PIMA CD4 CELL COUNT MACHINES FOR HIV-POSITIVE WOMEN

The use of point-of-care PIMA CD4 cell count machines for HIV-positive women and their families in Zimbabwe

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BACKGROUND

In Zimbabwe, HIV remains one of the leading causes of mortality (26 per cent) among pregnant women with an estimated Antenatal Clinic (ANC) HIV prevalence of 16 per cent reported in 2009. The burden of mother-to-child transmission of HIV in 2009 was estimated at 68,000 and these statistics clearly indicate the high HIV prevalence amongst women of childbearing age resulting in a high number of children being exposed to HIV.

The Global Plan for the Elimination of Mother-to-Child Transmission of HIV can only be achieved by providing comprehensive maternal newborn and child health (MNCH) services to over 90 per cent of women of childbearing age (WHO, 2010).
JUSTIFICATION OF INNOVATION

The maternal mortality ratio for Zimbabwe continues to be high at 612 per 100,000 live births (MICS 2014). Though down from 960 in 2010/2011 (ZDHS 2010-11), it is still higher than 550 in 2005/2006 (ZDHS 2005-06). The current under-five mortality rate stands at 74 per 1,000 live births (MICS 2014), which is an improvement over the 82 deaths per 1,000 live births in 2005/2006 but still way above the desired target of 34. For both, HIV and AIDS continue to be an important contributor.

Zimbabwe has a high Mother-to-Child Transmission of HIV burden, with an estimated 68,000 HIV-positive pregnancies in 2009. Under Option A (a treatment regimen option), until 2013, a CD4 count was needed to determine whether an HIV-positive pregnant woman was eligible for prophylaxis or lifelong antiretroviral therapy (ART). Therefore, the limited availability of CD4 testing meant that a significant proportion of women who needed ART for their own health could not access the treatment. In addition, in the absence of a viral load, the CD4 count provided an important tool for monitoring treatment response.

In 2010, a total of 41,042 HIV-positive pregnant women were seen in ANCs in public health institutions. Twelve per cent of these were assessed for ART eligibility using only WHO clinical staging, and 31 per cent were assessed using both WHO clinical staging and the CD4 cell count. The remaining 57 per cent were not assessed for ART eligibility (PMTCT 2010 annual report).

In order to accelerate the elimination of new paediatric HIV infections by 2015 the country has to improve access and availability of comprehensive PMTCT services to women and men of reproductive age within a strengthened sexual, and reproductive, maternal, newborn and child health (SRH/MNCH) programme.

In response to the MoHCW’s request to assist districts in increasing access to PMTCT services, UNICEF supported the establishment of PIMA POC CD4 cell count machines in 35 health facilities with a high number of ANC sites, in seven districts in Zimbabwe.

OBJECTIVE

The aim of this initiative was to demonstrate the effectiveness of PIMA POC CD4 machines in MNCH settings in providing increased access to PMTCT services (testing, expediting ART) which curb perinatal HIV transmission.

Specific objectives include:

- Assessing the use of the PIMA POC CD4 count machines for CD4 cell count and documenting best practices and challenges faced.
- Determining the effectiveness of the PIMA POC CD4 count machines in improving the assessment of ART eligibility within MNCH settings for pregnant women and their families; and access to ART for HIV-positive pregnant women in a timely manner during ANC.
- Documenting the process, and challenges if any, experienced in the procurement, distribution and maintenance of the POC CD4 machines.
- Deriving lessons learnt to inform future scale-up of the use of POC CD4 machines across different MNCH settings.
In response to the MoHCW’s request to assist districts with low coverage of PMTCT services, UNICEF procured 45 PIMA POC CD4 machines in 2010/2011. The J.F. Kapnek Trust, a UNICEF implementing partner, supported the distribution and implementation of PIMA POC CD4 cell count machines in 35 high-volume health facilities with over 100 pregnant women seen per month, located in the seven districts of Gokwe North, KweKwe, Mwenezi, Gokwe South, Hurungwe, Wedza and Gwanda. In addition, 10 other sites (two provincial hospitals, two district hospitals, two rural hospitals, two mission hospitals and two clinics) that provided similar services but did not have the PIMA POC CD4 count machines within the district or in the neighbouring district, were selected as study sites.

UNICEF Zimbabwe adopted an evidence-based approach to inform the PIMA POC CD4 count testing programme implementation. This includes consultations with the MoHCW and other key stakeholders. Roles and responsibilities were clearly defined from the outset of the programme. A total of 110 health workers from the 35 health facilities were trained to perform CD4 tests with these machines. The two-day training was conducted to enhance the health workers’ confidence to use all the required equipment at targeted sites. Although the priority use of PIMA POC CD4 count machines was for HIV-positive pregnant women, postpartum mothers and their families as well as HIV testing clients from hard to reach areas where there were no conventional CD4 machines also benefited from this.

A fault reporting system was put in place by Medsure (the local agent for procurement of machines) to handle machine faults. The MoHCW had put systems in place for storage and distribution of reagents through NatPharm and Drug Delivery Team Top-up.

RESULTS

Achievements and Challenges

Procurement, distribution and maintenance of the POC CD4 machines and health worker training

• The procurement process of the PIMA POC CD4 count machines was relatively long at the beginning because this machine had never been used before in the country and was not yet WHO prequalified at the time of procurement.

• The machines were found to be easily usable and maintained at the sites. The machines are battery powered, making them most suitable for remote areas with limited or inconsistent electrical supply.

• The two-day training enhanced the health workers’ confidence in handling CD4 counting among HIV-positive pregnant women. Following the delivery and training in the use of the machine, results have shown that with the right equipment, remote sites are able to provide quality CD4 count testing services for both HIV-positive pregnant women and their families.
There was an inconsistent approach to responding to the need to have more staff trained on the job; with only some sites allowing skills transfer from the trained staff to other staff.

Utilization of the PIMA POC CD4 count machines for CD4 cell count, responsiveness of patients and client management, and documentation of best practices

- There was no difference in performance between nurses and laboratory scientists on the PIMA POC device. This demonstrated that nurses could also operate the machine and that it could be used in non-laboratory settings.

- There was an improvement in client management as a result of the PIMA POC CD4 cell testing in all districts assessed. Prior to the use of the machines, clinical assessments were based on WHO staging and this created numerous challenges in client management – which, in this context, involves reliable clinical assessments, timely ART initiation and client retention due to less referral.

- Client exit interviews showed that the majority (79 per cent) of the clients said they knew what a CD4 cell count test was. Focus group discussions with clients in the seven districts confirmed this. Additionally, about 94 per cent of the clients indicated that they understood why the CD4 cell count test was required.

- Overall, the majority of the clients, when asked to rate friendliness of the health staff that provided services to them on the day of the visit, had a positive perception of them. About 94 per cent said that health staff were friendly. Additionally, about 88 per cent of the clients interviewed on their way out indicated that they did not wait long before they were served.

- Despite some concerns from the health care staff regarding increased workload and the need in some instances to work overtime, the machine was found to have improved service delivery. The number of pregnant mothers delivering before the CD4 cell count test was reduced.

Usefulness of the PIMA POC CD4 count machines in improving assessment of ART eligibility within MNCH settings for pregnant women and their families; and timely access to ART for HIV-positive pregnant women during ANC

- PIMA POC CD4 cell testing can be conducted in a Voluntary Counselling and Testing setting for staging HIV-positive clients, and can produce results similar to those obtained with a laboratory-based flow cytometer.

- Raw data from the J.F. Kapnek Trust showed that from the time of inception of the PIMA POC CD4 cell count machines at the 35 UNICEF supported sites (December 2010 to the end of June 2012) 21,742 people were tested using these machines and a total of 13,152 (60 per cent) had a CD4 cell count of less than or equal to 350 cells/μl hence making them eligible for ART initiation.

- The programme has been successful in improving ART eligibility and ART initiation at sites that were already initiating ART. Of the patients who received their CD4 cell count test result on the first visit, 121 (98 per cent) had the CD4 test result on their records. The median CD4 cell count was 234 IQR (144 – 332) which is below 350. These results clearly show that the majority of mothers had to go on ART. However, according to the WHO staging, the majority of mothers were either in stage I or II and were thus seen as not needing ART.
Out of the 35 PIMA POC CD4 sites that were visited, 18 were ART initiating sites. Data from these 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 initiated on ART was 30 (IQR-1-219), while it was 32.7 days (IQR-1-192) for ART initiating sites with no PIMA POC CD4 cell count machine.

It was largely acknowledged that patient management had improved due to reliable clinical assessments, and also patient retention had improved due to less referrals.

**LESSONS LEARNT**

The key lessons from this evaluation that can inform future scale-up of the use of PIMA POC CD4 count machines across different MNCH settings are the following:

- Both clients and service providers were generally satisfied with the presence of the PIMA POC CD4 count machine at their sites because results were produced on the same day and patient management was better, especially at sites that were also ART-initiation sites.

- Users trained on the job by other users who had undergone formal training expressed confidence in using the machine. However, there is a need for a clear training strategy that provides official training to all POC CD4 count machine users and their supervisors.

- Training of users should pay equal attention to both practical aspects and theory to enhance its effectiveness. It should include more emphasis on error codes, software, data storage and retrieval.

**CONCLUSION**

With support from UNICEF Zimbabwe, the introduction and use of the PIMA POC CD4 count machines in selected health facilities with MNCH settings has contributed to the improvement of service delivery at site. This is due to the provision of timely CD4 cell count results to pregnant mothers in order to assess their eligibility for ART, to improve their own health and prevent the transmission of HIV to their babies. The program has been successful in improving treatment literacy and the awareness of the need for CD4 cell testing and timely initiation on ART amongst pregnant women and their families. Additionally, there is widespread acknowledgement that patient management has improved due to reliable clinical and immunological assessments and, consequently, patient retention has also improved.

**RECOMMENDATIONS FOR NEXT STEPS**

- A quality assurance programme should be implemented to check the quality of results.

- Training should be provided for supervisors and additional staff members so that in the event of staff leaving, on site POC CD4 testing will continue.

- More PIMA POC machines should be placed in in hospitals, specifically in the ANC, Opportunistic Infection and outpatient departments. Ensure that there are two machines allocated to each health facility (or adequate reserve machines), especially in hard to reach places so that service is not disrupted if the battery runs out or there is a machine breakdown, for instance, and to cater to an increased patient load.
• In close collaboration with the MNCH team and Nurse-in-charge, the routine use of the PIMA POC machine Job Aids/SOPs to improve efficiency and accuracy of the CD4 Test results should be emphasized.

• MOHCW must develop a sustainability plan for this new technology which involves allocation of funds to procure and maintain the machines as well as provide the required training to the staff.

FOR MORE INFORMATION: www.unicef.org/evaldatabase/index_69965.html

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