a CD4+ cell test conducted. In developed countries such as the UK over the past decade, nearly all children born from HIV-positive mothers were negative, as these women were on ART during pregnancy in order to reduce MTCT.[6]

In response to the Ministry of Health and Child Welfare (MoHCW)'s request to assist districts reported as performing poorly in terms of Prevention of Mother-to-Child Transmission (PMTCT) services, in October 2010 UNICEF procured 45 PIMA Point of Care CD4+ machines. JF Kapnek Trust, a UNICEF implementing partner, supported the distribution and implementation of PIMA POC CD4+ cell count machines in 35 health facilities with high-volume ANC visits of over 100 pregnant women seen per month located in seven districts (five in each district) in the country. Ten PIMA POC machines were donated to the Zimbabwe Vitamin A for Mothers and Babies Project (Zvitambo Project). In December 2010, a total of 110 health workers from the 35 health facilities were trained and skilled to perform CD4+ tests with these machines and some have been conducting the tests since December 2010. The two-day training enhanced the health workers' confidence and the site performances showed that with the required equipment, sites can provide better quality CD4+ count testing services for both HIV-positive pregnant women and their families in hard-to-reach areas. Although priority was planned for use of PIMA POC CD4+ count machines by the HIV-positive pregnant women; postpartum mothers and their families; HCT clients from hard to reach areas where there are no conventional CD4+ machines also benefited from the POC CD4+ machines program.

After over 1.5 years of using these PIMA POC CD4+ cell count machines in MNCH settings and in view of MoHCW's plans to scale up the use of these machines to other health facilities nationwide, there was a dire need to generate evidence to inform the future deployment and use of this new technology in MNCH settings in the country and the region.

Materials and Methods

Study design. This study was a quasi-experimental study. This design assessed the change that the POC CD4+ machine may have made in improving access to CD4+ cell count testing and improved initiation to ART by pregnant women and their families. Data were compared to sites without POC CD4+ cell count machines.

Study sites. All 35 ANC high-volume health facilities (ie, sites that provide MNCH services to more than 100 pregnant women per month) that possess the PIMA POC CD4+ machine in seven districts of Gokwe North, KweKwe, Mwenezi, Gokwe South, Hurungwe, Wedza, and Gwanda, and 10 other high-volume ANC sites providing similar services but do not have PIMA POC CD4+ count machines within the district or in the neighbouring district were targeted. This was conducted in order to compare outcomes of individuals receiving program activities as compared to those that were not. For the 10 other sites with no PIMA POC CD4+ count machines, 2 were provincial hospitals, 2 district hospitals, 2 rural hospitals, 2 mission hospitals, and 2 clinics.

Study population. The study population comprised clients (HIV-positive pregnant women, lactating mothers, their families, and other users) receiving services from sites with and without the PIMA POC CD4+ machine. Key informants for the study included relevant project and support staff from UNICEF, JF Kapnek Trust, MoHCW, Medsure, and other implementing partners and also MNCH staff, counselors, lab staff, and ART personnel from selected sites.

Sample size and data sources. A total of 346 individuals were interviewed. At the national level, a questionnaire was administered to 23 staff members, with at least one from each of the supporting organizations, including UNICEF, JF Kapnek Trust, the MoHCW, in the AIDS and TB unit and Medsure, National Aids Council (NAC), Sexual and Reproductive Health, Elizabeth Glaser Pediatric Aids Foundation (EGPAF), Clinton Health Access Initiative (CHAI), Zimbabwe National Quality Assurance Programme (ZINQAP), NatPharm, Population Services International (PSI), Zvitambo project, and John Snow Inc (JSI). An example of a question asked was, 'What factors were considered in procuring these machines?' At the site level, a questionnaire was administered to 62 trained POC users, and an example of a question asked was 'What challenges do you have with the POC machine utilization at this facility?' An observation tool was applied to 22 of the trained users. A client exit questionnaire was administered to at least 4 clients per site that had had a CD4+ cell count test (ie, 142 from the 35 sites with POC and 42 clients from sites that do not have the POC); one question was, 'Why is it important to have a CD4+ cell count result?' One client focus group discussion was conducted in each of 7 districts (one site per district). Each FGD comprised of 5 to 10 people and had 5 different themes with questions. The themes were (a) knowledge level of CD4+ cell count—benefits of CD4+ count, (b) knowledge on available testing methods for CD4+ count (c) access to testing facility—challenges faced (money, transport, time) and treatment by staff (d) ART initiation, waiting period, follow up, other tests undertaken, and (e) perceptions of POC testing. Data collection also included use of audio recorders, and when necessary, with verbal consent, a camera was used to capture additional information. Lastly, data was abstracted from five health records from 45 facilities (total of 207) using a data abstraction tool (35 with PIMA POC CD4+ count machines and 10 without PIMA POC CD4+ count machines). This data abstraction tool included parameters such as: date of CD4+ cell count test requisition, date of testing, WHO staging results, etc.

Data entry and analysis. Quantitative data entry was done using Epi Info Version 3.5.3 and after data entry, data

was exported to Stata 10.1 for analysis. Qualitative data collected through in-depth interviews and focus group discussions were fully transcribed from recorders on the same day of the discussions, thus ensuring that all relevant issues discussed were captured. Content analysis was used to analyze the data. The transcribed data was subjected to classification, coding into various categories, and identification of different themes. A narrative and thick description with participants' quotations was used to capture participants' views.

Ethical considerations. Ethical approval of the study was obtained from the Medical Research Council of Zimbabwe (MRCZ), (Number MRCZ/A/1664). Permission to conduct the study was endorsed by the Ministry of Health and Child Welfare. Prior to interviews and focus group discussions, the researchers explained the study to the potential participants and also discussed issues of confidentiality and consent. Written consent to participate in the study was sought in line with MRCZ requirements.

Results

Figure 1 shows the number of PIMA POC CD4+ count machines procured by the different organizations over time. As of June 2012, there were 265 PIMA POC CD4+ count machines in the country, most of which were placed in MNCH settings.

Of the 62 trained users that responded to structured interviews, 47 (76%) were female. Overall, there was consensus from all trained users interviewed that the training they received was useful and relevant to the day-to-day operations of the POC machine. There were some facilities whereby if the trained user was not available, the machine could not be used. This was expressed by one of the key informants: "No one would use the machine if the trained users are not around. Some (patients) come as far as Gandawe and sleep on verandas so as to be attended to. It's not good. Please train more people." Another informant was quoted saying, "Besides trained user others cannot use the machine, so in his (the formally trained user) absence, clients are requested to go back and come back some other time."

In contrast, some health facilities made arrangements to have the formally trained PIMA POC machine users transfer their acquired skills during on-the-job training for the use of the machine by other staff members who did not have an opportunity to undergo formal training. An on-the-job trained user expressed much confidence in the use of the PIMA POC CD4+ testing machine as highlighted below: "I was trained and supervised by the trained user and I am now in a position to use the machine confidently whenever the trained users are not there." Another respondent said, "We conduct in-service training, and I am one of the product of in-service training… The only difference between me and the trained user is that the trained user received a certificate." Other reasons cited for conducting on-the-job training were related to a need to overcome staff shortages as highlighted by a key informant, "We are short staffed, that's why we did the in-house training, so that everyone (patient) who comes will be attended to. Three of our staff members were trained in-house."

It was highlighted that supervisors were left out of the formal training since only their subordinates were targeted for formal training. When supervisors of the machine users were not trained, such instances made their supervision role difficult. As indicated by one respondent; "Like myself (a supervisor), I was not trained, it becomes very difficult for me to supervise something which I was not trained on and have no idea on its operation. It's like I just follow them (the users) in whatever they are doing. I feel if they are to train more, we should be involved."

Another key informant stated that, "No training was done internally because of the instructions given by the trained users that those not (formally) trained should not touch the machine. It is difficult for me to supervise something I don't know about, so may you please also train the supervisors. It is

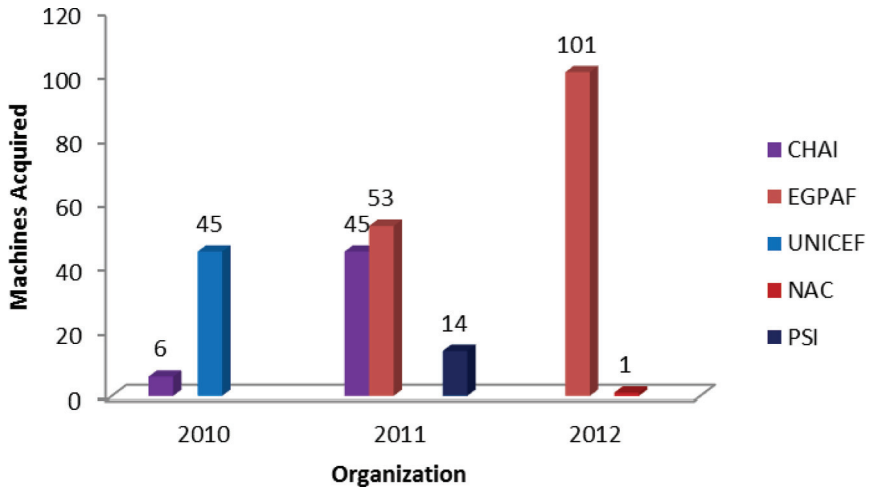

Figure 1. Numbers of Pima POC CD4+ cell count amchines procured by different organizations.

downgrading to receive instruction from a junior. We just rotate the trained users to use the machine."

Quality control measures. An internal quality control (QC) procedure is an important step that must be conducted by every user before processing patient samples. Concerning internal QC, nearly all users (98%) confirmed that they carry out internal quality control daily before analyzing samples. Of those observed, approximately 91% ran controls before running the tests for the day. If the quality control results were out of the range, the users checked the expiration date or reported the problem to superiors.

The Zimbabwe National Quality Assurance Program (ZINQAP) Trust provides external quality assurance (EQA) services for laboratories through provision of proficiency testing (PT) services and on-site assessments, among other services. ZINQAP are in the process of negotiating with UNICEF so that they can provide EQA services to the UNICEF sponsored PIMA POC CD4+ testing machines. A key informant had this to say about the challenges they are currently facing in providing EQA for POC CD4+ testing; "The challenge we have faced is the remoteness of the sites…Phones are not reachable" There are currently no EQA programs running for the 35 PIMA CD4+ cell count machines.

Machine maintenance and challenges in utilization of the machine. Our findings showed that the PIMA POC machine users perceived the machine as maintenance-free. One trained PIMA POC CD4+ count machine user indicated that "There is very little maintenance that we do. We just run controls and wait for the machine to do everything." Consistent with details provided by the machine, users regarding maintenance, a key informant from Medsure, who are also responsible for attending to the machine faults, said "The machine is maintenance free. You only need to keep it clean by dusting it." However, approximately 55% of the observed users dusted the machine on the day of assessment.

It is also important to note that the users also used the manuals when troubleshooting as indicated by one of the users; "If there is a problem we try to make use of manuals, so that we assist the mothers so that they don't go without being assisted." Fifty-eight percent of respondents indicated that they sometimes troubleshoot if the machine is dysfunctional. Some users indicated that there are times when the machine does not give results, resulting in the patients being requested to provide another blood sample.

Twenty-five percent of the PIMA POC CD4+ count machine users reported encountering some challenges after the installation of the PIMA POC CD4+ count machines. Quantitative data gathered from PIMA POC machine users revealed that while the majority reported that problems encountered after installation were resolved by Medsure (67%), approximately 33% of POC users reported that they were able to resolve the problems without the help of Medsure.

Other challenges described include lack of, or, erratic power supply resulting from load shedding and no electricity connection. Many of the clinics do not have solar power or generators as back-ups. This affects battery charging; hence, there is need for constant power supply. To resolve the power supply challenge, some clinics use facilities outside the clinical setting. These include schools and business clinics, while some used generators.

In addition, some key informants highlighted challenges related to a limited number of people they can service per day (in most cases, maximum of 20) and cartridge rejection before expiration date as well as frequent error codes. There are two methods used to draw blood from a patient depending on the type of test to be performed. For the PIMA CD4+ count testing, a finger prick is used and for the conventional machine a venous blood draw is conducted. One of the mentioned key benefits of the finger prick method is related to comfort and safety of the patient. One District Nursing Officer (DNO) mentioned that 'the finger prick is less traumatizing to the patient, less blood is taken for immediate use, so there is no suspicion that we are using blood for other purposes'.

There is also a general agreement that PIMA POC CD4+ machine is efficient in terms of resource use and that it is user friendly. A health personnel in Hurungwe district revealed that it 'uses fewer resources (syringes and needles), less technical expertise is needed and other staff can carry out tests as compared to drawing blood which needs highly technical individuals'.

Over and above the mentioned key benefits of utilization of the PIMA POC CD4+ count machine, some of the health personnel noted a number of challenges with the finger prick. It was disclosed that with the finger prick you cannot draw a sample for a full blood count (FBC), which can be done under the conventional venous blood draw. It was also highlighted that a full blood count is required to determine the type of ARVs a client can take, and this cannot be done with blood from a finger prick. There is also the problem of errors in tests, which means a finger prick may be done more than once, exposing the client to more pain. Additionally, unlike the finger prick, some health personnel noted that the venous drawn blood draw could be used for CD4+ cell testing and the remaining blood used for other tests.

Staff workload was the most prominent challenge reported by the POC users (Fig. 2) in all districts mainly because the health personnel responsible for CD4+ testing with the PIMA POC CD4+ machine were said to have other duties in addition to CD4+ cell testing and also because the number of those trained to use the machine was limited.

"We treat, conduct tests, CD4+ cell count, counselling, ART initiation, training, paper work, we do comprehensive. We are only 3 workers; One will also be doing ANC bookings, syphilis testing, HIV testing and supplies" POC machine user, Musita Rural Clinic.

Another health personnel in Karoi bemoaned the increased workload without corresponding increase in remuneration, and said 'I wish there was an allowance to

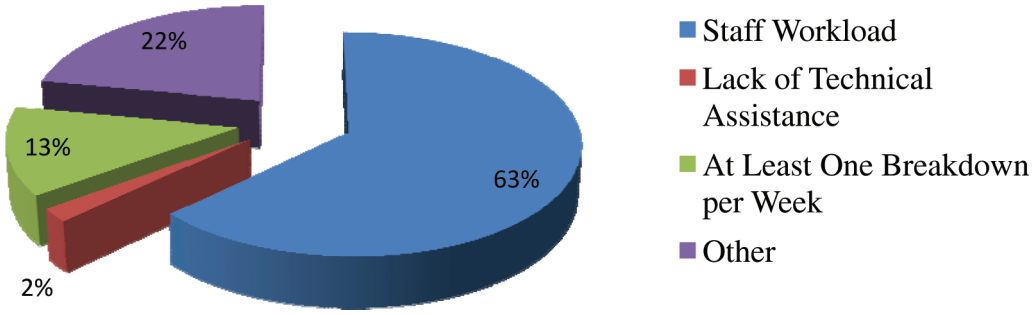

Figure 2. Challenges experienced in utilization of the POC machine.

compensate the nursing staff for additional work we are now doing'. Another key informant at a health facility indicated. 'Nurses want to be trained, after that they are complaining that this is lab work.' Based on the limited staff compliment, most districts indicated the need to train more staff.

Concerning breakdowns, a key informant from Medsure said that there is an average of two machines breakdown per week country wide. He also said problems are usually resolved in 4 to 6 hours. The major types of breakdown include hardware and alignment and loss of camera focus, making the machine fail. Another key informant from Medsure said, "There has been poor handling of the machines when using them. Some people were using sharp objects and you would see pen markings when switching and installing." These breakdowns were noted to be more frequent after the machine had been in use for more than a year as indicated by a key informant from JF Kapnek Trust "The CD4+ POC machines are good but after a year, they start showing problems which are hardware issues i.e. Blank screen appears and stuck cartridges. All the busy sites have had at least 2 breakdowns. For the sites that are not busy there has been maybe one breakdown. After 1 year, there are now major breakdowns."

Utilization and usefulness of the provided Job Aid. Job aids/standard operating procedures (SOPs) are step-by-step instructions on how to carry out a procedure. In this assessment, individuals were expected to regularly refer to these. For noting, it was observed that none of the POC sites had job aids visible or hanging on the wall, but all had SOPs in their manuals and most respondents used the terms interchangeably.

Results show that 93% of the users indicated that they sometimes refer to the job aids/SOPs, while the remaining 7% did not refer to them. However, findings from structured observations done on 22 sites showed that none of the trained users referred to their SOPs in their manuals during tests.

Utilization of PIMA POC CD4+ count machines by service providers. There was a general acceptability and appreciation of the POC CD4+ machine among the health personnel in all districts. The health personnel also indicated that they were happy with the introduction of this machine as it is assisting clients at a minimal cost, with very few referrals. Below are some highlights of what was said:

> "Patients were happy about the introduction of this machine because it has assisted them at a very minimal cost; no more referrals, and the service is also cost-free"
>
> —Health personnel at Goto Rural Health Center

> "Staff have appreciated the machine largely because there is no delay on ART initiation unlike before."
>
> —Mwami Rural District Hospital

> "They appreciate the machine and actually want an additional one since this machine is catering for all types of clients."
>
> —Hwedza Rural Hospital

> 'I think this machine is really complementing especially looking at the PMTCT program. It has really done a good job that now we can offer all the services quickly and within, so I would say its adequate'.

According to health personnel interviewed, clients are happy with the reduced turn-around time for CD4+ cell count results. For example, one health worker mentioned that "If you have seen our books, you will realize that clients are coming the second time for testing saying I want to see my CD4+ count. They now know what happens regarding the CD4+ test." In addition, one District Nursing Officer (DNO) revealed that "They are happy that they can have their CD4+ count fast and without paying." Another health staff cited that "They appreciate the machine, it has cut their expenses for getting the tests done on them and with the outreach team coming for initiation, clients are very happy."

It was also widely acknowledged that the PIMA POC machine is easy to use. Additionally, there was consensus that when compared to conventional machines, PIMA POC CD4+ machines reduced the service time to only 20 minutes rather than several weeks. There is a general perception that the method of using POC CD4+ machine for CD4+ count testing is adequate and is satisfying the needs of clients to a greater extent as compared to the conventional blood draw method.

Client perspectives on utilization of POC CD4+ machines. Client exit interviews showed that most (79%) of the clients understood the CD4+ cell count test. Consistent with these findings, focus group discussions with clients

also revealed that participants in the seven districts were knowledgeable of what a CD4+ cell count test is. One participant had this to say "CD4+ cell count is a test that examines the level of CD4+ cells in the body to determine whether one should be initiated on ART." Additionally, approximately 94% of the clients indicated that they understood why CD4+ cell count test was required. As one respondent highlighted: 'I must know my CD4+ count because I take pills and I need to know whether my CD4+ count is increasing or decreasing. I must know if the pills I am taking are the correct ones. I was given pills before I was tested for CD4+, so my CD4+ count has shown me the situation of my body soldiers. If there are many it is good, but if my CD4+ count goes down that means it is bad.'

Among the few participants that did not know why it is important, one thought this count was done "so that you know your life span".

Overall, most clients held more positive perceptions when asked to rate friendliness of the health staff that provided services to them on the day of the visit. About 94% were agreeable that health staff that provided services to them were friendly. Additionally, about 88% of the clients interviewed at the end of their visit indicated that they did not wait long before being served. "They used to collect our blood and send it somewhere, hence that will take some days but as for now there is a big difference, we now receive our results there and then".

Another client said, 'They treat us good, they have never treat us bad. … They treat us nicely, we have nothing to complain about.' There was only one site where complaints were stated. Three different clients said, 'Sometimes they will say its low without proper explanation.' 'Especially the young ones will end up making us think that we are dying.' 'The way we are treated will cause us to be ill and have BP (blood pressure).'

WHO staging versus CD4+ cell count testing. Data obtained from the data abstraction tool indicated that 44% of the patients were in WHO stage I on the first visit, 39% in stage II, 14% in stage III, 1% in stage IV, and the remaining 2% were not staged on the first visit. Of patients who received CD4+ cell count test results on the first visit, 121 (98%) showed the CD4+ test results on their records. The median CD4+ cell count was 234, interquartile range (IQR) (144–332), which is below 350. These results clearly show that most mothers required ART, and yet according to the WHO staging, most mothers were either in stage I or II, hence regarded as not needing ART (See Fig. 3). A nurse from Kana Mission hospital said that "It has improved patient care so much because some patients look clinically healthy but when the CD4+ count is done the count will be less than 350, especially with pregnant mothers, it's difficult to clinically stage but with the PIMA we can now put them on treatment (ART Initiation) before they deliver."

This finding further confirms that WHO staging alone may be misleading in the determination of ART eligibility, as 100 (48%) mothers were misclassified as not requiring ART as they staged as either 1 or 2 and yet their CD4+ cell count results were <350 cell/μL, indicating that they were eligible for ART in line with the current ART treatment guidelines.

Assessment of ART eligibility for HIV-positive pregnant women and their families. Data was collected from each patient's health card. This was extracted from 207 records with 169 (81.6%) from POC sites and the remaining 38 (18.4%) from non-POC sites. All records extracted were from female patients. The median age of the patients was 28 years (IQR 24–33 years). Most mothers (48.3%) were lactating, compared to 42.5% who were pregnant. Those mothers whose status was "other" (9.2%) were neither pregnant nor lactating. The entry point was mostly ANC (83.6%). Three of the records did not have information on patient entry point. Most mothers (75%) were active on ART and 3 (1.5%) were no longer taking ART.

Prior to use of the PIMA POC CD4+ count machines, clinical assessments were based on WHO staging, creating numerous challenges in terms of client management. In this context, client management involves reliable clinical assessments, timeous ART initiation, and client retention due to less referral. Our findings revealed that overall there is a significant improvement in client management as a result of the PIMA POC CD4+ cell testing machine in all districts assessed.

Raw data from the JF Kapnek trust concerning from the time of inception of the PIMA POC CD4+ cell count machines at the 35 UNICEF supported sites ie, as in December 2010 to end of June 2012 there were 21,742 people that had been tested using these machines and a total of 13,152 (60%) had a CD4+ cell count of less than or equal to 350 cells/μL, making them eligible for ART initiation, 11,190 (51%) were HIV-positive pregnant mothers, including those that had also delivered or given birth. Figure 4 shows the different entry points for those that were tested during that period.

There are 116 conventional CD4+ cell count machines throughout Zimbabwe that have an average daily throughput of 50 tests per day. There are sites such as Gweru Provincial Hospital that have 2 such machines on site, increasing the total tests that can be conducted per day. From the 45 sites that were visited, only 4 sites had conventional CD4+ cell count machines. These included the Rusape General Hospital, Kwekwe District Hospital, Gokwe South District Hospital, and Gwanda Provincial Hospital.

Access to ART for HIV-positive pregnant women. There is a significant difference in the mean number of days to receive a CD4+ test result at a POC site ie, approximately 2 days compared to a non-POC site with 37 days. Of the 35 PIMA POC CD4+ sites that were visited, 18 were ART initiating sites. Data from the 18 sites showed that the average time taken to initiate clients on ART was 15 days (IQR 1–149). For non-ART initiating PIMA POC CD4+ cell count sites the average number of days clients had to wait to be

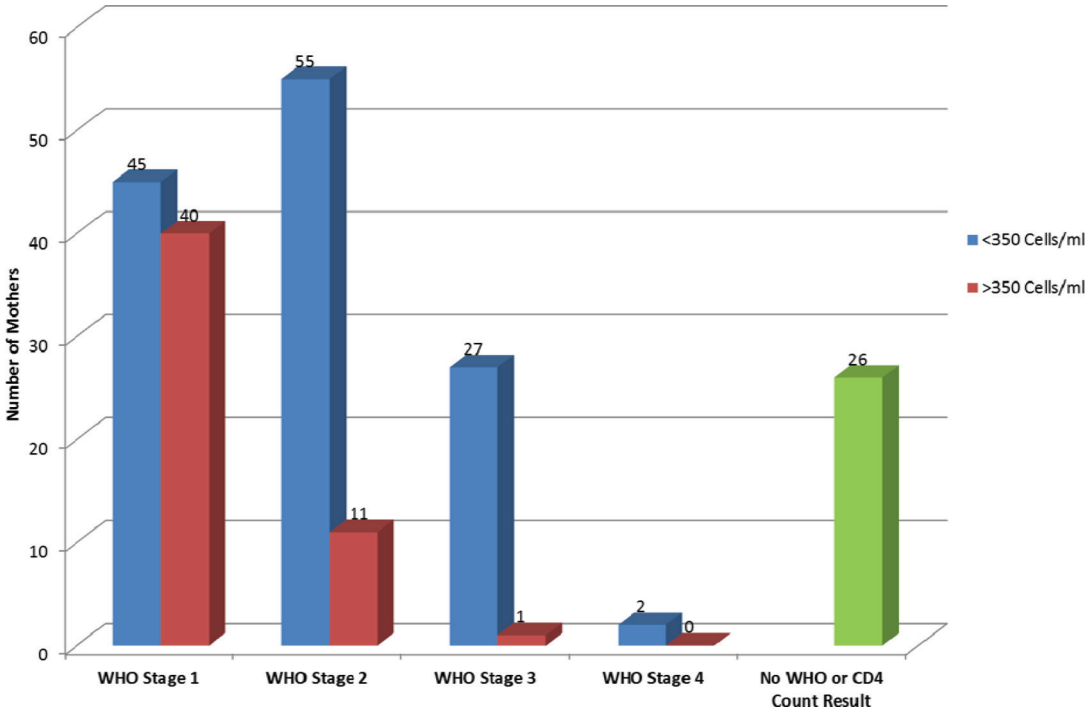

Figure 3. WHO staging of patients.

initiated on ART was 30 days (IQR 1–219), while this value was 32.7 days (IQR 1–192) for ART initiating sites with no PIMA POC CD4+ cell count machine (Table 1).

It was also established that for ART initiation, there are ART initiating and non-initiating centers. All provincial hospitals and some district hospitals initiated ART, but none of the clinics initiated ART as they waited for the outreach teams. Additionally, some health personnel raised concerns over the fact that even if they have increasing numbers of people having CD4+ count tests, they are still not in a position to initiate ART due to lack of training and accreditation by MoHCW. Delay of ART initiation when the outreach team does not arrive on time was cited as problematic in non-initiating centers. In relation to this, some centers refer clients to district hospitals for initiation, which poses numerous challenges. For example, they may refer clients, but the clients do not have money for transport. Failure to retain clients and client follow-up are also causes for concern.

However, it was also highlighted that some health personnel are being trained to initiate clients in non-initiating centers. At the same time, some health personnel, particularly in urban ART initiating sites, also pointed out that they are facing increased numbers of people referred to them for initiation.

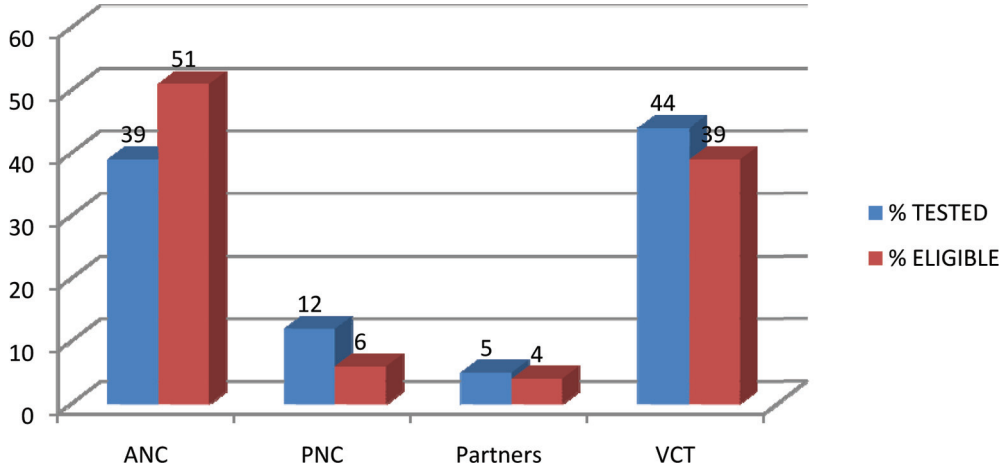

Figure 4. Proportion of clients tested from different entry points including ART.

Table 1. Time to qualify and initiate ART.

SITE	ART INITIATING SITE	RANGE OF DAYS TO QUALIFY FOR ART MEDIAN (IQR) DAYS	AVERAGE TIME TO INITIATE ART MEDIAN (IQR) DAYS
PIMA POC	Yes	0 days	15 (1–149)
PIMA POC	No	0 days	30 (1–219)
Non-POC	No	0 (0–3.5) days	32.7 (1–192)

Discussion

There are now a number of established studies that have found correlations of the PIMA POC CD4+ cell count machine results with the conventional flow cytometry tests,[7–11] but there is very little data that includes clinical data.

Partners such as UNICEF purchased the PIMA POC machines because no other machines were available for evaluating CD4+ POC in the country. Although other machines were developed and some are still under development, including the Mbio TM Diagnostics CD4+ system, Daktri TM CD4+ counter, Zymox CD4+ test, PointCare NOW™, CyFlow® CD4 miniPOC, Semi-quantitative CD4+ test from the Burnet Institute.[12,13] The JF Kapnek Trust, an implementing partner for UNICEF, mentored the trained users and ensured adequate supplies of cartridges and control beads. The JSI conducted quantification of the commodities, which are stored at the NatPharm and then distributed throughout the country by a delivery team top up unit (DTTU). Medsure addressed machine breakdowns. This system indicates the existence of a well-coordinated system for implementation of new technology.

There were two scenarios concerning training, ie, there was no clear strategy regarding whether trained users were allowed to train other staff members on site. At some POC sites, when the trained user was not available, patients were turned away, while at other sites with in-house training, there was continuity of service provision. One of the visited sites had an in house-trained user continually received error code results because of poor quality specimens. Other findings such as some trained users not running internal quality controls and improper waste disposal such as placing sharps in a normal bin are indicators of the in-house trainings. This clearly indicates the need for educating trainers to use the PIMA POC CD4+ cell count machine in all provinces throughout the country, including the training of supervisors, who also complained of supervising the use of a machine that they were not able to use. Additionally, refresher courses are required for lab scientists that run conventional machines to ensure continual professional development.[14] Job aids and standard operating procedures should be visible so that they can be used.

The presence of the PIMA POC CD4+ machine at sites has increased the staff workload as there is a shortage of health personnel. The prospect of additional staff employment is low; thus, a microscopist or other personnel should be employed at sites to run all the required point-of-care tests (ie, rapid HIV and syphilis tests, TB microscopy , CD4+ POC, etc) since other tests are required to determine these viral loads and for early infant diagnosis for HIV.[12,13,15]

In expressing the effectiveness of the PIMA POC CD4+ count machine, one health worker said "The PIMA really helps patients get results immediately as compared to long back where some who were tested would go and not return. We were losing our patients. Now with the PIMA, everything is done there and there." This finding is similar to observations made by Faal et al[16] that in South Africa, newly diagnosed HIV positive patients have blood drawn for CD4+ analysis at time of HIV diagnosis and are asked to return in one week for the result and further management; however, approximately 60% of patients do not return. One health worker from the Hwedza District cited that 'The method is adequate and satisfying as it has made the service easier and better as there is less room for wrong decisions, therefore with right information, client management becomes easy. Clients are happy, transport costs and delays have been eliminated or reduced."

Patient management has increased with use of the machines. Service providers do not have to wait for a long period of time for results. They are able to make critical decisions immediately, and they do not rely solely on WHO staging. One health worker at Chidamoyo Christian Hospital said that, 'For pregnant women WHO staging may not give you the correct clinical analysis, but POC will give you the correct information, then you make the right decision, before our lab will give us the results delayed.'

Our study demonstrated that a CD4+ POC site must also be an ART initiating site, as this would reduce loss to follow-up and ensure better patient management. A study by Hatzold et al[17] demonstrated that access to ART through point-of-care CD4+ cell count integrated with counseling and testing services in four PSI centers in Zimbabwe improved significantly from 275 clients in April 2010 to 1557 clients in September 2010. Before the Population Services International introduced point-of-care CD4+ cell testing, patients started ART after a mean of 60 days from first presentation at the clinic but after the introduction of point-of-care CD4+ cell testing, ART was started after a mean of 24 days ($P = 0.05$).[17] A separate study by Mahomva et al[18] indicated that the introduction of POC CD4+ machines in ANC contributed to a two-fold increase in the proportion of ART eligible HIV-infected pregnant women identified and initiated on ART in MNCH settings between

2010 and 2011. Identified ART-eligible pregnant women who received ART in ANC increased from 2498 (17%) in 2010 to 5890 (37%) in 2011.[18]

Study recommendation 1. Provide training for supervisors and for more staff members at sites such that in the event of staff movement, on site point-of-care CD4 testing will continue.

Action Taken: Trainings of additional health workers was conducted. District health managers should be included in the trainings.

Study recommendation 2. Ensure that there are two machines allocated to each health facility (or adequate reserve machines), particularly those in hard to reach places to cater for machine breakdowns so that services are not disrupted, when battery runs out on the other machine, or to cater for an increased patient load. There is need to add more POC PIMA machines at hospitals, specifically in the ANC, OI, and outpatient departments.

The MOHCW plans to have the POC devices at all sites country wide before allocating additional devices to sites already having one. As the HIV program moves to decentralize ART services to first-level care, the emphasis is place POC machines there first. In larger facilities, such as hospitals with large numbers of patients, but with laboratory-based CD4 count machines with higher throughput, additional devices would be considered useful in MNCH, OI, or outpatient departments.

Study recommendation 3. Ensure that PIMA POC CD4 cell count sites are also ART initiating sites.

The MOHCW has agreed to deeploy additional PIMA POC devices to ART initiating sites. All sites with PIMA POC devices will be converted into ART initiating sites. UNICEF has procured an additional 24 POC machines which have been distributed to opportunistic infection (OI)/ART initiating sites.

Study Recommendation 4. There is need to provide health facilities with power back-ups such as solar power.

UPS were procured and installed to all sites in which the PIMA POC devices were deployed but have no electricity supply at all or sites that experience frequent power cuts.

Study recommendation 5. Engage the government of Zimbabwe to unfreeze posts for health cadres and also to increase the health facility establishments to ease workload on personnel.

Continue lobbying with Ministry of Finance through MOHCW to allow for unfreezing of health worker posts and to allow expansion of the health services establishment to service the increased number of patients at service delivery facilities.

The Ministry of Health and Child Welfare has been lobbying to the Ministry of Finance. As of April 2013, 2000 nurses' posts were unfrozen as a response to the efforts. Deployment of the trained cadres is underway. At the same time, MOHCW has deployed additional medical officers at district levels with funding from the HTF.

Study recommendation 6. Daily or routine internal quality control procedures should be enforced.

As part of the training of use of the POC devices, the internal quality control procedures will be emphasized. In addition, district staff supervisors are being trained to observe and ensure POC device operators routinely conduct of internal control checks.

Conclusions

There was a well-coordinated strategy by the MoHCW for implementing this technology with assistance from partners. The PIMA POC CD4+ machines at the 35 UNICEF-supported sites have been of great service to the people as 21,742 patients had been tested using these machines from December 2010 through June 2012. Of those tested, 51% (11,190) were pregnant or lactating mothers; 2,657 (24%) were found to be eligible for ART. The machines improved client management because CD4+ cell count results were given on the same day compared to conventional machines where clients would be asked to come back a second day and in some instances they would not come back.

Both clients and service providers were generally satisfied with the presence of the PIMA POC CD4+ count machines at their sites because of the production of results on the same day and provision of better patient management, particularly at sites that were also ART-initiation sites, reducing ART—initiation waiting time by half (15 versus 30 days) compared to sites where POC CD4+ machines were used with no co-existing ART services. Thus, the biggest drawback was the limited number of ART initiating sites, requiring patient referral to a site that has such services. There is need for the MoHCW to expedite the accreditation of sites to be ART initiating for pregnant mothers to have increased access to these services for their own health and that of their unborn babies. While this is being negotiated, there is need for the outreach teams to visit more frequently to sites in order to initiate ART.

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Author Contributions

Conceived and designed the experiments: SMZ, EC. Analysed the data: SMZ, EC, VC. Wrote the first draft of the manuscript: SMZ. Contributed to the writing of the manuscript: SMZ, EC, WM, GM, FNK, AM, VC. Agree with manuscript results and conclusions: SMZ, EC, WM, GM, FNK, AM, VC. Jointly developed the structure and arguments for the paper: SMZ, EC, WM, GM, FNK, AM, VC. Made critical revisions and approved final version: SMZ, EC, WM, GM, FNK, AM, VC. All authors reviewed and approved of the final manuscript.

DISCLOSURES AND ETHICS

As a requirement of publication the authors have provided signed confirmation of their compliance with ethical and legal obligations including but not limited to compliance with ICMJE authorship and competing interests guidelines, that the article is neither under consideration for publication nor published elsewhere, of their compliance with legal and ethical guidelines concerning human and animal research participants (if applicable), and that permission has been obtained for reproduction of any copyrighted material. This article was subject to blind, independent, expert peer review. The reviewers reported no competing interests.

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