DECENTRALIZING CD4 TESTING: The Experience of Using PointCare NOW CD4/CBC Testing Machines in Military Health Facilities, Republic of Uganda
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<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>API</td>
<td>Acholi Pii</td>
</tr>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>CBC</td>
<td>complete blood count</td>
</tr>
<tr>
<td>CD4</td>
<td>cluster of differentiation 4; blood level used to assess a patient’s need for ART</td>
</tr>
<tr>
<td>DHAPP</td>
<td>United States Department of Defense HIV/AIDS Prevention Program</td>
</tr>
<tr>
<td>Hb</td>
<td>hemoglobin</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>MBR</td>
<td>Mbarara</td>
</tr>
<tr>
<td>MOR</td>
<td>Moroto</td>
</tr>
<tr>
<td>NAK</td>
<td>Nakasongola</td>
</tr>
<tr>
<td>NMS</td>
<td>National Medical Store</td>
</tr>
<tr>
<td>PC-NOW</td>
<td>PointCare NOW</td>
</tr>
<tr>
<td>UPDF</td>
<td>Uganda People’s Defense Forces</td>
</tr>
<tr>
<td>UPS</td>
<td>uninterruptible power supply</td>
</tr>
<tr>
<td>WBC</td>
<td>white blood cell</td>
</tr>
</tbody>
</table>
Executive Summary

Introduction:

The Uganda People’s Defense Forces (UPDF) has faced challenges in scaling antiretroviral therapy (ART) to and deploying HIV-positive individuals. These challenges arise primarily from the limited access to CD4 testing afforded the highly mobile Uganda military population. Since 2008, the U.S. Department of Defense HIV/AIDS Prevention Program (DHAPP) has been supporting UPDF in conducting centralized CD4 testing using FACSCalibur™ machines at two military hospitals (Bombo General and Gulu). DHAPP support improved access to CD4 testing by the military and families accessing HIV services in the two facilities where the machines were located, but access remained a problem in other, hard to reach military health facilities. To further improve access to CD4 testing, DHAPP provided additional support to UPDF to decentralize CD4 testing through use of PointCare™ CD4 machines. DHAPP procured and supplied six PointCare™ (PC-NOW) CD4 machines. Four of the machines have been installed to provide static service at Acholi Pii, Mbarara, Moroto, and Nakasongola, and the other two provide CD4 testing services for field troops on a rotational basis. Introduction of the new and different CD4 testing technology generated a need to understand and document its effect on access to HIV services and on the health care providers’ experience using PointCare™ CD4 machines. In view of this, DHAPP conducted an assessment of the impact of decentralizing CD4 testing using the PointCare™ technology on access to CD4 testing, turnaround time of testing results and clinical decisions, and clinicians’ experience.

Methods:

DHAPP conducted the assessment in the four UPDF hospitals (Acholi Pii, Mbarara, Moroto, and Nakasongola) where the PC-NOW CD4 machines were installed. Data were collected between July 2011 and February 2012. Baseline data were collected on the status of CD4 testing services at the facilities (numbers tested, time taken to report results to the clinician, enrollment in ART, supply chain schedule, and loss to follow). Data were then prospectively collected from the facilities on the same variables and the technicians’ performance on the new machines. The data were collected through review of records and interviews with facilities’ PC-NOW trained laboratory technicians, clinicians, and the UPDF HIV Directorate managers. We also analyzed data from the PC-NOW CD4 machine output to assess the machines’ and operators’ performance. We analyzed data comparing the facilities’ performance on CD4 testing and ART services in the periods before and after PC-NOW CD4 machine installation.

Findings:

Access to CD4 testing: The overall number of CD4 tests conducted by the facilities increased by 79%; the increase in number of CD4 tests was more marked in the previously most underserved facilities of Moroto and Acholi Pii. Fewer patients had their CD4 tested in Nakasongola after the PC-NOW CD4 machine was introduced; the turnaround time for delivering CD4 results to the clinician reduced by 99%; and about 85% of the patients received their results the same day they visited the clinic. The hematology results produced alongside CD4 counts are minimally used by the clinicians; CBC differentials are rarely used and Hb is occasionally used. The number of patients enrolled in ART increased by 35% after introduction of PC-NOW CD4 machine.
Daily use of PC-NOW CD4 machine: All facilities are under-using the PC-NOW CD4 machines. Reasons for under-use include the low availability of PC-NOW CD4 machine trained laboratory staff, irregular supply of PC-NOW CD4 reagents, irregular power supply, and high room temperatures at Acholi Pii and Nakasongola. Daily CD4 testing by the facilities is not feasible considering current estimated CD4 testing demand.

Performance of laboratory staff on PC-NOW CD4 machine: A full panel of results (CD4 counts, CD4%, and hematology) was obtained on 70% of CD4 samples run, and 89% (363/406) of the samples run with no full panel of results had hematology results. In addition, while 61% of the samples did not give results the first time run, 54% of those samples were re-run successfully. About 55% of all the failed runs failed because users failed to follow the proper procedure of either collecting the blood sample or of running a sample on the PC-NOW CD4 machine. High temperatures and the irregular power supply in Acholi Pii, Moroto, and Nakasongola affected the performance of the PC-NOW CD4 machine.

Recommendations:
- Facilities should conduct CD4 tests mainly on clinic days and any other planned days in case demand exceeds the machine’s daily capacity.
- Clinicians need orientation on the clinical interpretation of CBC differentials to improve use of hematology results and the quality of patient management.
- Facilities should attempt to cohort their patients for CD4 and workout their estimated CD4 demand for proper planning for use of resources; knowledge of average monthly enrollment in ART clinics and number of current active patients in the clinics would be very helpful.
- Users need enhanced training with emphasis on the following:
  - Sample handling techniques – sample collection and proper mixing of gold
  - Clinical and technical implication of flagging system
  - Troubleshooting
  - Proper handling and debugging of small minor problems – i.e., how to clean the bath, bleaching and greasing the syringes
- PointCare Technologies should train a UPDF senior laboratory technician/s to act as a PC-NOW CD4 machine expert and trouble shooter with advanced knowledge of the machines’ operation and maintenance, as the resident PointCare technician may not be able to reach all the machines everywhere they are used. In addition, continuing to refer constantly to the PointCare resident technician is not a sustainable practice.
- The PC-NOW CD4 machines should always be installed with their external power supply accessories so they function adequately in the field setting and to protect the machines from irregular and unstable power sources.
- Experts should determine whether high temperatures in the rooms housing the machines affect the performance of the PC-NOW CD4 machines to rule out any effect on the quality of results generated by the machines in those areas.
1.0 Background

In the era of increased availability of and access to ART, enumeration of an individual’s CD4 count is essential for quality management of HIV-infected patients. The individual’s CD4 count is vital in determining when to initiate ART and monitoring the course of immune suppression. Access to CD4 testing in low-resource countries is, however, limited and commonly centralized to ART centers far away from most patients who are in need of the service. In Uganda, CD4 testing mainly takes place at regional referral or district or private health facilities, most of which are located in urban centers. Because of this level of centralization, CD4 testing remains physically and economically inaccessible to most rural and poor HIV patients. The UPDF is one of those populations with limited access to CD4 testing in Uganda. The mobile nature of the UPDF keeps personnel in hard to reach areas where most health facilities do not offer a number of basic HIV chronic care services, including CD4 testing. Lack of knowledge of CD4 counts is a challenge not only to the HIV-infected UPDF personnel and the health workers taking care of them, but also to their commanders. Knowledge of CD4 counts is crucial for HIV-infected uniformed personnel to receive timely care and also for their commanders to make guided decisions on their deployment. In the UPDF, HIV infection is not a limitation for deployment, although HIV-positive personnel with low CD4 counts are not deployed on strenuous missions until their CD4 count rises to a desired level considered to be of minimal risk to the individual. However, implementation of this policy faced challenges due to limited access to CD4 testing facilities.

To address this problem, in 2008 DHAPP supported UPDF’s efforts to address the challenge of CD4 testing in the military by providing two FACSCalibur CD4 machines to two accredited HIV care and treatment UPDF health facilities. This support to a greater extent improved access to CD4 testing by the military and families in facilities where the machines were located, although patients who were receiving care and treatment in units faraway and in hard to reach areas remained grossly underserved by CD4 testing. Realizing that universal access to CD4 testing could not be achieved through only centralized CD4 testing but could be through both centralized and decentralized networks, DHAPP provided additional support in the form of the PointCare NOW (PC-NOW) CD4 testing machines to UPDF to decentralize CD4 testing services for troops in underserved, hard to reach areas and for mobile troops in operation areas.

The PC-NOW CD4 testing technology delivers two categories of testing: CD4 and CD4%, combined with hematology profiling. It is fully automated and therefore requires no manual pipetting incubation and vortexing. PC-NOW CD4 machines are factory calibrated and do not require gain adjustments or color compensation, nor do they require manual gating or interpretation of data. The PC-NOW CD4 testing machine gives one result in 8 minutes, runs up to 50 samples per day, and has a maximum length of time from blood draw to testing of 8 hours. It has flexible power options—UPS, battery pack, and solar panel for battery life and re-charges. It is easy and safe to use, requires minimal operator training, and its reagents do not need refrigeration. It is because of these characteristics that the PC-NOW CD4 machine was chosen over other CD4 testing technologies to decentralize CD4 testing for military personnel and families in underserved and operation areas.

DHAPP procured and supplied six PC-NOW CD4 machines to UPDF. Four of the six machines were installed at static facilities in underserved areas, while the other two are used for mobile field troops in operation areas. Since the PC-NOW CD4 testing technology was relatively new to UPDF technicians, DHAPP wanted to document the technicians’ experience.
using the PC-NOW machines and the machines’ impacts on HIV care and treatment services in the affected health facilities. In view of this, DHAPP conducted an assessment designed to establish the effect of decentralizing CD4 testing using the PC-NOW technology on the quality of HIV patient care and to document the technicians’ experience using the new PC technology.

Specifically, the assessment was to: establish the impact of decentralizing CD4 testing using the PC-NOW technology on access to CD4 testing and turnaround time getting results to clinicians; determine the level of use of the PC-NOW CD4 machines and related factors; and establish the PC-NOW logistics supply chain and the technicians’ performance and experience using PC-NOW for CD4 testing.

2.0 Methods

2.1 Study Site

The assessment was conducted at the four (Acholi Pii, Mbarara, Moroto, and Nakasongola) military hospitals where the four PC-NOW CD4 machines are installed. The hospitals are located in northern, western, northeastern, and central Uganda between 120 and 500 km from the capital city, Kampala. They are division headquarters hospitals and are among the 14 UPDF ART accredited centers that provide a comprehensive package of HIV prevention, care, and treatment services. They run ART clinics once or twice a week providing a range of HIV chronic care and support services. Table 1 summarizes the ART clinics’ HIV-positive patients’ enrollment status for the four hospitals as of July 2011.

<table>
<thead>
<tr>
<th>Facility</th>
<th># ever enrolled</th>
<th># current active</th>
<th># on ART</th>
<th>Avg # @ clinic day</th>
<th># of clinic days @ week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acholi Pii</td>
<td>2046</td>
<td>1745</td>
<td>566</td>
<td>60</td>
<td>1</td>
</tr>
<tr>
<td>Mbarara</td>
<td>1533</td>
<td>956</td>
<td>263</td>
<td>45</td>
<td>1</td>
</tr>
<tr>
<td>Moroto</td>
<td>1111</td>
<td>987</td>
<td>214</td>
<td>30</td>
<td>2</td>
</tr>
<tr>
<td>Nakasongola</td>
<td>1875</td>
<td>1565</td>
<td>564</td>
<td>75</td>
<td>2</td>
</tr>
</tbody>
</table>

The patients are followed up weekly, biweekly, monthly, or bimonthly depending on their clinical and immunological state and the physical access to their units of deployment, in the case of uniformed personnel. For follow-up, the clients either physically visit the clinics by appointment or are served from their respective sites of deployment, in the case of uniformed personnel deployed in places far from the clinics. As part of the routine patient management process, baseline and monitoring CD4 tests are determined at diagnosis and every six months for each patient under care in the clinics.

Each of the four facilities has an established laboratory that runs basic hematology tests (Hb, WBC count, and differential and other diagnostic tests for the common infections). Before July 2011, all four facilities were not conducting CD4 tests on site. They were referring either patients or blood samples for CD4 testing to the nearby (about 79 to 200 km) public, nongovernmental organization, or general military hospital.
2.2 Data Collection

Data were collected from only four of the six PC-NOW CD4 machines that were supplied; the other two machines were excluded in the assessment. Because those machines were deployed in operation areas and quite mobile, it would have been difficult to keep track of them for regular data collection. Baseline data were collected on the current status of CD4 testing services and other related care and treatment services at the four study facilities. We also collected data prospectively from the four facilities for a period of six months after installation of the PC-NOW CD4 machines. Both quantitative and qualitative data were collected through review of records and interview of laboratory technicians and health care providers working in the HIV clinics at the four facilities.

At inception of the assessment, six laboratory staff (four from the four facilities with the PC-NOW CD4 machines and two from the general military hospital) were centrally trained at the UPDF HIV Directorate for two days by the PC-NOW technician, assisted by an RTI laboratory specialist. The trainees were certificate and diploma holders in laboratory technology. The training covered the general basic operation of the PC-NOW CD4 machine including installation, operation, and trouble shooting. The PC-NOW technician installed the machines at each of the four sites and conducted a one-day, on-site support session for each trainee. Trial CD4 tests were run by the site-trained technicians under the supervision and support of the PC-NOW technician.

At the time of installation of the PC NOW CD4 machines, baseline data on the current status of CD4 testing for each of the facilities were collected. The data collected included: estimated number of CD4 tests done between January and June 2011; estimated number of CD4 tests per day/month; estimated CD4 needs; turnaround time taken to get results to the clinic; and the supply chain of the laboratory supplies. Subsequently, data on CD4 services utilization, PC-NOW functionality, and the PC-NOW logistics supply chain for each facility were collected and summarized on a monthly basis for six months.

3.0 Results

Data were collected from four facilities between July 2011 and February 2012. During this period, 1352 CD4 tests were run by the four facilities, reaching a total 1031 individual patients who had their CD4 tested. The service users included uniformed personnel, family members of the uniformed personnel, and civilians from the surrounding communities using the military facilities. The users were predominantly male (536 or 52%); 278 were female (27%), and 217 (21%) did not specify sex.

In the next section, a summary of key findings is presented under the subheadings of the main areas that were assessed.

3.1 Access to CD4 Testing

3.1.1 CD4 tests run by facilities

It was anticipated that use of PC-NOW CD4 machines to decentralize CD4 testing to the patients’ point of care would increase CD4 testing and also reduce the turnaround time returning CD4 results to the clinician, ultimately leading to improved quality of HIV-positive patient management at the respective facilities. In this assessment, the number of patients who had their CD4 tested six months before installation of PC-NOW machines was
compared to the number tested six months after at the four facilities. The results are presented in Figure 1.

**Figure 1:** Number of CD4 tests done six months before and after PC-NOW installation at the facilities

![Graph showing the number of CD4 tests before and after PC-NOW installation at the facilities.](image)

Overall, there was a 79% increase in absolute number of CD4 tests done at the four facilities six months after the installation of PC-NOW CD4 machines. Excepting Nakasongola hospital, CD4 tests increased in all the facilities, with Acholi Pii and Moroto registering a remarkably high increase compared to the rest of the facilities. Nakasongola’s dip in number of tests performed may be attributed to the fact that the unit had had a higher number of its patients tested before the PC-NOW machine was installed, since it is nearer to the central CD4 testing facility (Bombo General Military Hospital) than the rest, hence had lower demand. Nakasongola also experienced long periods of stock out of PC-NOW reagents during this period.

### 3.1.2 Turnaround time to get CD4 results to the clinician

The time a blood sample was collected and the time the results were sent to the clinician were recorded for every CD4 test that was requested by the clinician. The total time taken from sample collection to the clinician’s receipt of results in the clinic was estimated and compared with baseline data before the installation of the PC-NOW CD4 machine. After the introduction of the PC-NOW CD4 machine, the turnaround time getting CD4 results to the clinician was remarkably reduced. There was a 99% reduction of minimum (48 hours to 30 minutes) and maximum (4 weeks to 4 hours) total time after the introduction of the PC-NOW CD4 machines at the facilities.

One of the reasons the PC-NOW CD4 testing technology was chosen was its ability to test those patients who were eligible for CD4 testing at any time, with results received the same day the patient visits the clinic. To assess the extent to which this was achieved, we determined the proportion of patients who had their CD4 tested with PC-NOW machines, with full results obtained the same day. This was done through analysis of the PC-NOW CD4 machines’ results output. The results are presented in Table 2.
Of the patients who had their CD4 tested with PC-NOW machines, 88% obtained full results the same day. This implies that for those patients, the clinician had the CD4 results to make a clinical decision the same day the patient visited the clinic. The reduction of the time the clinician has to wait for CD4 results to make a clinical decision from one month to same day is a significant achievement that would positively impact the quality of patient management.

In order to better understand how obtaining full results in the laboratory impacted patient management in the clinics, it is important to establish the number of patients with full results who did not receive their results the same day. Since this information was not routinely documented in the clinics’ records, our assessment was based on clinicians’ experience. We interviewed clinic managers to get a sense of what proportion of patients did not receive their results the same clinic visit and also a sense of the extent to which the hematology results were used. Most patients received their results on the same day they underwent CD4 testing with PC-OW machines during our study period; only a small proportion, estimated at 10-15% by the clinicians, did not receive their results the same day. The reasons results were not obtained in the same day included: i) delays because certain samples needed to be re-run and because occasional power failure interrupted the running of samples; ii) patients opted to receive the results next time they visit the clinic; iii) clinicians at times were unable to see the patient a second time to divulge results due to a long queue or large workload; and iv) some patients traveled long distances and were unable to wait for long in the event of some delay in returning results.

With regard to the use of the hematology results produced alongside the CD4 results, the responses from clinicians interviewed on the subject suggested some use of Hb results with minimal use of CBC differentials for clinical decisions. The clinicians appeared more eager to see CD4 counts for the patients, but seemed to have little interest in hematology results. While CBC differentials were minimally utilized by clinicians, analyses of the results from the machines’ printouts revealed the CBC differentials produced clinically relevant results, some of which required urgent action by the clinician. Of the samples run, 23 had abnormally high levels of neutrophils (>70%), indicating a possible bacterial infection that may have presented an immediate threat to the patient.

While the ability to generate hematology results alongside CD4 counts is one of the reasons the PC-NOW CD4 machine was preferred, this benefit was still underutilized by the clinicians at the four facilities. This could be because the cadre of clinicians’ who run the ART clinics have limited knowledge of the interpretation of the CBC differential and the clinical implication of the results. Equipping the clinicians with basic knowledge to interpret...
CBC results would improve use and go a long way to improve the quality of patient management.

### 3.1.3 Enrollment into ART

We examined the frequency of enrollment into ART at the four clinics and compared it to that of six months before installing PC-NOW CD4 machine. In Figure 2 the number of new patients enrolled in ART per site is presented.

**Figure 2: Number of new patients enrolled in ART before and after PC-NOW installation**

There was an increase in the number of new patients enrolled in ART in Moroto, Mbarara, and Acholi Pii after the introduction of PC-NOW CD4 machines. Overall, there was a 35% increase in absolute number of new patients started in ART in the six months after introduction of PC-NOW CD4 machines at the four facilities. These results, however, should be interpreted with caution, as the increase could be a result of the influx of recruits and deployment exercises for the troops that took place during that period, drug availability, and better quality of other services.

Even though in this assessment we did not analyze the effect to retention into care and the time to ART initiation, the benefit of reduced turnaround time reporting CD4 results to the clinicians would contribute to higher ART initiation rates, better patient outcomes, and ultimately fewer patient visits. This argument can be supported by Mamsallah Faal, et al., 2011,¹ and Ilesh V Jani, et al., 2011,² findings that point-of-care CD4 testing reduced opportunities for pretreatment loss to follow-up, leading to more patients identified as eligible for, and initiating, antiretroviral treatment.

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¹ Mamsallah Faal, et al., 2011; Providing Immediate CD4 Count Results at HIV Testing Improves ART initiation, J Acquir Immune Defic Syndr 2011; 58: e54–e59

² Nâdia Sitoe, et al., 2003; Point-of-Care CD4 Improves Patient Retention and Time-to-Initiation for ART in Mozambique, AIDS Conference
Conclusion

- Number of CD4 tests conducted by the facilities increased by 79%.
- Increase in number of CD4 tests was more marked in the previously most underserved facilities of Moroto and Acholi Pii; fewer patients had their CD4 tested in Nakasongola after the PC-NOW CD4 machine was introduced.
- Turnaround time getting CD4 results to the clinician was reduced by 99%.
- About 85% of the patients with CD4 tests run and results obtained received their results the same day they visited the clinic.
- Hematology results produced alongside CD4 counts were minimally used by the clinicians – CBC differentials were rarely used and Hb occasionally used.
- Number enrollment into ART increased by 35% after introduction of PC-NOW CD4 machine.

Recommendation

- Orientation of clinicians on the clinical interpretation of the CBC differentials would improve use of hematology results and the quality of patient management.

3.2 Use of PC-NOW CD4 Machines by the Facilities

The PC-NOW CD4 machines run one blood sample at a time and up to 50 samples a day, at a rate of one sample every 8 minutes. A machine can effectively run on alternative external power sources – the machines are commonly supplied with a solar panel and back-up battery packs that enable them to run for about 48 hours in the absence of power from the main grid. These properties enable a facility to provide CD4 testing as a routine service on a daily basis without many power-related problems. We assessed the level of use of PC-NOW CD4 machines by the facilities based on the manufacturer’s guide to expected daily output. Using the PC-NOW machines’ results outputs, the frequency of CD4 runs and the number of runs per day were determined. Table 3 presents results.

Table 3: Level of PC-NOW use by facilities in relation to machines’ daily output

<table>
<thead>
<tr>
<th>Facility</th>
<th>Total # of CD4 runs</th>
<th>Total # of days CD4 run</th>
<th>Avg # of CD4 runs per day</th>
<th>Max # of CD4 runs per day (PC-Now Guide)</th>
<th>Level of PC-NOW use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acholi Pii</td>
<td>596</td>
<td>68</td>
<td>9</td>
<td>50</td>
<td>17.5</td>
</tr>
<tr>
<td>Mbarara</td>
<td>265</td>
<td>34</td>
<td>8</td>
<td>50</td>
<td>15.6</td>
</tr>
<tr>
<td>Moroto</td>
<td>323</td>
<td>21</td>
<td>15</td>
<td>50</td>
<td>30.8</td>
</tr>
<tr>
<td>Nakasongola</td>
<td>168</td>
<td>20</td>
<td>8</td>
<td>50</td>
<td>16.8</td>
</tr>
</tbody>
</table>
Moroto used the machine more than any other facility (30.8%), while use by the rest of the facilities was about the same. Generally the results reflect gross under-use of the PC-NOW CD4 machines by all the facilities compared to the machines’ expected daily output. However, it is important to note that even at this level of use, access to CD4 testing increased by 79% (Figure 1), which may be a reflection of previous under-service against a high demand.

We calculated the average number of days in a month the PC-NOW was used by each of the facilities. Use of the PC-NOW machines varied across the facilities: Nakasongola, 3 days; Moroto, 4 days; Mbarara, 6 days; and Acholi Pii, 11 days. While the assumption was that the introduction of PC-NOW machines would result in daily CD4 testing at the facilities, this never happened. The facilities mainly conducted CD4 tests on clinic days.

We interviewed clinic managers to establish their clinics’ CD4 demand, and all the facilities had limited knowledge of their CD4 demand. Since there are no cohorts of patients for CD4 testing and their military patients are highly mobile, with an influx of patients whenever there is a deployment, clinics find it challenging to have an accurate estimate of the unit’s CD4 demand. We estimated facilities’ CD4 demand based on the current number of active patients in their ART clinics and the average number of new patients enrolled per month based on past facility performance. Assuming each patient is to be tested twice a year, the estimated demand for CD4 tests per month for each facility is about 79 in Acholi Pii, 46 in Mbarara, 47 in Moroto, and 71 in Nakasongola. With this level of demand, the facilities realistically would need to run CD4 tests for only a maximum of 8 days in a month. In view of this and other possible factors in play, it is not feasible for facilities to run CD4 tests on a daily basis as earlier anticipated. Running CD4 tests on ART clinic days, which the facilities are currently doing, is possibly the most appropriate use.

We interviewed the laboratory technicians to better understand why the PC-NOW machines were only occasionally used. Use of the PC-NOW machines and the number of days the machines were under use was mainly affected by the following factors: i) availability of PC-NOW trained laboratory staff – in the beginning, facilities had only one trained laboratory staff member, and tests could not be run whenever that person was not at the facility; ii) availability of PC-NOW reagents – in the six months studied, all the facilities experienced periods of stock out, with Nakasongola most affected; and iii) irregularities in main power supply – the machines were not originally installed with their alternative power sources functional (solar panel and battery packs); Acholi Pii, Moroto, and Nakasongola were the most affected.
3.3 PC-NOW Supplies

In order to have uninterrupted laboratory services, reagents have to be continuously available at the facilities; however, this cannot be possible without an effective and efficient supply chain. We assessed the existing supply chain for other laboratory reagents to explore the possibility of integrating the PC-NOW supplies.

The four facilities were getting laboratory reagents from two sources, National Medical Stores (NMS) and Bombo General Military Headquarters, through a pull and push system. The reagents were ordered bimonthly from NMS and were normally received about one month after placing the order. Reagents were ordered from Bombo when the facilities were in need, and when the ordered commodity was in stock, it was supplied within one week. The system, however, had irregularities and was characterized by periods of stock outs of commodities, as was evidenced by stock outs of HIV rapid test kits at the four facilities.

The PC-NOW CD4 machine reagents were usually supplied as a kit of 100 tests and included liquipak, gold kit, phlebotomy kit, and a printing paper roll and ribbon for the printer. PC-NOW commodities were not on the list of supplies facilities were mandated to receive from NMS; they were supplied under an understanding between UPDF, PointCare, and DHAPP. We assessed the supply chain for the PC-NOW reagents between July 2011 and February 2012 and how it impacted services. In the next paragraph, the summary of the findings is presented.

The PC-NOW CD4 reagents were imported into the country from PointCare through the country agent for PointCare and delivered to UPDF HIV Directorate. The facilities ordered the reagents from Bombo when they were in need, and the quality supplied mainly depended on the available stock of kits. Between June 2011 and February 2012, 39 kits were received by Bombo. Table 4 shows the stocking pattern of the four facilities over a period of six months.

Conclusion

- All facilities were under-using the PC-NOW machines compared to the expected manufacturer’s daily output.
- Reasons for under-use included:
  - Availability of PC-NOW CD4 machine trained laboratory staff
  - Irregular supply of PC-NOW CD4 reagents
  - Irregular power supply
  - High room temperatures – Acholi Pii and Nakasongola
- Daily CD4 testing by facilities is not feasible considering the current units’ estimated CD4 demands.

Recommendation

- Facilities should conduct CD4 tests mainly on clinic days and any other organized day in case demand exceeds the machine’s daily capacity.
- Facilities should attempt to cohort their patients for CD4 and work out their estimated CD4 demand for proper planning for use of resources. Knowledge of average monthly enrollment in the ART clinic and number of current active patients in the clinic would be very helpful.
For the first three months following installation of PC-NOW machines, the facilities were well stocked. A relatively large start-up stock was supplied to the facilities, and the machines’ use was still low. The stock out experienced by the facilities was attributed to the following factors:

1) turnaround time for supplies to UPDF HIV Directorate – for the first four months, importation of reagents was delayed by the clearance and tax exemption procedures, as the process was not well coordinated between PointCare, the local agent, and UPDF, which delayed reagents’ reaching UPDF and ultimately the facilities; ii) expiry of some reagents in the supplied kits – packs of liquipak in the June consignment expired in Mbarara and Nakasongola in September 2011, and packs of liquipak in the October consignment expired in Moroto, Nakasongola, and Acholi Pii in January; supplied kits had just a month to expiration by the time they were received by the facilities; and iii) knowledge of testing demand – facilities lacked knowledge of their CD4 testing demand, hence did not place orders in a timely manner, but only ordered when they ran out of stock.

We interviewed the laboratory staff at the facilities and the UPDF Director of HIV Services to get their experience of the PC-NOW reagent supply chain in the previous six months. The facility laboratory staff said that whenever they placed an order and the reagents were available in Bombo, they always got the supplies within five days. Many times they ordered reagents, however, Bombo was also out of stock, especially during the months of October 2011 and January 2012. The Director of HIV Services agreed with the facilities that during the previous six months, the supply of PC-NOW reagents was erratic; ordering and importation of reagents from PointCare was not well coordinated; response to orders was not timely; PointCare was not supplying the required quantities; and reagents had short expiration periods. However, he went on to say the situation had changed: the process is now well coordinated; the tax exemption process and the clearance of imported reagents have been streamlined; reagents are now acquired within a week upon placing an order; and required quantities are supplied and have a distant enough expiration date.
3.4 Performance of Laboratory Personnel on PC-NOW CD4 Machines

The PC-NOW CD4 machine is fully automated with all procedures run internally and no need for external preparation of the test procedure by the technician. The machine has a built-in quality control mechanism and internal controls to guide the user. In case an operation step is missed or a blood sample used has a problem, the machine automatically gives a prompt information/flag for the operator to take action. If the operators’ guide is properly followed, maximum and high quality outputs are obtained. The PC-NOW CD4 machine is user friendly and requires minimal operator training.

At the installation of the machines, the Point Care technician, assisted by a RTI laboratory specialist, conducted a one-day training on how to run the PC-NOW CD4 machine for one laboratory staff member from each of the facilities. Two months after the training and installation of the PC-NOW CD4 machines at the facilities, two of the four trained staff were transferred from the facilities. A remedial action was taken, conducting on-site training of more facility laboratory staff on the operation of the PC-NOW CD4 machine. One day of training was conducted for laboratory staff at each facility, followed by ongoing support.

Conclusion

• The PC-NOW reagents have not been integrated with the other laboratory reagents supply chain, mainly because they have a different supply source and they are not on the list of reagents in the NMS.
• Facilities experienced periods of stock outs from around the 4th month due to uncoordinated ordering and importation of the reagents.
• The first and second consignment of reagents had a short period until expiration – some of the reagents expired before they could be used.
• Most facilities did not know their CD4 needs and could not accurately forecast and timely order; most quantities ordered were estimates, and orders were placed when facilities were at zero stock.
• The change of the resident PointCare technician and agent has greatly improved the effectiveness of the supply chain of the reagents.

Recommendation

• Facilities should work out their CD4 demand and use that base to order reagents from the Directorate. This will enable the Directorate to more accurately forecast and timely order sufficient quantities of reagents from PointCare, avoiding the problems of stock outs or overstocking.
• Further strengthening the recently improved coordination of the ordering and importation process of reagents will go a long way to improving the availability of reagents at the facilities and increasing access to CD4 testing.
• Currently the PC-NOW reagents are procured and supplied under an agreement between DHAPP, PointCare, and UPDF. UPDF should forecast and timely plan for the time after the current agreement for continuity of the service.
during monthly technical support visits and telephone call support to address emerging issues from the facilities. Over time, the number of laboratory staff members able to run the PC-NOW has increased to 5 in Acholi Pii, 5 in Mbarara, 2 in Moroto, and 5 in Nakasongola.

To ascertain laboratory staff performance on the PC-NOW machines, we reviewed records of CD4 tests at the facilities and analyzed the PC-NOW CD4 machines’ results outputs. The summary of the number of runs and number of CD4 runs with full panel of results are presented in Table 5.

Table 5: Number of CD4 runs performed and the frequency of obtaining full panel results

<table>
<thead>
<tr>
<th>Facility</th>
<th>Total # of CD4 runs</th>
<th>Total # of CD4 runs with result (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acholi Pii</td>
<td>596</td>
<td>418 (70.1)</td>
</tr>
<tr>
<td>Mbarara</td>
<td>265</td>
<td>178 (67.2)</td>
</tr>
<tr>
<td>Moroto</td>
<td>323</td>
<td>219 (67.8)</td>
</tr>
<tr>
<td>Nakasongola</td>
<td>168</td>
<td>131 (78.0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1352</strong></td>
<td><strong>946 (70.0)</strong></td>
</tr>
</tbody>
</table>

For every 10 CD4 runs, a full panel of results (hematology parameters, CD4 counts, and CD4 %) was obtained on seven. The performance was about the same across facilities and throughout the six months assessed. It is important to note that failure to obtain a full panel of results in most cases was not a total waste of reagents and time: 89% (363/406) of the samples run with no full panel of results nonetheless had hematology results for the clinician to use to make a clinical management decision for the patient.

The PC-NOW CD4 machine has a built-in quality control mechanism to ensure quality of results generated. Because of that mechanism, not all samples run would yield a full panel of results. Users may re-run a single sample if the first run does not produce a full panel of results; however, it is important for a user to know that some samples may never give full results because the quality of the patient sample is unsuitable for testing. During the period of the assessment, a majority (61%) of the samples that did not give results the first time run were re-run successfully in about 54% of the samples. See results in Table 6.
Mbarara, with the highest number of re-runs, had the lowest level of success, while in Nakasongola, with the least number of re-runs, 80% of the re-runs were successful. This is possibly a result of the limited knowledge and skills of the technicians. Mbarara had its trained technician transferred a week after the training; other laboratory staff were then trained on-site. Those staff had difficulties with troubleshooting the machine the first month, and hence had a higher number of failed tests compared to the rest of the facilities. The RTI laboratory specialist reported having received more callbacks from Mbarara because of a failure to obtain results due to user error.

3.4.1 Reason for not obtaining full panel of results

For the CD4 runs without a full panel of results, we analyzed the machines’ data outputs and also interviewed the technicians to understand the reasons results were not obtained. Table 7 summarizes the causes of runs without a full panel of results, as per the analysis of the machines’ results printouts.

### Table 6: Number of CD4 re-runs performed and frequency of obtaining results on re-run

<table>
<thead>
<tr>
<th>Facility</th>
<th>Total # of CD4 runs with no results</th>
<th>Total # of CD4 re-runs (%)</th>
<th># Of CD4 re-run with results (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acholi Pii</td>
<td>178</td>
<td>118 (66.3)</td>
<td>61 (51.7)</td>
</tr>
<tr>
<td>Mbarara</td>
<td>87</td>
<td>64 (74.6)</td>
<td>25 (39.1)</td>
</tr>
<tr>
<td>Moroto</td>
<td>104</td>
<td>49 (47.1)</td>
<td>34 (69.4)</td>
</tr>
<tr>
<td>Nakasongola</td>
<td>37</td>
<td>15 (40.5)</td>
<td>12 (80.0)</td>
</tr>
<tr>
<td>Total</td>
<td>406</td>
<td>246 (60.6)</td>
<td>132 (53.7)</td>
</tr>
</tbody>
</table>

### Table 7: Distribution of the flags on the CD4 runs with no full panel of results

<table>
<thead>
<tr>
<th>Facility</th>
<th># runs without results</th>
<th>Runs aborted (W-CL)</th>
<th>Needle % gap error</th>
<th>User error: Gold mixing (G)</th>
<th>Damaged or clotted sample (N)</th>
<th>Patient profile causes interference (L,l,L5, LM, NH)</th>
<th>Other instrument clog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acholi Pii</td>
<td>178</td>
<td>76</td>
<td>64</td>
<td>5</td>
<td>11</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Mbarara</td>
<td>87</td>
<td>23</td>
<td>33</td>
<td>12</td>
<td>8</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Moroto</td>
<td>104</td>
<td>74</td>
<td>10</td>
<td>15</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Nakasongola</td>
<td>37</td>
<td>12</td>
<td>12</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>406</td>
<td>185(46%)</td>
<td>119 (29%)</td>
<td>35 (9%)</td>
<td>24 (6%)</td>
<td>13 (3%)</td>
<td>17 (4%)</td>
</tr>
</tbody>
</table>
These findings show that a substantial number of runs without results were caused by users failing to follow the proper procedures of either collecting the blood sample or running the sample on the PC-NOW CD4 machine. Important to note however are four different factors. First, most runs (46%) without full results were aborted early, preventing the waste of gold and decreasing the use of other reagents. This not only reduced the cost of the test but also reduced the time, since this took only about 2 of the 8 minutes for the full test. Second, about 9% of the runs without full results were due to failure to mix gold properly, thus damaging the sample, pointing to inadequate techniques of sample handling by the users. Third, 4% of the runs that failed to give results were due to an abnormality of patient cells that may have interfered with the reporting of CD4. It should be noted that users in some cases re-ran these samples 3 to 8 times, yet these samples never gave results on a PC-NOW CD4 machine due to the patient’s profile. This may have been caused by users’ limited knowledge of the machines’ flagging system, which led to wasting reagents. Last, from the results it is important to note that while the L1 flag is known not to prevent reporting of CD4 but only to indicate the presence of platelets or unlysed red blood cells in the sample, the analysis shows a large number of run samples with the L1 flag without CD4 counts. This outcome needs further analysis and the PointCare expert’s view, as these results contradict the earlier given technical interpretation of the flag.

The reasons routinely recorded by the technicians at the facilities for failing to obtain full results do not defer from those of the analysis of the machines’ results output. They include: low cell count, damaged sample, inadequate mixing of gold, needle motor gap error, old sample, and temperature error. Finally, a complaint was raised by a technician and clinician about the observed discrepancy of CD4 results of the same patient tested on a PC-NOW CD4 machine and on a FACSCalibur™. This concern was not followed up by the assessing team. While this may be the result of the technician’s failure to follow the operation procedures of the PC-NOW machine, as it was in the case of one unit for which controls were not run before samples, it is important to note that for this observation to be technically valid, proper methods of comparing the performance of the two technologies must be followed.

3.4.2 Technicians’ experience and observations

The facilities received support from the RTI laboratory specialist and the resident PointCare technician. The RTI laboratory specialist visited facilities and supported the PC-NOW CD4 machine trained laboratory staff on a monthly basis and through telephone calls whenever staff experienced a problem running samples. The resident PointCare technician was consulted on cases that could not be resolved by the RTI laboratory specialist and also was tasked with carrying out preventive maintenance of the machines. The technicians observed that most callbacks from the facilities were due to i) limited knowledge of troubleshooting, and ii) failure to recognize and interpret the flags and perform functions recommended by PointCare. More specific observations that were made by the technicians are summarized in Table 8.
Table 8: Observations made by technicians on PC-NOW use by the four sites

<table>
<thead>
<tr>
<th>Observation</th>
<th>Possible Cause</th>
<th>Action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Instrument taking long to complete start-up cycle</td>
<td>• Users do not run clean and bleach cycles as recommended</td>
<td>• Cleaned and bleached instrument baths and valve 2</td>
</tr>
<tr>
<td>• Instrument rejecting to give CD4 counts, terminating process and fags W_CL</td>
<td>• Instrument baths very dirty and snapped rings; sampling syringe broken</td>
<td>• Printer cleaned and ribbon replaced, and counting head soaked in distilled water and cleaned</td>
</tr>
<tr>
<td>• Users do not run clean and bleach cycles as recommended</td>
<td>• Users do not run clean and bleach cycles as recommended</td>
<td>• Users reoriented on proper handling and debugging of small minor problems</td>
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<td></td>
</tr>
<tr>
<td>• Users reoriented on proper handling and debugging of small minor problems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The machine was leaking from syringe valve area – Acholi Pii</td>
<td>• Machine had some valves that were faulty and some tubes that had leaks</td>
<td>• Complete preventive maintenance was performed and machine worked normally</td>
</tr>
<tr>
<td>• The machine was leaking from syringe valve area – Acholi Pii</td>
<td>• The areas have high temperatures, affecting the cooling system of the machines</td>
<td>• Need to have a supplementary external cooling mechanism for the rooms where the machines are located – a desktop fan or AC</td>
</tr>
<tr>
<td>• Instrument sending error messages of over temperature and motor gap error – Acholi Pii, Moroto, and Nakasongola</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The areas have high temperatures, affecting the cooling system of the machines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The machines are run on irregular power supply source with poor voltage (200 to 270V ac) regulation and unstable frequencies (20 to 70 HZ)</td>
<td>• Need to have a supplementary external cooling mechanism for the rooms where the machines are located – a desktop fan or AC</td>
<td>• All machines should have their external power supply block delivered and installed</td>
</tr>
<tr>
<td>• Running of samples is often interrupted, machines UPSs are not functioning properly or totally down</td>
<td>• The machines are run on irregular power supply source with poor voltage (200 to 270V ac) regulation and unstable frequencies (20 to 70 HZ)</td>
<td>• All machines should have their external power supply block delivered and installed</td>
</tr>
<tr>
<td>• The machines lack the external power supply block (battery pack and solar panel)</td>
<td>• The areas have high temperatures, affecting the cooling system of the machines</td>
<td>• Need to have a supplementary external cooling mechanism for the rooms where the machines are located – a desktop fan or AC</td>
</tr>
</tbody>
</table>

Although the PC-NOW CD4 machine is known to be user-friendly, requiring minimal user training, it was observed that most times a user failed to generate results on the machine the cause was user-related. Most users lacked knowledge of proper handling and debugging of small minor problems, troubleshooting, and the routine maintenance of the machine. The supporting technicians attributed this to the quality of the initial training of the units’ laboratory staff on operation of PC-NOW CD4 machines: a very short time was spent on some of those components, while others were not covered at all. Improved knowledge of and skills in use of the PC-NOW CD4 machine for laboratory staff would significantly reduce the re-run of samples leading to waste of reagents and would reduce the patients’ waiting time. More patients would receive their results the same day, which would result in better patient management.

The PC-NOW CD4 machine has an external power supply source with a battery back-up pack that can run for 48 hours when fully charged. It also has a solar panel to use in case of absence of a main power supply source. It was observed that the external power supply sources and the solar panels of all four machines were at first not installed. The machines were run on irregular power sources with poor voltage and unstable frequencies, which affected the functionality of the UPSs. Because of the unstable power supply, units often experienced abrupt shutdown of machines when running samples. This kind of interruption would leave the machine with a lot of unclean fluids, which led to clogging and either counting errors or even failure to give results, which partly explains the many re-runs in Acholi Pii and Moroto. If this situation is not timely addressed, the irregular power sourcing may damage the machines.
Finally, according to the PC-NOW user guide, the machine is recommended for indoor use at an altitude up to 2,000m, temperature of 18 °C to 34 °C (64°F to 93°F), and maximum relative humidity of 80% for temperatures up to 31 °C, decreasing linearly to 70% relative humidity at 34 °C. The observed high room temperatures in Acholi Pii, Moroto, and Nakasongola limited the machines’ daily output and may have affected the machines. The likely effect on the quality/accuracy of results generated by the machines may need to be explored and explained by an expert.

Conclusion

- There was a high turnover (50%) of the original PC-NOW CD4 machine trained facility laboratory technicians in the first 2 months, contributing to a high number of failed CD4 runs.
- On-site training of new users and ongoing follow-up support of previously trained users increased the number of competent PC-NOW CD4 users at the facilities.
- A full panel of results (CD4 counts, CD4%, and hematology) were obtained on 70% of CD4 samples run; 89% (363/406) of the samples run with no full panel of results had hematology results.
- 61% of the samples that did not give results the first time run, were re-run successfully in about 54% of the samples.
- Mbarara had the highest number of re-runs without results, due to limited knowledge of the basic operation of the machine by the user.
- About 55% of all the failed runs were due to users failing to follow the proper procedure of either collecting the blood sample or of running a sample on a PC-NOW CD4 machine.
- The high temperatures and irregular power supply in Acholi Pii, Moroto, and Nakasongola greatly affected the performance of the PC-NOW CD4 machine.

Recommendations

- The users need enhanced training with emphasis on the following
  - Sample handling techniques – sample collection and proper mixing of gold
  - Clinical and technical implication of flagging system
  - Troubleshooting
  - Proper handling and debugging of small minor problems – i.e., how to clean the bath, bleaching and greasing the syringes
- PointCare Technologies should train a UPDF senior laboratory technician/s to act as PC-NOW CD4 machine expert and trouble shooter with advanced knowledge of the machines’ operation and maintenance, as the resident PointCare technician may not be able to reach all the machines everywhere they are used. In addition, continuing to refer constantly to the PointCare resident technician is not a sustainable practice.
- The PC-NOW CD4 machines should always be installed with their external power supply accessories operational so that they appropriately function in the field setting and to protect machines from irregular and unstable frequencies power sources.
- The case of high temperatures affecting the performance of the PC-NOW CD4 machine should be examined by an expert to rule out any effect on the quality of results generated by the machines in those areas.