UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE
NATIONAL AIDS CONTROL PROGRAMME

NATIONAL HIV POINT-OF-CARE TESTING GENERIC IMPLEMENTATION GUIDELINE FOR HEALTH CARE SETTINGS

SEPTEMBER, 2015

NATIONAL HIV POINT OF CARE TESTING GENERIC IMPLEMENTATION GUIDELINE FOR HEALTH CARE SETTINGS

Published in 2015

National AIDS Control Programme,

P. O. Box 11857,

Dar-Es-Salaam

Tel.: +255 22 2131213, Fax: +255 22 2138282,

E-mail: info@nacp.go.tz

Website: www.nacp.go.tz

ISBN: 978-9987-650-93-5

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immunodeficiency syndrome
Amref Health Africa	formerly African Medical and Research Foundation (AMREF)
ART	Antiretroviral therapy
CD4	Cluster of differentiation 4
CE	Conformite Europeenne (Europen Conformity)
DHS	Demographic and Health Survey
DSS	Diagnostic services section
EID	Early infant diagnosis
EQA	External quality assessment scheme
FACS	Florescence Antibody Cell Sorter
FDA	Food and Drug Authority
HIV	Human immunodeficiency virus
HR	Human resource
HSHSP	Health Sector HIV and AIDS Strategic Plan
HVL	HIV viral load
IQC	Internal Quality Control
LIS	Laboratory Information System
LTFU	Loss to follow up
M&E	Monitoring and evaluation
MOHSW	Ministry of Health and Social Welfare
MSD	Medical Stores Department
NACP	National AIDS Control Programme
NHLQATC	National Health Laboratory Quality Assurance and Training Centre

NHLSSL	National Health Laboratory Service Supplies List
NHLPC	National Health Laboratory Practitioners' Council
NPV	Negative predictive value
^{o}C	Degrees centigrade
PHLB	Private Health Laboratory Board
PIMA	A point of care CD4 enumeration machine
PMS	Procurement management system
POC	Point of Care
POCT	Point of care technologies
PPV	Positive predictive value
QA	Quality assurance
QC	Quality control
SOP	Standard operating procedure
TAT	Turn around time
TB	Tuberculosis
TOT	Trainer of trainer
TWG	Technical working group
US	United States
VCT	Voluntary counseling and testing

ACKNOWLEDGEMENT

The Point of Care (POC) Testing Generic Implementation guideline is a result of strong commitment from the Ministry of Health and Social Welfare (MOHSW) through the National AIDS Control Program (NACP) in collaboration with Clinton Health Access Initiative (CHAI) and other stakeholders toward ensuring the execution of Health sector HIV and AIDS Strategic Plan III (HSHSP III) is achieved by 2017. The NACP would like to sincerely thank (CHAI) for providing funding and technical support that enabled technical team to develop this guideline

The NACP acknowledges the support from the following organization for allowing their staff to work hand –in –hand with NACP staff to review the CD4 POC testing implementation plan and develop this POC Testing Generic Implementation Guideline in to Tanzanian context: Amref Health Africa (formerly African Medical and Research Foundation – AMREF), Ariel Glasier Paediatric Healthcare Initiative (AGPAHI), Centers for Disease Control and Prevention (CDC), Christian Social Services Commission (CSSC), Department of Defense (DOD)/Walter Reed Program (WRP), Elizabeth Glasier Pediatric AIDS Foundation (EGPAF), John Snow Inc. (JSI)/Supply Chain Management System (SCMS), Medical Store Department (MSD), Tanzania Health Promotion Support (THPS), United Nations Children's Fund (UNICEF).

Last but not least the NACP would like to convey sincere thanks to all MOHSW staff from Departments, Sections, Programs and Professional Councils (appendix 1) for their valuable contributions towards developments of the guidelines. Specifically, the NACP commends the tireless efforts of the secretariat team for coordination process and finalization of the document.

Dr. Angela A. Ramadhani
Program Manager
National AIDS Control Program

FOREWORD

Point of care (POC) testing is defined as medical testing that is offered at or near the site of patient care, this includes simple laboratory tests that are performed at the bed side of the patient. The POC testing add significant benefits to the patients as they receive early diagnosis and prompt effective interventions.

In HIV programs, POC testing plays an important role in facilitating early diagnosis and treatment initiation along the cascade of continuum of care. It more significant in countries like Tanzania, where there is limited access to diagnostic and monitoring tests for HIV patients.

Currently, Point of care technologies (POCT) that are simple to use and require minimal training to the users are becoming available. These technologies are intended to improve care and treatment services by increasing accessibility to testing at the lower health facilities, which are remote and hard to reach. The important impact of POCT includes the reduction of Results Turnaround time (TAT) which in turn reduces patients who are lost to follow up while waiting for the results. Furthermore the same day results will aid the treatment monitoring as well as identification of patients on treatment failure which will increase patient retention. Like other testing platforms, POCT have challenges, which include service, maintenance, quality assurance and supply chain management.

In 2012 Tanzania successfully evaluated one CD4 POCT, which was followed up with the implementation. Currently the scaling up to more care and treatment facilities is on going

The CD4 POC implementation plan has been used as the guidance in deploying CD4 Point of care testing. However, as the country is planning to introduce more POCT for CD4, EID and HVL, the necessity of having the generic implementation guideline was deemed necessary hence, the development of these guidelines.

NACP believes that this generic POC implementation guideline will help to standardize and ensure effective and successful introduction, implementation and monitoring of POC testing in Tanzania.

Dr. Neema Rusibamayila
Director of Preventive Services

DEFINITION OF TERMS

The following definitions apply to the terms used in this document:

Monitoring: is the routine tracking of service and program performance using information collected on an ongoing basis. Monitoring is used to assess the extent to which a program is achieving its intended activity outputs and targets.

Evaluation: is the episodic assessment of changes in results that can be attributed to program activities. It uses monitoring data as well as additional indicators and information that are not collected through routine information collection. Evaluation explores the causes of failure to achieve the expected results as planned and allows for mid-course corrections that may be necessary.

Evaluation is concerned with measuring both the progress in program implementation and the outcomes and impact of program activities on target populations.

An indicator: is a quantitative or qualitative measure that helps to determine how well a system or program performs and progresses towards meeting its objectives.

Duplicate testing: is a model of EQAS, where a subset of samples of at least 5%-10% of monthly testing volume is initially tested on the POCT, while a venous blood sample from the subset of patients' samples is sent to the nearest referral laboratory for testing using the reference technology.

80% shelf life: is a lengthy that a commodity may be stored without becoming unfit for use for not less than 80% in calculating the total shelf life.

EXECUTIVE SUMMARY

This Point of care generic implementation guideline describes an implementation guideline on introducing the wide spread use of POCT in CD4, EID and HVL tests in Tanzania. Tanzania has been conducting HIV laboratory tests since early 1990. The main focus of NACP is to increase access to care and treatment services by expanding HIV laboratory testing services through Point of care testing. Over the past three years, the country has introduced CD4 POCT including bringing in Alere PIMA device, which currently accommodate 38% of onsite CD4 testing to care and treatment health facilities. This is in line with Health Sector HIV/AIDS Strategic Plan (HSHSP) III. The Ministry of Health and Social Welfare (MOHSW) in collaboration with implementing partners has realized the achievement brought by CD4 POCT that includes reducing the turnaround time of CD4 testing to the same day of the clinic visit, earlier initiation of ART up to two weeks and decrease of LTFU patients who were frustrated by waiting for the results for more than one month. The device showed a major impact to support laboratory service and bring services closer to the patients. (NACP unpublished data)

The program has five central laboratories that serve more than 4,000 PMTCT and 1,200 CTC facilities, which still face the challenge of providing reliable testing services due to frequent equipment breakdown and long TAT. Therefore, there is still a need to expand the POC testing service to EID and HVL tests and bring services closer to the patients. Success in this will constitute the provision of quality testing at ART health facilities.

The POCT are rapidly evolving with new devices coming to market and a number of countries looking to introduce them. These recent developments of technologies have made it necessary for the country to revise the POC CD4 implementation guideline and come up with an updated POC generic implementation guideline to reflect the changes that have taken place.

The scope of the document covers but is not limited to the following areas: product selection, regulatory approval processes required from importation of the devices going through evaluation/validation up to registration, setting criteria for selecting sites to encourage the right deployment of POCT, training and certification for healthcare service providers, quality assessment on devices and testing being done at health facilities, service and maintenance of

POCT after being deployed to cut service interruption, quality data management and monitoring and evaluation of the POCT services to assess if intended impact is met.

As POCT will continue to be procured, the document will be periodically updated to reflect the new developments in diagnostic landscape. The contribution from implementers and users of POCT will be vital and will be used in revision of this guideline.

CHAPTER 1: INTRODUCTION

Background

Tanzania has a high burden of the HIV and AIDS epidemic. Since 1983, when three cases of AIDS were reported, the HIV epidemic has spread to all regions in the country. The overall prevalence is 5.1% among adults and 7% among children. HIV prevalence is higher among women (6.2%) than among men (3.8%), and people living in urban areas have higher prevalence than those in rural areas for both men and women (THMIS 2011-2012). Tanzania is one of the sub-Saharan African countries where HIV/AIDS is a major public health problem. Several factors that have been reported to contribute to the high prevalence include but are not limited to promiscuous sexual behavior, concurrent sexual partners, presence of other sexually transmitted infections (e.g. herpes simplex virus), and inadequate comprehensive knowledge of HIV transmission (UNAIDS, 2012: UNICEF, 2010).

Prior to 2012, Tanzania has been conducting laboratory based CD4 testing for ART eligibility and monitoring using manual, semi-automated and fully automated conventional CD4 platforms. However, due to laboratory based CD4 testing challenges, in 2012 Tanzania introduced POCT to increase access to CD4 at lower level health facilities. Currently the country has 450 CD4 POCT (PIMA machines);and as the country is considering also introducing POCT for early infant diagnosis (EID) and HIV viral load (HVL) testing, this guideline will provide guidance on the adoption and implementation of POCT ranging from product selection, importation processes, technical evaluation to site selection, deployment and monitoring and evaluation (M&E). The Ministry of Health and Social Welfare (MOHSW) through National AIDS Control Program (NACP) will administer this guideline. MOHSW HIV care and treatment partners must follow this document as they continue to support to scale-up HIV and AIDS services to clients.

Justification

In resource-limited settings such as Tanzania, inexpensive, accurate, quick and user friendly diagnostic POCT are essential to address challenges in access to diagnosis of infectious diseases such as HIV, TB, malaria and other communicable diseases.

Currently, EID and HVL testing are offered at five (5) zonal referral and national laboratories but CD4 testing has been decentralized to over 450 lower level health facilities through

provision of POCT. Even though efforts have been made to address access to onsite testing, there are still gaps in reaching all patients who require a CD4 test. Even patients who do have reliable access to testing often have to make multiple visits to health facilities for blood draw, test results and routine clinical care. In many cases, the sacrifice made by patients during clinical visits amounts to significant time and resources lost seeking services, that are inefficient and often result in long Turn Around Time (TAT) of results that lead to late initiation and poor clinical outcomes.

Additionally, existing conventional systems rely on ineffective sample transport networks that travel across difficult terrain that hampers quality and integrity of the samples due to the sample handling and cold chain requirements. The sample transport network systems are often limited and expensive. Frequent instrument breakdowns and limited capacity at zonal referral and national laboratories constrain the total throughput, leading to backlogs and long waiting periods between tests.

Currently, varieties of POCT that are user friendly and require minimal training are becoming available in the market. This translates to increased and improved access to these essential services at lower level health facilities. The overall impact can result in reduced TAT of results, improvement in early identification and triage into ART, and reduced LTFU of patients who drop off through the cascade of care and treatment.

POCT have been included in Tanzanian Health Sector HIV and AIDS Strategic Plan III (HSHSP III) of 2013 to 2017, which elaborates on the target for diagnostics service in CD4, EID and HVL at all levels of health facilities.

Presently, there is only a National Implementation Plan for POC CD4 Testing (MOHSW 2011), but the current pipeline of POCT in CD4, EID and HVL, has necessitated the development of a generic POC implementation guideline that addresses different test types and the strategies that will be adopted to successfully implement them in the country.

CHAPTER 2: REGULATORY PROCESS

Adoption and implementation of appropriate high-quality POCT requires guidelines that will ensure that only POCT that meet high quality standards are approved for clinical care in the country. It is essential to establish a clearly defined, transparent approval mechanism for POCT within the regulatory authority body and to ensure compliance with the guiding principles.

POCT regulatory approval processes ensure implementation and procurement of appropriate high-quality POCT and supplies, proper distribution and maintenance, as well as proper handling practices.

The Private Health Laboratory Board (PHLB) of the MOHSW will administer POCT regulatory approval processes in terms of importation, regulation and registration. NACP and NHLQATC will manage POCT product selection, implementation, quality assurance and M&E of POCT performance.

Procedures for Regulatory Approval

The Private Health Laboratory Regulations Act, 1997 (No.10 of 1997) provides for control of importation of health laboratory products and supplies. The law requires that any persons dealing with importation of POCT must be registered under the National Health Laboratory Service and Supplies List (NHLSSL) and the POCT users must be trained and certified by the recognized national authority.

For The POCT to be successfully evaluated and implemented in the country, the PHLAB shall be notified in writing on the need of evaluation, and then the board will review and come up with decisions on the request.

After the board's decision on evaluation, the Board Registrar shall appoint the laboratory that will carry out the evaluation exercise and submit the evaluation report back to the board where further decisions will be made.

Following the board's review on the POCT evaluation report, the Board Registrar shall notify the manufacturer/supplier or partner in writing on the decision accompanied by a copy of the evaluation report. The POCT that will pass evaluations, either in Tanzania or a neighboring

country, will be considered for registration in the country. The Board will only consider approval and registration of POCT or supplies evaluated in the country.

Procedure for listing and updating approved POCT

The MOHSW has the responsibility to ensure that all POCT used in the country are of the best quality and standard.

The approved POCT have to be listed on the national equipment list if it has to be considered for deployment through National AIDS Control Programme or Partner. This can be achieved through evaluating products entering into the country by rigorously assessing supplier and/or company data. Evaluation and monitoring of these products, whether new in the market or already established, provides confidence that the products will continue to meet acceptable standards.

Requirements for adverse incident reporting

An adverse incident is an event that causes or has the potential to cause unexpected or unwanted effects for example, an incorrect result will lead to delayed or inappropriate care and treatment, which may result in serious deterioration in health of a client, including death. Any adverse incidents involving POCT should be reported to NACP using specified adverse incident reporting forms. All communication on adverse incident reporting should be coordinated by NACP.

Recall of POCT products and supplies

The MOHSW will regularly conduct post market surveillance of POCT products and supplies in use in the country. These could be products that are already in the market or donated and in use at health facilities. A product will be considered unsatisfactory and be recalled from use if POCT products and/or supplies do not perform to the standard. NACP will inform the supplier on sub standard of POCT products and supplies

CHAPTER 3: PRODUCT AND SITE SELECTION AND DEPLOYMENT

Product Selection

The product selection process should be transparent and carefully consider a wide range of criteria, including POCT's performance (sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV)) and operational characteristics, such as throughput and power requirements, climate and environmental factors, international regulatory approvals such as WHO Pre-qualification, Conformite Europeenne (CE) mark or US-FDA, and instruction and display language for the machine. POCT must be approved and listed on the national equipment list in the national operational plan in order for them to be deployed. NACP and Diagnostic Service Section (DSS) of MOHSW will lead the product selection process and make decisions.

The minimum product selection criteria for POCT include but are not limited to:

- Robust, operable in extreme environmental conditions such as temperatures 10-40^{o}C, humidity 0 to 85%, altitude 0 to 3,500 meter, without the requirement for air conditioning
- Simple and user friendly for laboratory and non-laboratory health service providers
- Minimal operational steps
- Minimum extra sample preparation e.g. dilution, centrifugation
- Minimum or no requirement for preventive maintenance
- Reagents, supplies and consumables must be stable at room temperature for 80% shelf life
- Capability to export data through connectivity or memory device and send to the national data manage system
- Minimum throughout of 10 samples per day
- Cost per test comparable to existing conventional platforms
- Built-in QA/QC process
- User and environment friendly with clear disposal guidance

Site Selection

In Tanzania, there are currently 250 (210 FACSCount and 40 FACSCalibur) sites offering conventional CD4 testing, including regional hospitals, district hospitals and some health centers. HVL and EID are performed at five (5) zonal referral and national laboratories (Muhimbili National Hospital, Bugando Medical Center, Mbeya Referral Hospital, KCMC Hospital and NHLQATC). Additionally, there are 1,209 Care and Treatment Centers (CTC), including sites that can initiate patients onto ART and sites that refill ART prescriptions but cannot initiate ART. There are also 4,914 PMTCT sites that can offer HIV prophylaxis and 6,123 (CTC plus PMTCT sites) sites that are offering Option B plus for pregnant women, and 5,520 stand alone VCT sites that offer HIV diagnosis. Altogether, this amounts to a total of 11,643 potential POC sites, where POCT would be the only means of increasing access to on-site testing by complementing to the facilities where conventional does not suffice (NACP Program Data, December 2014).

Many sites currently have access to CD4 testing through referral and sample transportation to regional and district hospitals. This access is erratic and results in long TAT and high LTFU, even in urban areas. Studies have shown that more than 50% of patients diagnosed HIV-positive are lost before receiving a baseline CD4 result, even in urban health centers that are close to conventional CD4 laboratories and have reliable access to sample transportation. The high patient volume at larger urban sites mean that even low LTFU may result in more patients lost[1].

Patient volume: In the current economic climate where it is necessary to maximize the value for money from investment in HIV care and treatment program, the overall strategy for implementing POCT will be to prioritize sites, where the investment in POCT will have the greatest impact on patients. The sites without access to on-site testing account for approximately 50% of the HIV disease monitoring testing volumes (NACP unpublished data), assuming all patients receive the recommended number of tests per year. Placing POCT at the high volume CTC sites would maximize the impact on LTFU and ART initiation rates countrywide. Sites without access to on-site testing will also be prioritized for

[1]Jani IV, Sitoe NE, Alfai ER, Chongo PL, Quevedo JI, Rocha BM, Lehe JD, Peter TF. Effect of Point of care CD4 cell counts tests on retention of patients and rates of antiretroviral therapy initiation in primary health clinics: an observational cohort study. Lancet 2011 October 29:378 (9802)

POCT deployment, due to the long TAT and high LTFU resulting from referring samples to conventional laboratories.

Key populations: However, some sites with conventional platform instruments may also receive POCT. For example, specific entry points, where there are high numbers of priority patients, such as pregnant women presenting at the maternity ward or new patients being diagnosed at the VCT site within a regional or district hospital may be considered. These patients can also benefit from receiving expedited same-day on-site testing and being linked to care immediately. Likewise, as CD4 testing and EID are the primary indicators for eligibility for ART initiation, on-site access to testing will maximize patient impact at sites, where ART initiation is offered. Therefore, patient care centers can be prioritized for POCT deployment.

Other criteria: Additional criteria for site selection may include TAT from sample collection to receiving results, the distance from the nearest conventional testing site, infrastructure, LTFU rates and human resources (HR) capacity. HIV prevalence in each region may be considered to increase access to more patients but also can account for areas where there may be limited numbers of patients enrolled due to low coverage of ART services, but there may be growth potential in patient numbers due to the high underlying HIV burden.

Deployment Planning

The deployment of POCT should follow the procedure established by this guideline. A technical team in the MOHSW under Diagnostic Service Section (DSS) in collaboration with NACP, MSD, PHLB and other stakeholders must lead product and site selection for all POCT. Deployment of CD4, EID and HVL POCT should:

- Define goals of deployment of POCT in sites
- Set targets at the facility level for the following indicators
  - Number of total POCT performed annually
- Set targets for the number of sites successfully passing competency assessment following POCT user training
- Implement capacity building of service providers with the involvement from manufacturers and suppliers
  - Master trainer and Engineers
  - TOT and site-level training
  - Training package
  - Service and maintenance, mentorship, training and refresher training

CHAPTER 4: SUPPLY CHAIN AND MANAGEMENT

Supply Chain

A supply chain management system includes procurement, storage, distribution and inventory management. The procurement, distribution and inventory of POC products and supplies are coordinated by NACP through MSD. NHLQATC through MSD shall inspect all batches of reagents before distribution to POCT heath facilities. Quantification and procurement processes for new or upgraded POCT to be procured will be guided by the Diagnostic section of the MOHSW. The supply chain management system should entail the following areas:

Procurement

All procurement activities shall comply with the regulations of the MOHSW, which will select the modes of tendering and procurement and establish prices, including reagent rental.

Inventory Management

Storage and distribution of products and supplies will be conducted through Medical Store Department (MSD) for NACP supported commodities. Consumption data on POCT products and supplies will be collected biannually, and the equipment operational status and stock data of POC products and supplies will be reported monthly. Given some POCT will have connectivity capability consumption data will be reported daily.

Waste Management

Used and expired POCT products and supplies shall be disposed of according to government regulations[2]. The disposal process is overseen by the procurement department of the MOHSW as indicated in the waste management disposal guideline.

[2] Health Laboratory Safety and Waste Management Manual, MOHSW, November 2006

CHAPTER FIVE: TRAINING AND MENTORSHIP

Training

Training and mentorship is a critical component on implementation of the POCT to maintain high quality of POC testing and the skills of POCT operators. Training for POCT will be conducted at different levels of service provision. The training will be conducted not only to equip individual operators with the ability to perform high quality testing that impacts patient care and management, but also to build capacity within the MOHSW to conduct trainings and mentorship. A well-designed training and mentorship program will ensure POC testing is conducted by certified facilities and operators, strengthen mentorship and supervision at all levels of the healthcare system, and achieve maximum impact on patients. POCT will be deployed only at facilities where staff have been trained and certified. Also POC testing should only performed by trained and certified health staff. The structure of a training program should follow:

Training of Trainers

Master trainers should be identified and trained at the national, zonal, and/or regional levels, who will then cascade the training down to the facility level. TOT will occur immediately after approval is given for the national rollout of new POCT. TOT will be trained for 3-5 days, targeting senior laboratory personnel from the MOHSW diagnostic services and regional hospital laboratories. TOT from each of the four zones and from 25 regions will be included in the training and expedite the dissemination of this training down to the regional, district, and facility level. The training will emphasize the technology-neutral deployment of POCT, by focusing on the operational systems necessary to support on-going testing, such as quality assurance, data management and clinic workflow. This training will be held at a central location, bringing together staff from across the zones and regions.

The following are proposed roles for each group in the training and supervision of health facility staff on POCT:

Diagnostics Services Section (DSS)/MOHSW: The DSS will be responsible for maintaining and updating data on which sites and personnel are certified as well as making sure that zonal and regional teams conduct health facility supervision visits.

NACP laboratory team and DSS will be responsible to plan, co-ordinate, prepare training material, and certification

The Manufacture/ Supplier will be responsible for conducting TOT training including supporting logistics

Operator training and certification

Trained health service providers will undergo a certification process to determine competency to use POCT. This will include a certification of each individual who will provide testing. This will be observation exercise where each operator performing 5-10 POC tests under direct supervision. No operator will be permitted to give POC testing results to patients until this certification process is complete. In the case that an operator does not perform adequately during the certification process, this can be addressed with retraining.
The National Health Laboratory Practitioners' Council will be responsible for Operator certification

Mentoring and supervision

The DSS, zonal and regional laboratory personnel will be required to provide strong mentorship and supervision to all POCT and operators. Master trainers who have undergone the TOT will schedule periodic visits to each POC testing facility and be required to observe each operator to ensure that the sample collection and test procedure is correct, and to ensure that the recommended operational standards for POC testing are being followed. Immediately following operator training, each facility should be visited within a maximum of three months to conduct mentoring and supervision. Any non-conformity events identified relating to the correct technical operation or the appropriate operational deployment of the POCT will be managed by conducting operator quarterly on-site mentorship and refresher training.

CHAPTER SIX: QUALITY ASSURANCE

It is important to ensure that results produced at all health facilities with POCT for CD4, HVL and EID are accurate, reliable and prompt for diagnosis and management of HIV and AIDS. The DSS through NHLQATC shall perform quality checks to all batches of reagents and/or cartridges before distribution to health facilities. All testers should be thoroughly trained in all aspects of sample analyses (pre-examination, examination and post-examination) and certified competent before performing any tests. Quality assurance (QA) of HIV POCT will be effectively provided through the following mechanisms:

Internal quality control

Controls materials must be run as recommended and pass before running test samples, if applicable to the technology. Interpretation should be based on the acceptable ranges. If any IQC results fall outside of the acceptable ranges, trouble-shooting mechanisms must be performed prior to running patient samples. For POCT with inbuilt quality control with each test run, the accuracy or inaccuracy of test result will be based on the control result. All control results should be documented and recorded according to SOPs. The IQC results should be also stored automatically in the testing device, which can be retrieved when needed. For the POCT without internal memory IQC results should be documented in the registers. Supportive supervision will be conducted for all health facilities by trained supervisors from districts and/or national level, and appropriate corrective action taken to address poor and non-responding sites.

External Quality Assessment Program

Health facilities with POCT shall enroll in an external quality assessment schemes (EQAS) either nationally or internationally. EQAS will be coordinated by NHLQATC. After enrollment the health facilities will be provided with all procedures necessary for testing including the calendar and logistic issues. Supportive supervision will be conducted for all health facilities by trained supervisors from districts and/or national level, and appropriate corrective action taken to address poor and non-responding sites.

Operator quality monitoring

For POC facilities that are not enrolled on EQA program ongoing performance monitoring will be needed to ensure that testers are consistently competent, testers will be thoroughly trained in all aspects of testing processes (pre-examination, examination and post-examination). Operators that successfully complete the quality monitoring process will be certified as competent by the supervisor. Monitoring operator using duplicate tests will be done every six months. Samples for duplicate testing will be prepared at nearby convectional or POC facilities in three (High, normal and low) duplicates. Thereafter, samples will be transported to an intended POC facility for retesting according to sample transportation SOP. The results from POC site and higher-level laboratory will be compared and the discrepancy between the two should not exceed ±10% for quantitative tests; and known or unknown for qualitative tests. For POCT that has connectivity capability, connectivity can be used to monitor operator performance. Appropriate corrective action including refresher training and mentoring should be carried out to operators with unallowable result discrepancies. The laboratory personnel or POC supervisor at higher-level health facility will be responsible for managing this process.

CHAPTER SEVEN: SERVICE AND MAINTENANCE

It is critical to develop a system to ensure that equipment is well maintained to avoid disruption in testing services. Service and maintenance of devices at health facilities with POC will be provided through the following mechanisms:

Device swap-out service

The POCT should be designed to be robust enough to operate and be transported across challenging environments that have high humidity and temperature ranges and excess dust. However, they are subject to regular wear, tear and occasional breakdown. Therefore, to ensure that all devices are kept running with minimal disruption of testing services in case of breakdown, a full swap-out service is to be adopted. Non-functional devices will be replaced by a new functioning device by the vendor at no additional charge to a customer. In order to maintain testing continuity, it is recommended that at least 10% of new devices be kept at the government zonal equipment maintenance centers. The zonal centers will be strengthened to provide swap-out services. The vendor should be able to provide the swap-out services within 48 hours after receiving information through the service and maintenance communication channel about equipment break down. For POCT that has connectivity capability, connectivity can be used to monitor device performance and identify early non performing devices for quick swap-out.

Device warranty

POCT should be purchased with a minimum of two-year warranty after equipment installation, training, validation and deployment inclusive of the full swap-out service. It is critical that budgeting for the subsequent service and maintenance after the warranty expires be determined on the performance of the manufacturer/supplier, equipment performance and reagent consumption in the first year.

Device leasing option

A separate option of providing service and maintenance is to lease POC devices rather than purchasing them. By leasing devices for a fixed period of time the country foregoes additional upfront capital cost of servicing and maintains the fleet of POC devices. The cost of the device and service and maintenance is bundled into the reagent rental price per test. For instance, at expected testing volume per health facility in Tanzania, the overall reagent rental cost of POC, inclusive of service and maintenance could be negotiated to be inclusive of the cost of the test.

CHAPTER EIGHT: DATA MANAGEMENT AND MONITORING AND EVALUATION

Data Management

Data management comprises of all the disciplines related to managing data as valuable resources. On decentralizing POC testing to lower levels of healthcare facilities within Tanzania, it is important that systems are developed to monitor the data generated by POCT through these methods of testing. Data management systems shall be developed at all levels, and can potentially leverage mobile technology to collect and analyze data from every health facility conducting POCT. Data management systems will be put in place at the following levels:

Health facility Level Data Management:

To ensure that POCT achieves its intended purpose of accelerating early initiation of eligible patients onto ART and early identification to treatment failure, a system should be put in place to ensure the effective management of patient data at the health facility level. There should be standardized recording and reporting tools at all health facilities.

The system shall dictate how POC results flow from the healthcare worker who performs POC testing to the patient, and how results are recorded into health facility logbooks and the patient's file.

The impact of POC testing on patient outcomes relies on effective data management systems to minimize barriers around misplaced test results and wastage of critical resources that delay clinical decisions to improved health outcomes.

Testing data can be stored in the POC device's memory if the POC device has an inbuilt data storage mechanism. This information may include details of the operators, device maintenance, QC, device malfunction and test results.

Health facility level data management will be covered in both the Training of Trainers and the health facility on job training modules.

The Facility should have the system in place for data security, archiving and back up.

District and Regional level data management

Data from POCT at the health facility level should be revised and crosschecked at district and regional level by using mobile technology and LIS among other advanced methods. District/Regional provides immediate technical assistant and supervisors of POC and uses the data for programmatic planning such as supervision and mentorships.

National level data management

Data from POCT at the health facility level should feed into the national database. The systems to capture and send POC data from facility level to national level should be harmonized and agreed by LIS TWG.

Standard Operating Procedures (SOPs) should be in place to ensure complete and efficient data flow to the national level. These SOPs should specify how often data should be collected and entered into the national database, and how quality control of the data should be conducted. There should be a system in place to ensure all data sent to the national level is protected and secured.

Monitoring & Evaluation

Monitoring and evaluation of HIV POCT play an important role in determining the effectiveness, efficiency and impact of POC testing in HIV and AIDS program by ensuring that:

- Clinic and patient impacts of POC testing are maintained;
- Resources devoted to a program are used appropriately;
- Services provided are accessed by the target population;
- Program activities happen in a timely manner;
- Expected results are achieved.

The main goals of introducing POCT in Tanzania is to increase timely uptake of CD4, EID and HVL testing, increase timely receipt of results to improve and accelerate ART initiation of eligible patients.

A monitoring &evaluation (M&E) framework should be implemented to measure the scale-up and to assess the impact of this program in achieving these goals. The following indicators are used to measure the success of the program:

Program scale-up:

To measure the goals of scaling up POCT in public health facilities in Tanzania, targets will be set for some or all of the following indicators:

1. Number of POC devices in use;
2. Number of sites trained to perform POCT;
3. Number of healthcare workers trained and certified to perform POCT;
4. Number of sites successfully passing EQA for POCT;
5. Number of POC tests performed on HIV-positive patients;
6. Percentage of total HIV-positive patients tested for CD4, EID and HVL using POCT.

Evaluating the impact of the program

This program is expected to generate significant patient benefits and separate indicators that will be used to measure the impact of POC testing on patient outcomes. These indicators will be measured by comparing the sites where POC is implemented to a baseline assessment of the same health care facilities before the introduction of POC and/or by comparing POC health facilities to control facilities that are not introducing this intervention. The indicators measured to reflect the main goals of this program are:

1. Increase timely uptake of POC testing and timely receipt of results

    - **Access to POC testing:** will be measured first by calculating the percent of appropriate patients receiving a HVL, EID or CD4 test, including newly-diagnosed HIV-positive patients and HIV-positive patients returning for follow-up visits.
    - **Turn-around time:** will be measured by calculating the average time (same day) between sample collections to results received by the patients. Data from the laboratory POC testing registers will be used as a data sources.

2. Improve and accelerate treatment of eligible patients

- **Access to treatment:** Patients tested using HIV POC diagnostic (EID) and ART eligibility (CD4) tests will need to be enrolled onto ART care and treatment. This will be measured by calculating the number and percent of eligible patients that received POC testing and the number and percent that have accessed treatment. For HVL, this will apply to those patients being switched to 2nd line treatment.
- **Time to ART initiation:** will be measured by calculating the average time between receiving POC testing results and the time to ART initiation for patient who are determined to be eligible for treatment as stipulated in the national HIV care and treatment guideline. For HVL, this will apply to those patients being switched to 2nd line treatment.

Data sources

M&E data on POC testing can be collected by three main methods:

- Routine monitoring is carried out through program monitoring and is usually conducted quarterly and reported biannually, so that progress and trends can be measured.
- Periodic assessment of particular aspects of the POCT services, such as site assessments for quality assurance (QA) and quality improvement purposes can be used to monitor and improve performance.
- Population-based survey data from national data collection program such as the Demographic and Health Survey (DHS). These national surveys are carried out periodically, usually every three to five years

Systems for collecting and analyzing routine monitoring data for POC testing

M&E system for national POC testing requires the following data collection systems.

1. A national inventory of POC testing sites that contains basic information about all sites providing POC testing. Maintaining this inventory is critical for the NACP to track the POC testing services in the country and to know which sites should be expected to send routine monitoring data. It also provides a basis for sampling sites that should undergo periodic supportive supervision. In addition it may be helpful to manage the fleet in

general as well as trained operators

The MOHSW partners that procure and place POCT to the supported health facilities should consult the NACP for proper placement and to provide information to update the national inventory.

This inventory should be kept in an electronic format, in either a simple database or spreadsheet, and it should be updated as new sites are established and/or when services change at existing sites (example upgrading POC testing facility to be conventional).

2. A site-level POC testing register to record basic information about the people coming for testing at the POC testing facility. Formats for collecting these data may be stand-alone or integrated into existing data collection tools, when POC testing is one of multiple services provided to patients.
3. A site-level POC logistic register to record the POC testing commodity information. The register should be compiled by the facility in charge and submitted to the national level on the agreed reporting periods.
4. Standard data collection tools and reporting formats for sites to report centrally or to regional and district offices to ease the process of aggregating data across sites.

NACP must consider how data should be collected at the site level. Data should be aggregated from the whole reporting period (e.g. each month).

At some point along the reporting chain, data may be entered into electronic databases for ease of transmitting and aggregating the data. If POCT have connectivity capability, some data can be sent in an electronic format to the central database.

Operational Research

Operations research is a specific evaluation that can be used to improve a range of services along the full continuum of care for HIV and AIDS clients. It is most often used to compare program approaches, when there is no consensus about the best way to respond to a given programmatic problem.

The main objective of operational research is to provide managers, administrators and policy makers with the information they need to develop, improve and scale up program. In POC testing, operational research can be thought of as a practical and systematic process for identifying and solving programmatic POC testing related problems.

The process includes:

- Identification and diagnosis of problem
- Selecting program strategies
- Testing and evaluation of strategies
- Analyzing data and results
- Dissemination of information
- Utilizing information and scale up

References:

1. Jani IV, Sitoe NE, Alfai ER, Chongo PL, Quevedo JI, Rocha BM, Lehe JD, Peter TF. Effect of Point of care CD4 cell counts tests on retention of patients and rates of antiretroviral therapy initiation in primary health clinics: an observational cohort study. Lancet 2011 October 29:378 (9802)
2. MOHSW: Health Laboratory Safety and Waste Management Manual, November 2006
3. UNAIDS: Progress report summary, 2011
4. UNICEF: Children and Women in Tanzania, 2010.
5. NACP: WHO and UNICEF Report: Rapid Assessment of Pediatric HIV Treatment Service Delivery in Tanzania, July 2014
6. Tanzania HIV/AIDS Malaria indicator Survey 2011-12, March 2013 report.
7. The treatment 2.0 Framework for action: Catalysing the next phase of treatment, care and support. http://data.unaids.org/pub/Outlook/2010/20100713_outlook_treatment2_0_en.pdf
8. National Implementation Plan for Point of care CD4 testing, December 2011
9. Private Health Laboratory Regulations Act, 1997
10. Elke Wynberg, Graham Cooke, Amir Shroufi, Steven D Reid and Nathan Ford. Impact of Point of care CD4 testing on linkage to HIV care: a system review

APPENDICES

Appendix 1: Names of Participants

1. Dr. Anath Rwebembera - NACP
2. Dr. Charles Massambu - MOHSW
3. Dr. Fausta Mosha - NHLQATC
4. Dr. Julius Muhuza - HJFMRI
5. Dr. Mtebe Majigo - MUHAS
6. Dr. Patrick Mwidunda - NACP
7. Dr. Peter Maro - CHAI
8. Dr. Robert M. Josiah - NACP
9. Mr. Abdul Mwanja - MSD
10. Mr. Abubakary Kiangi - NACP
11. Mr. Baraka Mpora - NACP
12. Mr. David Ocheng - Amref Health Africa
13. Mr. David Temba - MDH
14. Mr. Dickson Majige - MOHSW
15. Mr. Emmanuel Lesilwa - CSSC
16. Mr. Emmanuel Shayo - JSI
17. Mr. Haji Msuya - CHAI
18. Mr. Joseph Mziray - NHLQATC
19. Mr. Michael Mwasekaga - CDC
20. Mr. Pavel Mtango - NACP
21. Mr. Selestine Katto - NACP
22. Mr. Terito Madeye - THPS
23. Mr. Victor Muchunguzi - NHLQATC
24. Ms. BahatiMfaki - NACP
25. Ms. Carolyn Riwa - NHLQATC
26. Prof. Said Aboud - MUHAS