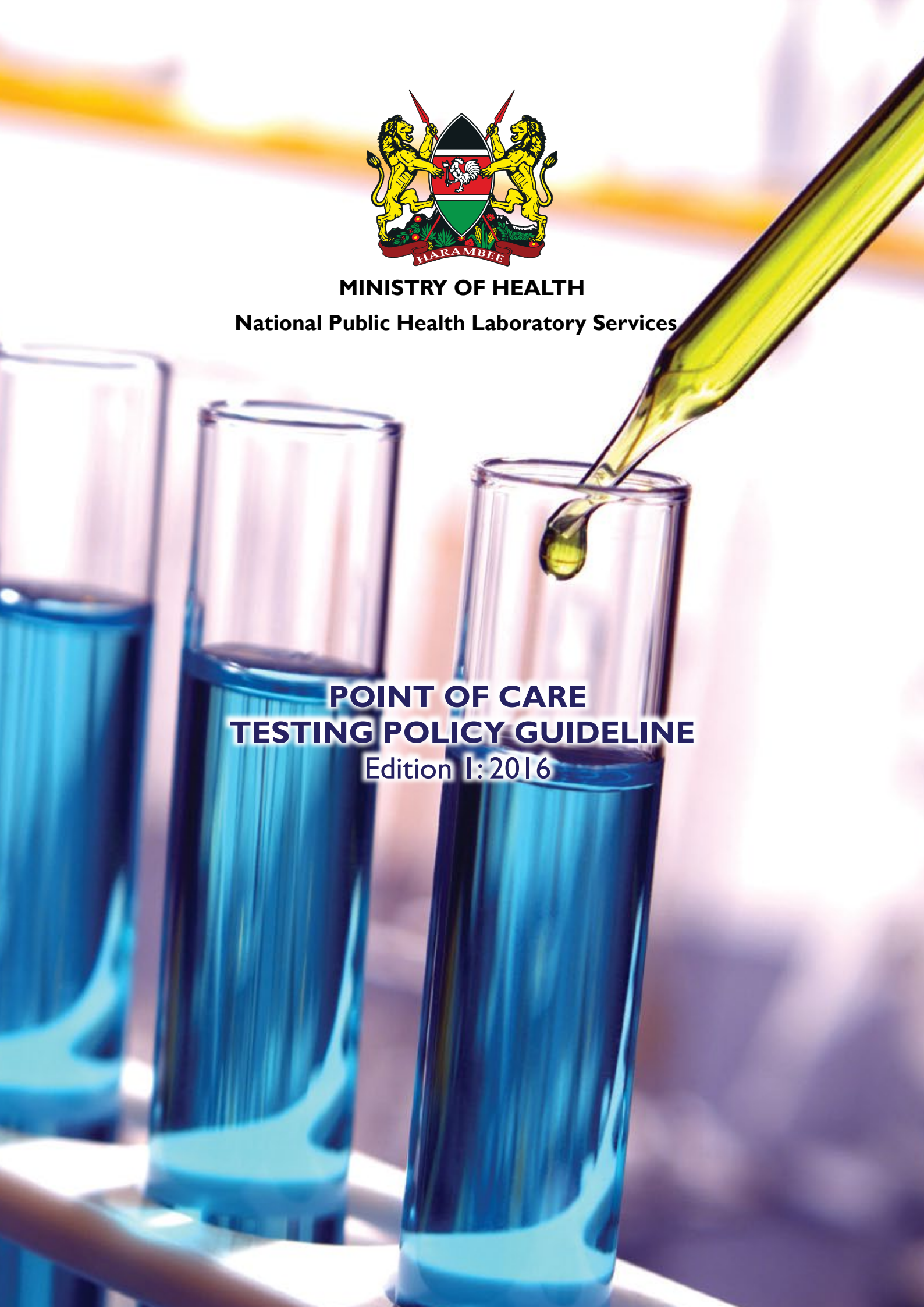

MINISTRY OF HEALTH

National Public Health Laboratory Services

POINT OF CARE TESTING POLICY GUIDELINE

Edition 1: 2016

Foreword

The Government of Kenya (GOK) has recognized the need for the development and use of Point-of-care testing (POCT) for bedside or near patient testing. The rationale of using POCT is largely based on a need for shortening the time to decision making being the provision of timely results that clinically and cost-effectively contribute to patient management.

POCT is an affordable, convenient and indispensible diagnostic tool for health care service providers. A well-structured national guideline for the use of this technology is necessary to guide users due to the high variability in equipment performance, methods employed for a single test, and uncertainty that may arise in the reliability of the results obtained by non-laboratory staff. This integrated National Policy Guideline aims to achieve standardized practice of POCT and comprehensive governance in all aspects of this technology at the Ministry of Health (MOH) in Kenya.

I would like to congratulate the committee that has developed this National POCT Guideline. It is my hope that with the launch of the National POCT Guideline, all laboratory practitioners and clinicians responsible for delivering effective management of these services will implement and manage this service effectively and in accordance with the national regulatory standards.

Dr. Kioko Jackson K.

Director of Medical Services

Table of Content

Acknowledgements

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Their dedication, hard work and tireless contributions are highly appreciated. Special gratitude goes to the following contributors who participated in the development of this document.

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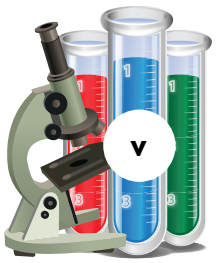
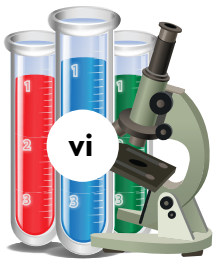


Abbreviations

ART	Antiretroviral Therapy
CLSI	Clinical and Laboratory Standards Institute
CV	Curriculum Vitae
EQA	External Quality Assessment
FBO	Faith Based Organization
HCSP	Health Care Service Providers
HIV	Human Immunodeficiency Virus
HMT	Hospital Management Team
HQ	Headquarters
ID	Identification
IQC	Internal Quality Control
ISO	International Organization for Standardization
IVD	InVitro Diagnostics
KEBS	Kenya Bureau of Standards
KMLTTB	Kenya Medical Laboratory Technicians and Technologists
LAM	Lipoarabinomannan
M&E	Monitoring and Evaluation
MCP	Multiple Concurrent Partnerships
MOH	Ministry of Health
NASCOP	National AIDS and STI Control Programme
NBTS	National Benchmark Tests
NGO	Non-Governmental Organization
NHRL	National HIV Reference Laboratory
NPHL	National Public Health Laboratories
OJT	On -Job Training
OPD	Out Patient Department
POC	Point of Care
POCT	Point of Care Testing
PPE	Personal Protective Equipment
QC	Quality Control
QI	Quality Improvement
QMS	Quality Management System
RHTK	Rapid HIV Testing Kits
SDP	Service Delivery Point
SDPP	Social Development Partnerships Program
SIV	Simian Immunodeficiency Virus
TB	Tuberculosis
TOR	Terms of Reference
TOT	Training of Trainers
TWG	Technical Working Group
WHO	World Health Organization



DEFINITION OF TERMS

Competency	Demonstration of mastery skills in a given trade or task
Quality Audit	An assessment for compliance against a quality standard
Scheme Provider	Institutions that are accredited by ISO 17043 or approved to provide EQA Services
External Quality Assurance	A system for objectively checking the laboratory's performance using an external agency or facility
Quality Control	Measure put in place in procedures to guarantee quality results
Internal Quality Control	Measures put in place within the procedure to guarantee quality results
Verification	To check on specified features specified by manufacturer in meeting the stated functions or needs of the user
Validation	Checking appropriateness and utility of the technology for the intended purposes to inform product development or use in a given setting
ISO 15189	International Standard for Quality Management System and Competency testing for medical and clinical Laboratories
ISO 22870	International Standard for Quality Management System and Competency testing for Point of Care Providers
ISO 9000:2005	Standard for Quality Management System definitions of operational terminologies
ISO 17043	International Standard for Quality Management System and Competency for EQA Scheme Providers
Healthcare Service Provider	Any individual, institution or agency that provides health services to healthcare consumers applicable to POCT.
POCT	Testing done within the proximity of the patient setting
External Quality Audits	Is an Independent assessment exercise by highly trained and skilled auditors done for the purpose of gathering evidence of nonconformity and conformance to a standard
Internal Audits	Is auditing done within the organization by itself with ascertain degree of conformance and nonconformance to inform quality improvement plans
Rapid Tests	These are assays that are simple to perform with immediate results to the client while still at the health facility, screening site or to other healthcare providers

Certification	Issuance of authority through documentation that individual/institution has passed the necessary requirement of exam and competency to perform the described tasks
Recertification	Compliance to scheduled or periodic competency assessments and Continuous education modules in a given area of operation
Registration	Listing of providers with meeting regulatory and statutory policy compliance to provide given services
Deregistration	Striking off providers not meeting regulatory and statutory policy compliance to provide given services
Mentorship	Hands on exposure guidance to nurture acquisition of necessary delivery skills in a given trade
Professional Ethics	Is a code of conduct required in discharging functions, duties and services in a given field - Violation of this leads to unethical conduct
Regulatory bodies	Government appointed Authorities to license, regulate and oversight Professional Practice
Health Management Organs	Health Teams charged with managing services at National, County and Facility level

Executive Summary

Evidence based medicine is being mainstreamed as a standard for improving clinical practice in Kenya. This technology is replacing the empirical model of syndromic management because it is more robust and efficacious. Points- of-care testing (POCT) technologies have been helpful in supporting laboratory practice and bringing services closer to patients who are in urgent need of it. The technological and scientific innovative function and the apparent simplicity and functionality of POCT presents many challenges for health care implementation personnel. In particular, the ability to determine the value that POCT may bring to the patient care process, bridging gaps and leveraging equity in access, improving the uptake and coverage of laboratory tests to support disease diagnosis and treatment.

The objective of this guideline is to streamline POCT services and provide leadership to standardized laboratory practice. In addition, this guideline explores mandatory requirements that need to be enforced as a part of a quality management system (QMS) in compliance with ISO 22870.

POCT provides laboratory testing at or near the site of patient care outside the traditional clinical laboratory setting. A systematic review demonstrates that POCT has the potential to improve patient management if undertaken within a comprehensive QMS. However, timely POCT results are not necessarily equivalent to results obtained from traditional clinical laboratories. To comprehend and distinguish the reasons for this discrepancy, a good understanding of the technology involved is required. In addition, concerns over the quality of results call for a hierarchy of laboratory system regulations implemented that can optimize the value and benefits for patients. POCT operational practices are a product of a consultative process by many professional groups, to maximize patient benefits and minimize testing errors. The International Organization for Standardization (ISO) and the Clinical and Laboratory Standards Institute (CLSI) have produced standards to address many operational and technical issues. These standards are nested in quality management systems and integrate the competency of the results generated to optimize POCT benefits in the long run. In this regard, the National Public Health Laboratory Services (NPHLS) envisions providing guidelines, through partner and stakeholder involvement, to streamline the implementation of POCT by healthcare service providers and guard against misuse and erroneous results.

The scope of this document covers, but is not limited to, the following thematic areas: evaluation, validation or verification of the suitability of POCT technologies for specific country needs as a regulatory requirement for registration; set criteria for the assessment of healthcare needs and determining the appropriate deployment of POCT, training, competency assessment, and the certification of healthcare service providers before allowing them to test patients with these technologies; enforce regulations of POCT in line with other professional statutes and ethical requirements enforced in medical practice through relevant Acts of Parliament governing medical practice; explore a robust and comprehensive quality assurance system to monitor and track the quality of the results being generated with compliance measures in place; conduct audits by trained auditors who will administer a checklist to look for evidence of compliance or noncompliance; set up mechanisms for placement of POCT equipment through necessary procurement statutes, technical support systems for field operations, and information systems for both logistical and testing data management; develop equipment service contracts, standard operating procedures, inventory control and supply chain, and EQA participation for both national and international schemes.

CHAPTER 1

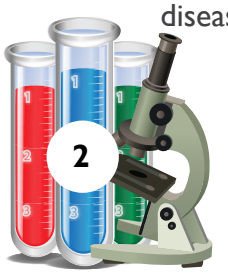
Introduction and Background

1.1 Introduction and Background

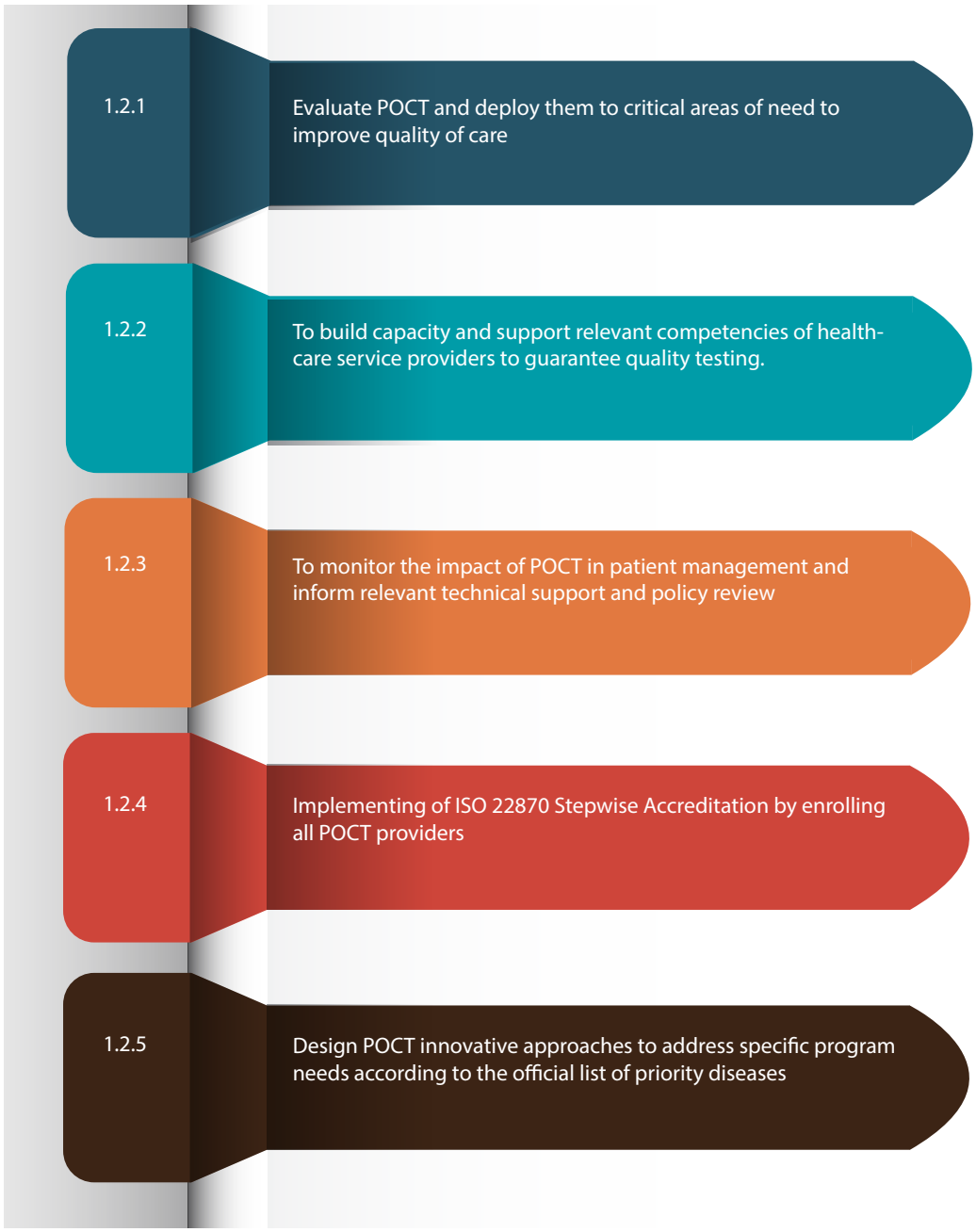
POCT is defined as medical testing at or near the site of patient care (ref). These are simple medical tests, which can be performed near the patient care. The driving notion behind POCT is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results quicker, which allows for immediate clinical management decisions to be made. The need for POCT in Kenya is extremely high, especially when there is already an existing demand for CD4, HIV viral load, malaria, TB, other infectious diseases and non-communicable disease screening at service delivery points. ese POCT s will be useful in providing immediate screening at primary healthcare settings hence directing evidence based prevention, treatment, and monitoring of therapeutic outcomes.

This policy guideline describes an implementation plan to streamline a thoroughly thought out plan of governance for POCT in Kenya. This plan will be executed by MOH in collaboration with county health management organs and through relevant programmatic units including National AIDS STI Control Program (NASCOP) and National HIV Reference Laboratory (NHRL) for HIV and related testing, Malaria Control Program (MCP) for malaria rapid testing, TB Program for Lipoarabinomannan (LAM) testing, Gene Xpert and Kenya National Blood Transfusion Services (KNBTS) on ABO and Rhesus-typing among others. The implementation of this guideline is scheduled to start in the first quarter of 2016, with roll-out completed by the end of 2019. Funding for the implementation of POCT in Kenya will come from MOH and county governments through the support of development partners.

POCT will be implemented in Kenya through innovative approaches, packaged to address special needs in mobile clinics, Maternal and Child Health (MCH), Diabetic clinics, outpatient departments and in health centers/dispensaries with weak laboratory support, among others. Amid evolving diagnostic technologies being made available to health facilities, there is an urgent call to setup structures and systems that support the objective scale-up of devolved laboratory POCT and re-define the scope and control mechanisms of testing. This is intended to ensure feasible, affordable, and accessible quality assured point of care testing and support evidence-based disease diagnosis and monitoring in areas initially exhibiting challenges of poor service coverage and uptake. Implementation has already begun in CD4 systems for baseline and monitoring of antiretroviral therapy (ART) and rapid HIV testing kits (RHTK), which have been validated and approved for use in Kenya. Other testing technologies for screening of cancer using urine samples are evolving and may change the landscape of cancer screening at POCT once available for use in Kenya. This technology will inform successful identification of disease conditions, including cancer detection in the primary stage, allow rapid screening of preventable and treatable infections including neglected lifestyle-associated diseases, such as cardiovascular diseases, diabetes, and other priority diseases targeted for intervention.



This policy guideline will be updated periodically to reflect new developments in the fast-changing technology landscape for POCT in clinical and nursing practice. These standards for POCT are based upon the requirements of ISO 22870:2006 –POCT–requirements for quality and competence. The requirements of the international standard are intended 'to apply when POCT is carried out in a hospital, clinic, or by a healthcare organization providing ambulatory care' and make it clear that they are not intended for application to patient self testing in a home or community setting. Kenya intends to apply ISO 22870:2006 and ISO 15189 in preparation for accreditation of their POCT facilities and medical laboratories respectively. As ISO 22870:2006 gives specific requirements applicable to POCT, the organization wishing to have its POCT facilities accredited shall also meet the requirements of the current edition of ISO 15189 for both QMS and competency.



1.2. POCT Pronged Focus Areas
1.3 Policy Statements

1.3.1 Summative POCT Thematic Areas and Respective Policies

1.3.1.1 *Thematic area:* Authorization and Licensure of POCT Technologies

Policy Statement

POCT's shall be validated for suitability and intended use in healthcare setting by relevant appointed MOH reference laboratories or relevant institution to inform the KMLTTB for approval and registration. Technically, KMLTTB shall provide a framework and leadership to ensure validation is expedited.

1.3.1.2 *Thematic area:* Structures Supporting POCT Implementation

Policy Statements

1. POCT's shall be aligned to fit national, county, sub-county, and facility level health management organs, a laboratory POCT point persons shall be identified and trained with advanced POCT skills by relevant management organs in concurrence with laboratory county coordinator, selection criteria based on performance, competencies, and experience shall inform selection of these officers.

2. NPHLS shall provide quality assurance through EQA scheme to support POCT. These labs based on their mandate shall also participate in POCT capacity development.

1.3.1.3 *Thematic area:* Training and certification and re-certification of POCT Personnel

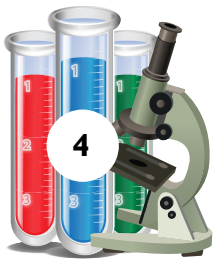
Policy Statement

POCT target group shall be Healthcare Service Provider (HCSP) undertaking the various types of point of care testing. All HCSP who undertake POCT must have been trained and certified as competent to perform the test. Competence to perform the test shall be regularly monitored.

1.3.1.4 *Thematic area:* POCT Context and Utility

Policy Statement

POCT shall be implemented at all levels of the health care system; both designated sites as well as mobile sites. Testing algorithms shall be approved by MOH. The scope of POCT shall cover patients and customers who are at home, work place, hospitalized, outpatient or provider initiated in defined condition.



Policy Statement

New technologies meeting (Refer 1.1) shall be expeditiously mainstreamed and incorporated in the testing algorithm based on the level of testing.

1.3.1.5 *Thematic area:* Biosafety Practices in POCT

Policy Statement

All POCT processes and procedures shall be undertaken in a way that does not put the patient, POCT service providers and general environment at risk of contamination with infectious and toxic materials. Laboratory safety policies in compliance with ISO 15190 shall be strictly adhered to. Attested standard operating procedures for each waste management shall identify all specific safety precautions to be followed.

1.3.1.6 *Thematic area:* Training of POCT Service Providers

- ***Policy Statement***

  Training and mentorship shall be undertaken by certified trainers who will have been trained and certified by either the equipment manufacturer or by qualified national or county laboratory super user / TOTs. The training program will be tailored to the technology, its complexity and scope of testing. Certification and re-certification of service providers shall be implemented.

- ***Policy Statement***

  POCT target group shall be HCSP undertaking the various types of point of care testing. All HCSP who undertake point of care testing must have been adequately trained and certificated as competent to perform the test. Competence to perform the test shall be regularly monitored and the specific processes and procedures shall be provided in this guide.

1.3.1.7 *Thematic area:* POCT Quality Management Systems

Policy Statement

A quality management system and competency monitoring systems shall be mainstreamed to support POCT product selection and testing processes to guarantee the reliability of test results generated for use in clinical decision making.

1.3.1.8 *Thematic area:* POCT Personnel Management

- ***Policy Statement***

  There shall be adequate POCT SDP, well trained using an approved curriculum/training package, properly certified and properly quality assured personnel to carry out POCT services at facility level, a biodata to manage personnel information shall be implemented at facility level.

- ***Policy Statement***

  The management through partner, stakeholders, MOH, and county health management organs shall provide leadership, and conducive working environment to support quality POCT at designated service delivery points.

- ***Policy Statement***

  There shall be comprehensive personnel documentation requirements on: confidentiality, job description, immunization, orientation, on-job training (OJT), records, tester ID, current CVs in line with requirement ISO 15189:2012 that covers clinical laboratory QMS and competency, ISO 22870 for POCT and ISO 9001:2008 for QMS.

- ***Policy Statement***

  There shall be structured levels of technical supervision using an integrated POCT checklist, provided by the national reference laboratories, to monitor use and relevance of POCT in clinical and research settings.

- ***Policy Statement***

  Independent quality audits carried out by qualified auditors shall be executed in POCT for purposes of continuous quality improvement; identification of nonconformities, documentation and providing technical support, preparation and implementation of POCT corrective action plans in liaison with facility health management organs.

1.3.1.9 *Thematic area:* POCT Equipment Management

- ***Policy Statement***

  All purchased, placed or hired equipment shall have minimum certification requirements from International and National standards for In vitro diagnostics (IVD) or equivalent to guarantee existence good manufacturing practice.

- ***Policy Statement***

  Equipment meant for use shall be inspected by KEBS for IVD certification compliance or the equivalent for clearance.

  Equipment shall be subjected to validation by KMLTTB through appointed reference laboratories and relevant institution to inform approval and registration.

- ***Policy Statement***

  The equipment, devices, and reagents shall be verified on its suitability for intended use; manufacturer/appointed vendor must implement this process through MOH and Appointed authorities (Refer 1.1).

- ***Policy Statement***

  POCT equipment inventory at the national, county, and facility level shall capture: acquisition date, equipment model, serial number, unique equipment ID, service contracts, location, and date of deployment into service (Lab, Clinic, Ward, OPD etc.)

1.3.1.10 *Thematic area:* Selection of POCT technologies

- ***Policy statement***

  The selection for use of POCT technologies shall be informed by coverage of clinical laboratory services, conditions to be tested, implementing capacity, level of healthcare testing infrastructure, workload and personnel and expansive geographical coverage.

1.4. POCT Objectives

- To harmonize and standardize POCT through provision of policies and guidelines to support implementation.
- To design and execute a comprehensive quality assurance system in liaison with counties to guarantee quality of POCT results (SDP).
- To provide monitoring and evaluation mechanisms to assess the impact of POCT services.

CHAPTER 2

POC Structures and Quality Management Systems

2. 0 POC Structures and Quality Management Systems

The MOH and county health management organs, in collaboration with stakeholders, shall provide leadership and a conducive working environment to support quality POCT at designated service delivery points to optimize both evidence based clinical outcomes and patient benefits. This guideline describes POC management structures, including implementation and quality assurance strategies. Clear management levels at National, county, and health facility to oversee the implementation should be clearly described and their roles specified. This guideline supports a multidisciplinary oversight committee at National, County and facility levels with clear terms of reference terms of reference clearly stated. At the County and health facility level the oversight role can be vested in an existing committee e.g. quality management committee. In all these committees the technical advisory/committee secretary shall be the laboratory coordinator or manager to guide decision on technical issues. Counties will plan, mobilize resources, and execute POCT at their respective facilities. The ownership of POCT testing models is vested on County health administrative organs.

2.1 Composition of the committees

2.1.1 National Level advisory

The point of care testing committee shall be composed of the following representatives or their designee:

- Head National Public Health Laboratory Services {1} Chair
- Point of care testing coordinator {1} Secretary
- Managers of designated Reference Laboratories in related point of care testing {3}
- Development Partners {2}
- Clinical National Program Managers in related point of care testing {2}
- Regulatory; KMLTTB representative {1}
- Laboratory Logistician {1}
- Data Officer {1}
- NPHLS Quality Assurance Officer {1}
- Research Institution {2}

2.1.2 Terms of reference (TOR) for National POCT technical working groups (TWGs)

- Provide policies and guidelines for POCT implementation.
- Set up linkages with existing MOH and county health administrative structures to support POCT.
- Strengthen integrated approaches in application of POCT technologies to address priority diseases and services.
- To provide technical advisory services and coordination in liaison with counties to support implementation of POCT.
- Review and approval of POCT curriculums, trainers and training packages.
- Review of validation reports of POCT technologies.
- Coordinate EQA services both national and international targeting POCT personnel.
- Evaluate impact and value of POCT in clinical setting to determine relevance and suitability in various clinical settings in the country.
- Plan and execute audits using qualified laboratory auditors to inform quality improvements initiatives based on ISO 22870 for POCT, ISO 15189 for medical laboratories and 19011 for auditing QMS and competency.
- Participate in preparation of work plans to source for funds to support POCT.
- Review M/E reports for planning and service improvement.

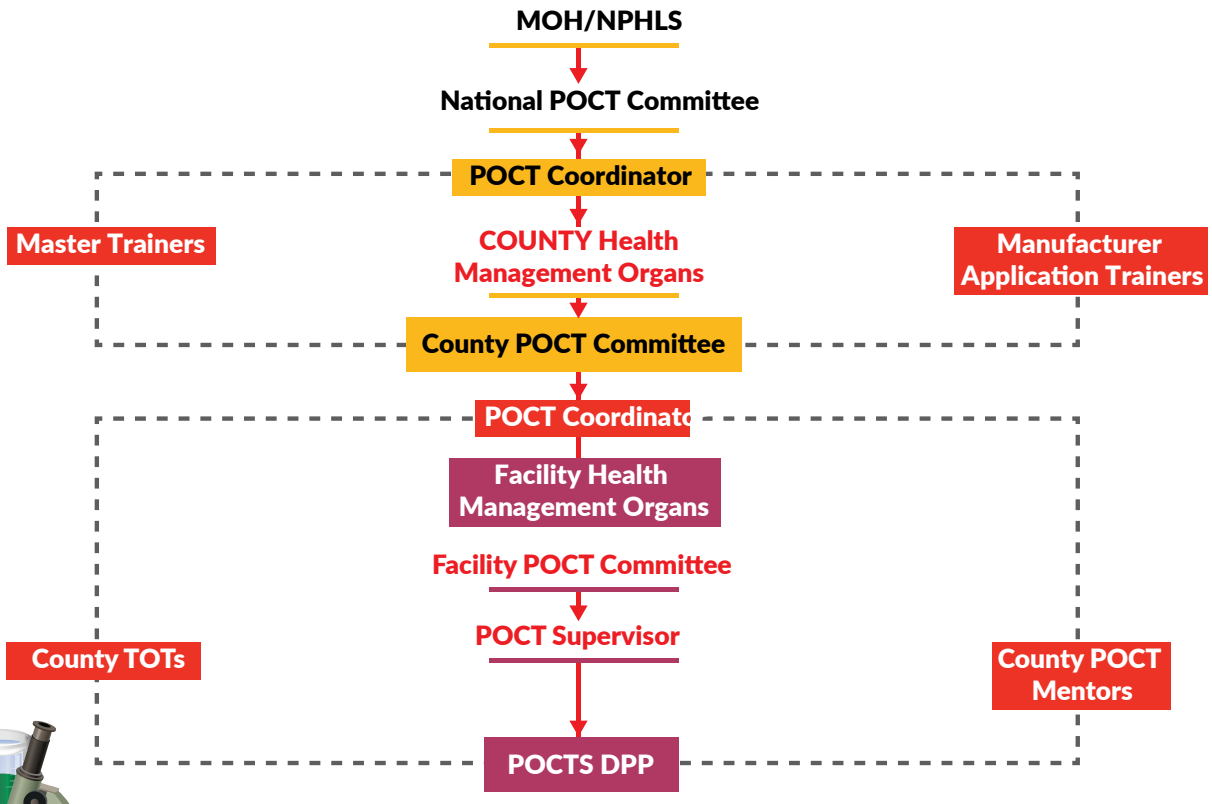


Figure 2.1 POCT Management Committees

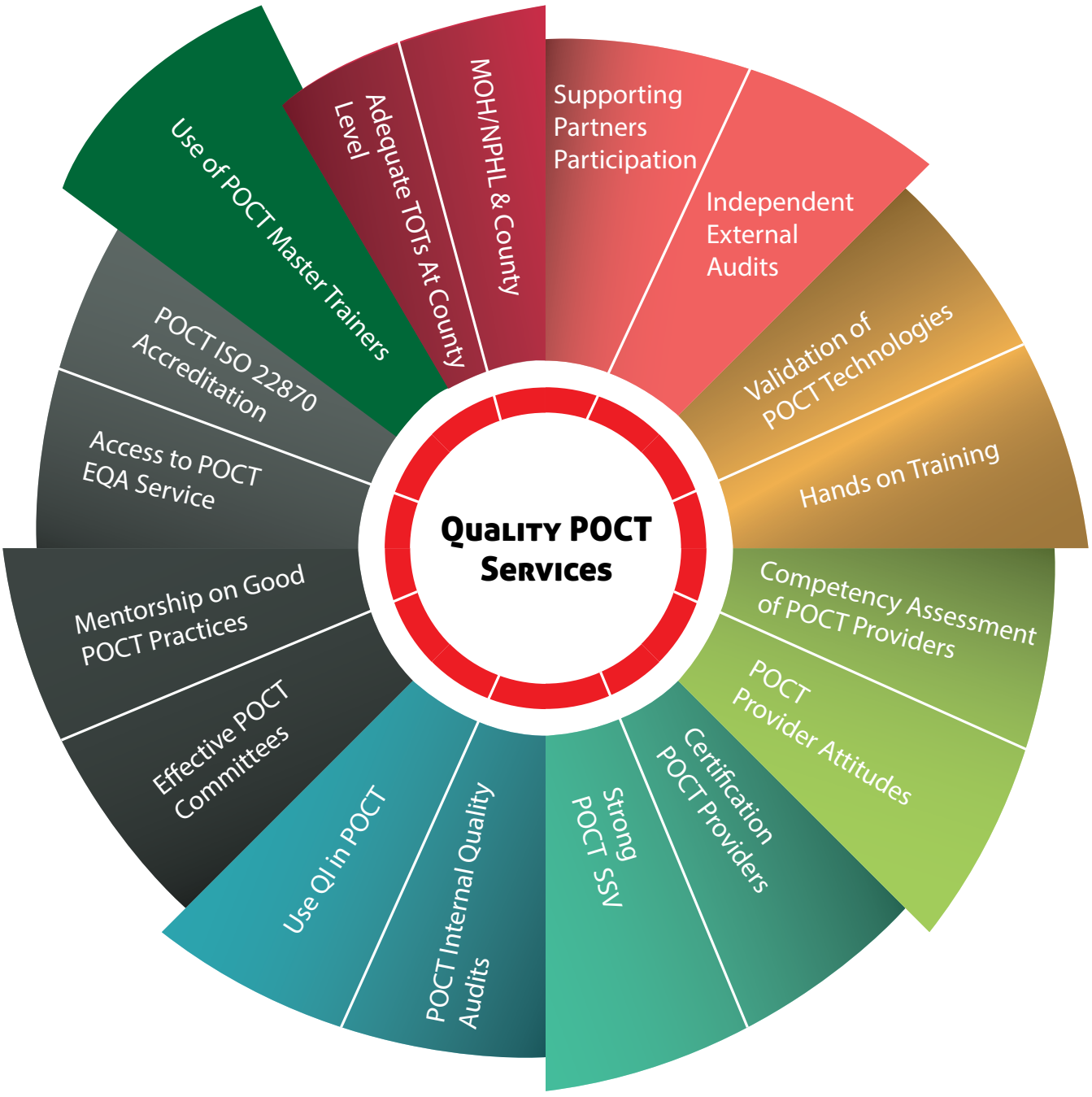


Figure 2.2 POCT ideal Concept

2.3 County Level Advisory Committee

The point of care testing committee shall be composed of the following representatives or their designee:

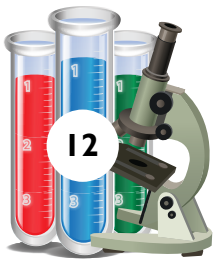
- County executive of Health;- {1} Chair
- County Health Director;- {1} Co-Chair
- County Laboratory coordinator;- {1} Technical Secretary
- Clinician- Clinical committee member;- {1}
- County Chief Nurse ;- {1}
- Facility Point of care testing coordinator-{1}
- Development Partners- {2}
- Research Institute/University -{1}
- Data specialist -{1}

2.3.1 TOR for County POCT TWGs

- Set up advisory and coordination linkages with existing MOH and sub-county health administrative structures to support POCT.
- Oversee implementation of POCT in their respective county jurisdiction.
- Strengthen integrated approaches in application of POCT technologies to address priority diseases and services.
- Review county POCT performance audit reports conducted by independent third party based on ISO 22870 for POCT, ISO 15189 Specific for medical laboratories and ISO 19011 for auditing QMS and technical competency.
- Review M&E reports for planning and service improvement.
- Sourcing and allocation of funds to procure POCT technologies to serve county needs.
- Setting up POCT centers of excellence in practice and technology use.
- Coordinate implementation EQA services targeting POCT personnel at county level.
- Liaise with national POCT TWG in planning for audits to inform quality improvements initiatives based on ISO 22870 for POCT.
- Supporting forums evaluate POCT services in their respective jurisdiction.
- The TWG for POCT shall develop and revise standard operating procedures and job aids during the planning phase and pilot these tools during the implementation phase, with revision carried out every two years or as needed.

2.4 Health Facility Level

The point of care testing coordinator shall work closely with the County POCT TWG.



2.4.1 TOR for Facility POCT Coordinator

- Assign POCT oversight to the trained and certified hospital personnel.
- Review of periodic reports of performance for all areas/points performing POCT testing and recommends corrective actions as necessary.
- Approve proposals to decentralize testing at point of care within the facility.
- Ensure that a comprehensive POCT service providers practicing register for the facility is available and well maintained.
- Enforce use of guidelines and necessary SOPs at POCT and documentation tools to capture quality data to reflect on practice and other important aspect of POCT.
- Ensure quality assurance system is in place and operational at the POCT.
- Increase efficiency, effectiveness and quality of POCT services delivered by HCSP.
- Report to the county POCT technical committee on POCT progress implementation.

2.4.2 TOR for Facility POCT Health Care Service Provider

- A custodian of quality POCT services at the facility.
- Participate in implementation of SOPs and relevant job aids at POCT work stations.
- Participate in implementation of planned competency assessments for POCT services provided at the designated POCT service delivery points.
- Participate in quality intervention through laid down processes.
- Implement POCT practices in conformance to guidelines, international standards and regulation.
- Receive appropriate training, mentorship, supervision and technical support on POCT practice.
- Compliance with competency testing mechanism spelt out in this policy guideline.
- Pursue quality improvement projects in POCT through innovative and guided packages to address priority areas of healthcare service provision.

2.5 Operational Research

Operational research is useful as a tool for directing services, including quality improvement monitoring and evaluation systems. Expediting innovative approaches, while targeting special areas of healthcare needs to inform policy, operational guidelines, and scale up initiatives. This includes the evaluation of accessibility and acceptability of services desired by users, planning for commodity management, service benchmarking, and service integration. POCT should be refined to support optimal resource allocation, health care workforce planning, and infrastructure development.

CHAPTER 3

POCT Implementation

3.0 POCT Implementation

3.1 Authorization and Licensure of POCT Technologies

The following activities will be carried out in accordance with policy requirements (refer 1.3.1.1) to fulfill MOH and KMLTTB functions:

1.0.1 Pre-qualification of POCT technologies, approval and registration by KMLTTB.

1.0.2 Appointing relevant institutions to implement POCT validation and give feedback.

1.0.3 Registration and licensing of POC equipment approved for use in Kenya.

1.0.4 Carry out inspection sanctioned by MOH according to KMLTTB Act. 2000, Kenya Medical Practitioners and Dentist Act and Public Health Act.

1.0.5 Provide information to facilities on validated point of care devices in the country.

NOTE: Any POCT technology being mainstreamed and incorporated in the country for use in testing patients at clinical and research setting in private, public, FBO, NGOs, or other institutions providing health care services, shall follow the above criteria.

3.2 Structures Supporting POCT Implementation

The following activities will be carried out in accordance with policy requirements (refer **1.3.1.2).**

3.2.1 POCT committees will be formed from national to county level and their responsibilities clearly stated in their TORs.

3.2.2 Participation in the committees will be voluntary as part of officers routine work.

3.2.3 Inter-linkage between national and county committees based on mutual synergy and cooperation will be fostered to benefit clients.

3.3 Training and certification of Super/ User TOTs (master trainer)

The following will be carried out in accordance with policy requirements (refer **1.3.1.3**).

The MOH through the division of NPHL, in concurrence with county health management organs, and development partners, will implement a cascaded model of training to ensure appropriate capacity of POCT across the board. A minimum of 2 master trainers shall be trained in every county on integrated POCT technology for cascading it down to county and sub-county facilities. The equipment manufacturer's application specialist shall train a super user who shall in turn train TOTs for subsequent roll out. To ensure master trainers (super users) are able to provide comprehensive ongoing support, the training module for TOTs shall typically last for 4-5days. The training should typically include technical training in device operation, operational training on clinic integration and teach back methodology.

3.4 Training and certification of POCT Personnel

The following activities shall be carried out in accordance with policy requirements to fulfill POCT provider training needs (refer to 1.3.1.3).

3.4.1 Training curricula/materials shall be prepared by the national level and stakeholders for adoption in specific areas of need.

3.4.2 POCT target group shall be HCSP undertaking the various types of point of care testing.

3.4.3 Each facility shall provide a minimum of 2 trainee POCT operators and the duration shall be in line with the POCT training policy.

3.4.4 In the event of POCT personnel transfers, their replacement must be formally trained by certified master trainers.

3.4.5 Basic principles of analytical methods and its limitation on the clinical relevance of the results produced; the latter should include knowledge of results that must be made known to clinician immediately and results which are indicative of an error or failure in the procedure or a possible interfering substance.

3.4.6 All HCSP who undertake POCT must have been trained and certified as competent to perform the test.

3.4.8 Competence to perform the test shall be regularly monitored and the specific processes and procedures shall be provided in this guide.

3.4.9 Competency associated with noncompliance (unsatisfactory performance) shall be followed up by technical support of POCT trainers/super users or POCT point persons or trained designee for intervention (corrective action implementation).

3.4.10 Orientation of new certified POCT providers on tools and procedures of quality sample collection, packaging and transportation to referral testing laboratory hubs shall be done by supervisors for specific tests.

3.4.11 To address variability of test results between sites due to operator performance, onsite training and mentorship will be necessary.

3.4.12 Refresher trainings shall be provided annually and when need arises.

3.5 Training curriculum content

3.5.1 Basic principles of the analytical method, its limitations and the clinical relevance of the results produced; the latter should include knowledge of results that must be made known to the clinician immediately and results which are indicative of an error or failure in the procedure or of a possible interfering substance.

3.5.2 Patient Preparation and sample management procedures; the correct procedure for preparation of the patient and the potential for production of an erroneous result that may arise from incorrect preparation of the patient or incorrect sample type.

3.5.3 Provision of Procedures for preparation of the reagents, operating devices and/or equipment e.g. warming of reagents stored in the refrigerator to room temperature before use, to ensure correct performance of the test within provided SOPs.

3.5.4 Provision for mechanisms for clinician notification for results recall, issuance of corrected version of results followed by occurrence and corrective action documentation by POCT service providers.

3.5.5 Most common incorrect procedural steps that may lead to the production of an erroneous result. The correct way for documenting and reporting a result, including the identification of results that must be brought to the immediate attention of a clinician or are inappropriate and indicative of an error or failure in the procedure, and the correct way to identify his/her unique ID as part of the patients record of the result.

3.5.6 Provision of correct quality control procedures, recording of such data and its interpretation, all of which must be completed and validated before release of the patient result.

3.5.7 The correct procedure for disposal of consumables, reagents, and used analytical devices and any decontamination procedure required.

NOTE: HCSP represents medical officers, clinical officers, nurses, laboratory technicians, counselors and public health officers.

3.5.1 Mentorship of POCT Personnel

3.5.1.1 Integrated mentorship checklist shall be developed prior to facility mentorship.

3.5.1.3 Observation of practices in integrated POCT technologies and operation in clinical setting shall be conducted.

3.5.1.4 Structured POCT monthly mentorship will be provided for the first six months by qualified mentors shall be conducted following introduction of POC technologies followed by a quarterly mentorship.

Mentorship and supervision reports will be channeled to county coordinator's offices, reference laboratories and MOH.

3.5.2 Health Care Service Provider (HCSP) Certification for fitness in POCT

3.5.2.1 After successful completion of POCT training course the trainer shall test the individual's competence to perform the POCT procedure, this shall cover every scope of testing provided in the training. Competency test shall be very dependent on the procedure.

3.5.2.2 The trainee shall only be deemed competent, and therefore certified, when the trainer is confident the individual has completed the test satisfactorily. A central record shall be maintained of all those who have been shown to be competent to perform the POCT procedure.

3.5.2.3 This record should be kept up to date and any individual who fails competency assessment shall be removed from the register until their competence has been re-established.

3.5.2.4 A copy of this record shall be kept with the standard operating procedure. Each certified operator shall be given a unique ID registration, which shall be entered into the record of the completed test/log of POCT performed and also entered into the patients' record of the result.

Facility shall implement a system of verification to guarantee cushioning patients against erroneous results:

- No POCT Operator will issue his/her ID to authorize a third party to engage in testing or give their ID to another person in order for a test to be undertaken.
- Use another person's ID for testing at POCT service.
- Perform a POC without proper certification and ID.

3.5.3 HCSP Re-certification for fitness in POCT

3.5.3.1 Competency assessment records shall be used for re-certification of POCT HCSP.

3.5.3.2 If any operator is shown to be performing below the required standard, a supportive course of action should be implemented; if this fails then certification must be withdrawn until competence can be demonstrated. The following guidelines should be followed and documented.

3.5.3.2.1 In the first instance of poor performance the operator in question shall be contacted by the POCT governance committee and an informal review of performance standard instituted through discussion of the issues and concerns, usually with the identified trainer.

3.5.3.2.2 Additional quality control procedures and/or training shall be implemented as appropriate.

3.5.3.3 Closer monitoring of performance shall be implemented.

3.6 Context and Utility

The following activities shall be carried out in accordance with policy requirements to ensure that POCT is done at all levels of the health care system both designated site as well as mobile sites. The testing algorithm shall be approved by the ministry of health (refer to **1.3.1.4**). Institutions and partners with capacity to perform POCT in collaboration with MOH are allowed to carry out the testing activities.

They include the following:

a) Research and training institutions.
b) National and referral hospital.
c) County hospitals.
d) Sub-county hospitals.
e) Health centers.
f) Dispensaries.
g) Faith based organization health facilities.
h) Mobile sites.
i) Private institutions.

All testing shall implement MOH approved testing algorithm. All clients seeking POCT are free to seek services regardless of their location of origin. The approved algorithm shall flexible to include new technologies for POCT.

3.6.1 Site Selection

The following activities shall be carried out in accordance with policy requirements for selection of sites for POCT use. This shall be informed by coverage of clinical laboratory services, conditions to be tested, implementing capacity, level of healthcare testing infrastructure, workload and personnel and expansive geographical coverage (refer to **1.3.1.4**)

- POCT is not ideal for every site, and shall not be intended to replace conventional clinical laboratory testing.
- Different POCT technologies shall be optimal for different settings, site selection criteria shall be based on infrastructure, capacity, need, etc.
- A robust site-selection process and plan is required between governments and stakeholders.
- A process and criteria that effectively maps and prioritizes health facilities for adoption of new POCT technologies shall be developed.

The processing for conducting a site selection includes the following steps:

- Utilize the POC TWG used in the evaluation process to initiate the selection process and agree on responsibilities.
- Conduct a mapping exercise of all health facilities considering their need for POCT technologies based on the set criteria.

3.7 POCT Biosafety Policy statement

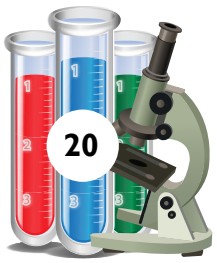
The following activities shall be carried out in accordance with policy requirements to fulfill POCT provider biosafety needs (refer to **1.3.1.5)**.

- Waste segregation at the SDP shall entail the color coding of the bin liners according to WHO safety protocols.
- Chemical waste disposal shall be implemented by the aid of Material Safety Data Sheets (MSDS).
- General waste disposal procedures shall be availed to POCT HCSP
- Chain of custody documentation for waste generation, autoclaving and incineration/disposal shall be enforced at service delivery point.
- Appropriate waste management commodities and PPE shall be availed to POCT HCSP.
- PEP in accidental exposure to contaminated blood and body fluids shall be provided.
- Immunization of Hepatitis B vaccine and any other appropriate vaccines shall be provided to POCT HCSP to protect them against Hepatitis and any other infectious acquisition.
- Automated prickers' for finger pricking blood with current validated international safety standards shall be encouraged.
- For venous blood draw vacuum technology tubes and eclipse needles shall be used to guarantee safety of HCSP at work place and markedly reduce occupational related injuries.

3.8 POCT Personnel Management

The following activities shall be carried out in accordance with policy requirements to fulfill POCT Personnel Management needs (refer to **1.3.1.8)**.

- Cascaded approach of training using standardized curriculum /or training package shall be implemented to target POCT personnel at the SDP.
- All POCT providers shall be certified and authorized to commence provision of POCT once training and competency assessment requirement has been fulfilled.
- Post training competency shall be immediately provided upon completion of training and those who perform satisfactorily shall be registered as POCT providers.
- POCT provider shall be issued with ID bearing official names and registration number.



- An integrated registration system shall be implemented to track POCT providers' practices in their respective scope of testing menu.
- POCT provider performance history and performance indicators shall be hosted in an appropriate information system with access control.

The following activities shall be carried out in accordance with policy requirements to fulfill POCT provider conducive working environment to support quality POCT at designated service delivery points (refer to **1.3.1.8**).

- POCT technologies shall be operated in an environment prescribed by manufacturers for optimal equipment/or device performance.
- MOH and its development partners shall be engaged to contribute to designing and building better facilities to deliver suitable controlled environmental conditions required for quality POCT services.

The following activities shall be carried out in accordance with policy requirements for personnel management to support quality POCT services to **1.3.1.8**).

- Detailed job descriptions for POCT providers trained on the technologies and certified competent shall be included in tasks assigned to HCSP.
- A standardized confidentiality tool/document shall be developed for all POCT providers to attest.
- Support mechanism shall be put in place to secure Immunization against Hepatitis B virus and other diseases to protect HCSP.
- POCT HCSP shall be oriented on requirements of the Job and records of this kept in personnel files.
- All POCT HCSP shall be issued with IDs which must be worn at SDP during working hours.
- Updated current CVs and other necessary documentation in compliance with ISO 15189:2012 shall be maintained.

The following activities shall be carried out in accordance with policy requirements for technical supervision provided by the NPHL to monitor use and relevance of POCT in clinical and research settings (refer to **1.3.1.8**).

- Supervisory functions shall be built on an integrated model using standardized checklist.
- The POCT super users shall provide technical leadership to supervisory teams on implementation of checklist items.
- Structured supervision within the facility and county shall be carried out to support quality testing in POCT SDP.

The following activities shall be carried out in accordance with policy requirements to ensure independent quality audits carried out by qualified auditors shall be executed in POCT for purposes of continuous quality improvement, identification of nonconformities, documentation, and providing technical support, preparation and implementation of POCT corrective action plans in liaison with facility health management organs (refer to **1.3.1.8**).

- An objective laboratory audit system based on ISO 15189 standards and WHO Afro checklist, ISO 2287 for POCT shall be used to guide quality improvement in QMS and competency testing exercise.
- Documentation of findings of non-conformities, acknowledgement sheet for acceptance and preparation of action plans.
- Documentation of corrective action plans and implementation timelines shall be followed up.
- POCT management organs in liaison with county, partners and national level shall schedule audits to inform service improvement.

The following activities shall be carried out in accordance with policy requirements to ensure POCT personnel are trained and certified to provide quality services in line with ISO 15189: 2012(E) and ISO 22870:2006 for POCT (refer to **1.3.1.8**).

- The POCT structure shall promote co-operation and commitment within the testing network.
- Each personnel shall be trained on POCT and be issued with a certificate to be allowed to carry out POCT.
- All HCSP working at POCT sites shall abide by appropriate established procedures to ensure that staff shall handle human samples, tissues or remains according to relevant legal requirements.
- The POCT sites shall be concerned with the creation of conditions in which each operator is encouraged to make his best possible contribution to the effective working of the undertaking.
- The POCT sites shall encourage spirit of mutual respect and trust between management and workers through sound relations to raise the morale of the operator for productive efficiency.
- Training Programs, on-the-job training, classroom and computer-based training modules will be available through national and county coordination.

The following activities shall be carried out in accordance with policy requirements to fulfill requirements for professional ethical practices (refer to **1.3.1.8**).

- The failure of POCT testing sites to use their resources for the society's benefit in ethical way may lead to restrictions to offer the services.
- All personnel shall sign a written job description designed to give clear responsibilities and scope of work.
- Each of the HCSP who are at POCT sites shall have to be guided by the need to maintain confidentiality of patient information.

The following activities shall be carried out in accordance with policy requirements to ensure competency following appropriate training, the laboratory shall assess the competency of SDPP to perform POCT according to established criteria, re-assessment shall take place at regular intervals and targeted training provided when necessary as an intervention for corrective action implementation (refer to **1.3.1.8**).

- A consistent standard for evaluation of competency should be applied to all operators POCT to track testing inconsistencies to expedite corrective actions.
- Competency assessment records shall be kept for the entire time an individual is employed at the POCT site.
- A list of all tests and procedures for each sub-specialty shall be made and updated in line with current evolution of POCT technologies.
- The competency assessor, in discussion with the staff, shall select items from the test list and schedule the exercise to take place periodically.
- Competency assessment must be specific for each job description and scope of testing provided at POCT SDP.
- The assessor shall fill in the corresponding checklist by directly observing the operator and checking the different records needed for the assessment.
- For a new operator, direct observation is used to assess the operator's ability to accurately follow the approved testing procedures.
- An assessment of competence is done twice in the first year of employment and annually thereafter.
- Experienced operator or POCT super users shall have an evaluation for ongoing competency.

Direct observation of performance of the following shall be made:

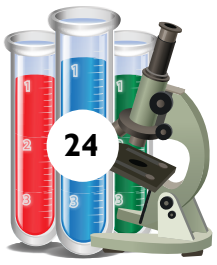
- Routine clinical tests, monitoring test result documentation and reporting processes, reviewing intermediate test results, QC records, proficiency testing results, and preventive maintenance records.
- Assess test performance byre-testing selected previously analyzed specimens to validate the reported results.
- Reviewing the results of internal blind testing samples or external proficiency testing samples; assessing problem-solving skills.

Competency assessment failure: if an operator fails one or more areas of the competency assessment, the assessor shall analyze the problem so that the proper corrective measures can be identified and implemented. Analysis of the problem starts with inspection of the protocols used for laboratory practice. The protocols shall be clear and concise; if they are inadequate or confusing, this may account for the operator's competency failure. In proficiency testing, it shall be ensured that the proficiency sample is adequate and that a problem with the sample itself is not the cause of competency failure. If the violation of protocols of competency failure, the following questions shall be answered:

- Did the operator perform the test incorrectly (i.e. did he/she not follow the proper test procedure)?
- Did the operator misunderstand the purpose or background of the performed test (i.e. is he/she unable to solve problems or adapt the test results to the clinical situation)?
- Did the operator misunderstand the components of the test or instrument being used?
- Was the operator unable to resolve QC problems?
- Did the operator perform the test accurately but make an error in the documentation?

The following activities shall be carried out in accordance with policy requirements to fulfill staffing levels as per MOH staffing policy (ref). The implementation of POCT shall have scheduled support supervisory visits to monitor POCT Service Provider performance and testing practices (refer to **1.3.1.8**).

- Depending on the facility level be it national, county, sub-county, health center or dispensary, staff requirements shall be allocated duties as per the needs of the workload.
- National and county supervisory committees shall give technical assistance to all the POC testing sites. The visits will be scheduled periodically.
- Reports shall then be generated at both levels for consumption.



3.9 Equipment Management

The following activities shall be carried out in accordance with policy to ensure minimum requirements for acquisition procedures are followed (refer to **1.3.1.9**).

- Each piece of equipment shall be accompanied with documentation from the relevant authorities on its acceptability and suitability prior to installation.
- Each item of equipment shall be uniquely labelled, marked or otherwise identified.
- Each facility shall learn the basic maintenance and handling of equipment. This will be integrated into the operators' training.
- A maintenance service agreement shall be considered between the suppliers and the user so as to provide loaner equipment within a pre-determined maximum turn-around-time.
- In-country distributors and service engineers shall be in place before procurement and uptake occurs.

The following activities shall be carried out in accordance with policy requirements to ensure POCT reagents and methods are verified for suitability for intended use; confirmation through objective evidence that specified requirement have been fulfilled in compliance with ISO 15198 and ISO 22870 (refer to **1.3.1.9**).

- All POCT reagents and consumables shall be shipped and stored according to manufacturer's specifications.
- Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall have to be verified for performance before use in examinations.
- The POCT site shall establish an inventory control system for reagents and consumables.

The following activities shall be carried out in accordance with policy requirements to establish inventory system for all the POCT equipment at facility level and where applicable each, equipment shall also have a service contract in place according to manufacturer's direction (refer to **1.3.1.9**).

Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records will include, but not be limited to, the following:

- Identity of the equipment.
- Manufacturer's name, model, and serial number or other unique identification.
- Contact information for the supplier or the manufacturer.

- Date of receiving and date of entering into service.
- Location.
- Condition when received (e.g. new, used or reconditioned).
- Manufacturer's instructions.
- Date of acquisition.
- Contractual agreement.
- Replacement/retirement plan.

3.10 POCT Quality Management Systems (QMS)

A QMS and competency monitoring systems shall be mainstreamed to support POCT product selection, testing processes to guarantee the reliability of test results generated for use in clinical decision making. This is an integral component of a laboratory quality system. It's a tool used to ensure that quality of results produced by a laboratory testing will not compromise the clinical care of patient (refer to **1.3.1.7**). The goal of QMS shall ensure that:

- Annual competence verification is mandatory for all POCT providers.
- Requirements for regular proficiency testing are met.
- Panels for POCT are assigned to as many operators as possible.
- Multiple sites are surveyed for POCT.
- Reports generated provide basis for corrective interventions and service improvement.
- Performance of IQC by POCT providers.

3.10.1 External Quality Assessment (EQA) and Proficiency Documentation

EQA shall be provided by independent external assessment institutions that are accredited or approved as scheme providers both at national and international levels. The POCT provider competency of specific analyses or tests using a panel shall be compared in with peers performance reports generated to participants.

Necessary interventions shall be carried out in targeted areas to improve the quality of POCT services provided. Proficiency and competence are regulatory requirements and therefore external proficiency for POCT shall be randomly assigned to the various operators to meet the compliance thresholds of annual re-certification. A comprehensive data base of POCT Service providers shall be drawn up using standardized tool generated by MOH in collaboration with county level to capture POCT SDPP to enable tracking of performances and efficacy of targeted interventions. All the EQA panels provided by various schemes shall be tested together with patient samples under same conditions to mirror quality of patients' results. The EQA outcomes from participating POCT providers shall inform continuous quality improvement.

Health management organs shall explore ways of building capacity to expedite intervention on unsatisfactory performance to strengthen quality systems in patient disease diagnosis, treatment and monitoring. County supervisory technical teams shall support and supervise POCT service and provide relevant technical assistance in challenges scenarios to healthcare service providers involved.

Facility management through POCT lead persons and POCT technical oversight committees shall ensure that there is sufficient capacity to use EQA results to inform service improvement at the POCT service delivery points. Facility HMTs shall liaise with their respective county health management organs and POCT coordinator to ensure capacity of their service providers is adequately built to cater for the needs of POCT personnel to fulfill their primary role as custodians of quality POCT services to the clients under their care. Records shall be maintained to permit evaluation of the quality and reliability of the data produced and assists in creating a mechanism of communications of QA issues to and from POCT testing office to testing personnel.

The ministry of health and partners shall coordinate the development and planning of all quality assured process control activities for point-of-care testing. Implementation shall provide the planned level of quality assurance specimens to point-of-care testing sites following training. If quality control specimens and external quality assessment panels are produced within a country, the coordinating laboratories need to develop a clear plan for obtaining the samples.

3.11 POCT Monitoring and Evaluation (M&E)

Monitoring progress and evaluating results shall be key functions to improve the performance of those responsible for implementing POCT services. M&E shall show if the POCT service/ program is accomplishing its goals by identifying weaknesses and strengths, areas of the program that need revision, and areas of the program that meet or exceed expectations. Data shall be used to document current status of activities for performance monitoring.

3.11.1 POCT Data Management

Data from POCT devices shall be stored either electronically or manually. Data management tools shall help the POCT sites to perform its duties of monitoring the various aspects of POCT by electronic or manual record. The device's records shall include information regarding the operators, device maintenance, QC, device malfunction, test data, and other information that can be captured. The data collected from advanced POCT equipment shall be uploaded into a platform that shall allow online viewing. Communication channels shall be established for providers to seek technical assistance from various reference points designated during trainings and mentorships.

3.12 Operational Research (OR)

OR shall be used to improve the quality and decision-making for POCT. OR opportunities shall be used to explore and support resource allocation, health care workforce planning, infrastructure planning, and commodity management, service benchmarking and service integration. Opportunities to apply operational research for POCT should focus on description, analysis, and improvement of day-to-day activities or operations of the program.

3.13 Strengthen the supply chain for quality assurance

It is vital that the ministry of health and partners focus on strengthening the supply chain and logistics to ensure that high quality test kits and consumables are available to testing sites and that stock-out are minimized. The ministry of health is a key hub for organizing logistics and supply chain coordination, devising and overseeing strategic planning, to ensure that policies and plans are implemented accordingly. Program managers need to ensure inventory control at the site level.

REFERENCES

- **ISO 15189-2012** International Standard for Quality Management System and Competency testing for medical and clinical Laboratories
- **ISO 17043-2007** Is an International standard for Quality Management System and Competency for EQA Scheme Providers
- **ISO 22870** International Standard for Quality Management System and Competency testing for Point of Care Providers
- National point of care policy guidelines, Malasyia. (July 2012
- National guidelines for HIV testing and counseling in Kenya. (2008)
- CLSI. Selection Criteria for Point-of Care Testing Devices; Approved Guideline. CLSI document POCT09-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
- International Standards Organization, Geneva (2012) Medical Laboratories – ISO 15189: Particular. Requirements for Quality and Competence, 3ndEdition.
- Elke Wynberg et al., Impact of point-of-care CD4 testing on linkage to HIVcare:a systematic review, JIAS 2014, 17:18809.
- Paul Drain et al., Diagnostic point-of-care tests in resource limited settings, Published online December 10, 2013 http://dx.doi.org/10.1016/S1473-3099(13)70250-0
- Gabriela Patten et al., Impact on ART initiation on point-of-care CD4 testing at HIV diagnosis among HIV positive youth in Khayelitsha, South Africa, JIAS, 2013; 16, 18518
- Phil Seidenberg et al., Early infant diagnosis of HIV infection in Zambia through mobile phone texting of blood test results, Bulletin WHO, 2012;90:348-346

APPENDICES

Appendix 1: Actions that can be taken with an operator who fails competency include

1. Having the operator reread the protocol and discuss it with the supervisor in order to clarify any misinterpretations.
2. Having the operator produce a flow chart to assist him or her in properly performing the protocol.
3. Having the operator observe another trained and competent operator.
4. Having the operator practice the failed protocol with known specimens.
5. Having the operator correctly retest the specimen originally tested during the failed competency assessment.
6. Reinstitution of formal training will be necessary if the above mentioned methods fail to confirm that the operator is competent.
7. Regardless of the selected corrective measures, it is necessary to repeat the competency assessment once the corrective measures have been completed. Successful accomplishment of competency for the operator who has failed the original competency assessment is to be documented.
8. As a last resort, the operator can be permanently removed from selected duties and reassigned to another work area.

MINISTRY OF HEALTH

National Public Health Laboratory Services