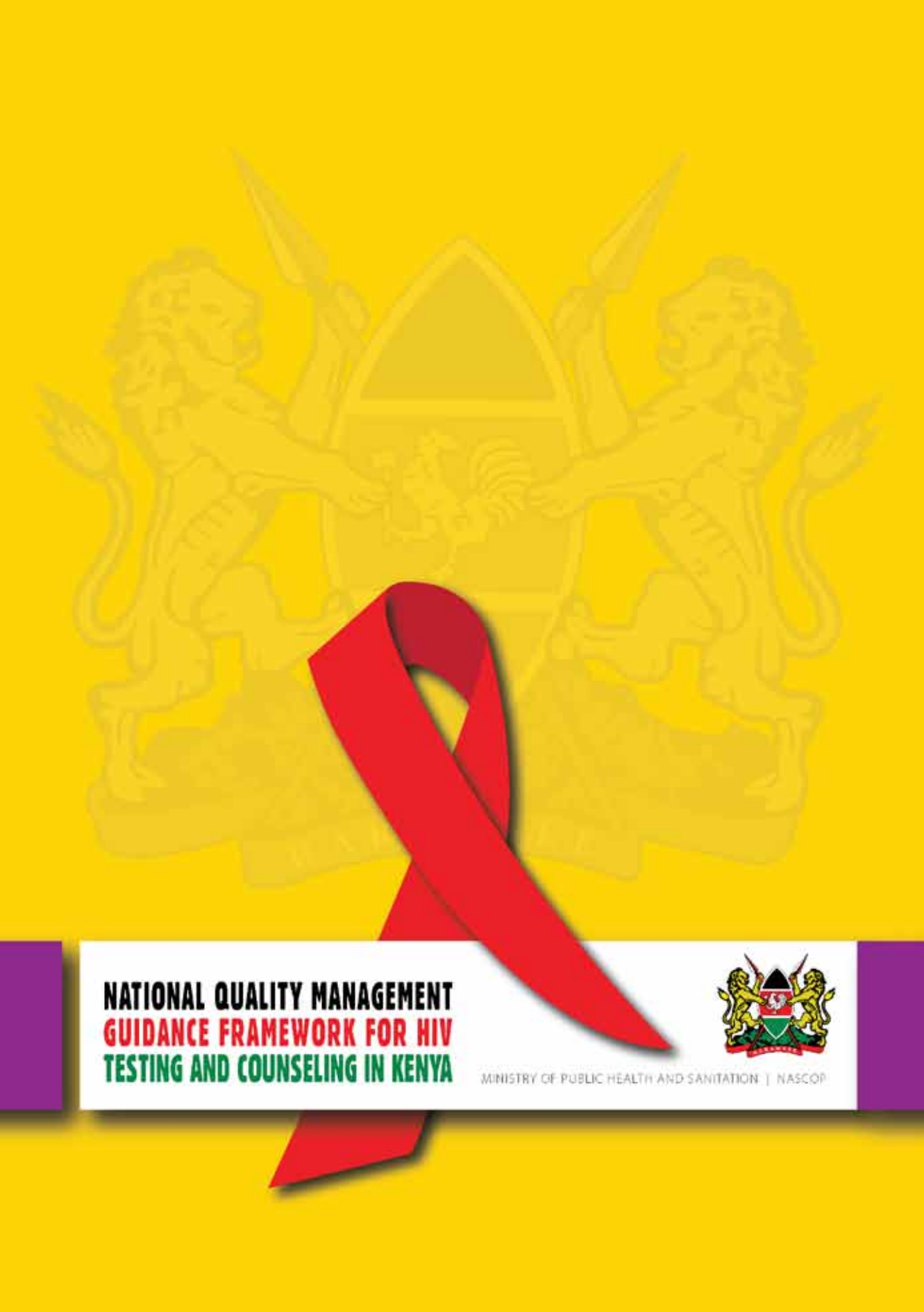

NATIONAL QUALITY MANAGEMENT GUIDANCE FRAMEWORK FOR HIV TESTING AND COUNSELING IN KENYA

MINISTRY OF PUBLIC HEALTH AND SANITATION | NASCOP

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Acronyms

AIDS .....Acquired Immune Deficiency Syndrome

AKMLSO.....Association of Kenya Medical Laboratory Scientific Officers

CDC.....Center for Disease Control and Prevention

CITC .....Client-Initiated Testing and Counselling

CME..... Continuous Medical Education

CPD.....Continuous Professional Development

CT .....Counselling and Testing

DAR .....Daily Activity Register (MOH642)

DASCO.....District AIDS and STI Control Officer

DBS.....Dried Blood Spot

DCDRR .....Daily Consumption and Data Report & Request Form

DMLT.....District Medical Laboratory Technologist

DHMT.....District Health Management Team

DHRIO .....District Health Records and Information Officer

DTC.....Diagnostic Testing and Counselling

DMOH .....District Medical Officer of Health

DSRS.....Department of Standards and Regulatory Services

DSW .....German Foundation for World Population

EID.....Early Infant Diagnosis

ELISA.....Enzyme-Linked Immunosorbent Assay (Test)

EQA .....External Quality Assessment

FBO.....Faith-Based Organization

FCDRR .....Facility Consumption and Data Report & Request Form

FGD.....Focus Group Discussions

FHI.....Family Health International

FP .....Family Planning

FTP .....File Transfer Protocol

HBTC .....Home Based Testing and Counselling

HCI.....Health Care Improvement Project

HCW .....Health Care Workers

HIV.....Human Immunodeficiency Virus

HMIS .....Health Management Information System

HTC.....HIV Testing and Counselling

IDU .....Intravenous Drug Users

IQA .....Internal Quality Assurance

JICA .....Japan International Cooperation Agency

KDHS .....Kenya Demographic Health Survey

KEMRI .....Kenya Medical Research Institute

KEMSA .....Kenya Medical Supplies Agency

KMTC.....Kenya Medical Training College

KNASP.....Kenya National HIV/AIDS Strategic Plan

KNH.....Kenyatta National Hospital

LMU .....Logistics Management Unit

LVCT .....Liverpool VCT Care and Treatment

M&E .....Monitoring and Evaluation

MCH .....Maternal and Child Health

MOH.....Ministry of Health

MOMS.....Ministry of Medical Services

MOPHS.....Ministry of Public Health and Sanitation

MSM.....Men who have Sex with Men

MHTC .....Mobile HIV Testing and Counselling

NACC .....National AIDS Control Council

NASCOP .....National AIDS and STI Control Programme

NGO.....Non-Governmental Organization

NHRL.....National HIV Reference Laboratory

NPHL .....National Public Health Reference Laboratory

NQAS.....National Quality Assurance Strategy

NQAT.....National Quality Assurance Team

NQMG .....National Quality Management Guidance

NQMT.....National Quality Management Team

PASCO .....Provincial AIDS and STI Coordinator

PCR.....Polymerase Chain Reaction

PHMT .....Provincial Health Management Team

PHRIO.....Provincial Health Records and Information Officer

PITC.....Provider-Initiated Testing and Counselling

PMLT.....Provincial Medical Laboratory Technologist

PMTCT.....Prevention of Mother to Child Transmission

PMO .....Provincial Medical Officer of Health

PT .....Proficiency Testing

PWP.....Prevention With Positives

QA .....Quality Assurance

QI .....Quality Improvement

QM .....Quality Management

SDP.....Service Delivery Point

SOP.....Standard Operating Procedure

SPEAK .....Technical Cooperation Project for Strengthening of People Empowerment against HIV/AIDS in Kenya

STI .....Sexually Transmitted Infection

SW.....Sex Worker

TB .....Tuberculosis

TOT.....Trainer of Trainers

TWG.....Technical Working Group

UNAIDS .....Joint United Nations Programme on HIV/AIDS

URC .....University Research Council

USAID.....United States Agency for International Development

VCT .....Voluntary Counselling and Testing

WHO.....World Health Organization

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Foreword

The Government of Kenya has taken the lead, with support of development partners, to systematically put in place mechanisms to ensure the achievement of universal access to HIV testing.

The Ministry of Public Health and Sanitation - National AIDS and STI Control Programme (NASCOP) developed and launched the National Guidelines for HIV Testing and Counselling in Kenya. This was an important step for Kenya in keeping in line with the international guidelines and recommendations on quality HIV Testing and Counselling (HTC) services.

The Health Ministries: Ministry of Public Health and Sanitation (MOPHS) and Ministry of Medical Services (MOMS) through NASCOP recognize that there is need to minimize missed opportunities for HIV Testing and Counselling. It is for this reason that there has been a push towards diversifying testing approaches in the recent past. This push has seen an unprecedented scale-up of counselling and testing models and HIV testing service delivery points. The scale-up, however, must be achieved while guaranteeing that the quality of the HIV Testing and Counselling is not compromised. This will be achieved through ensuring that the service providers have the necessary capacity and structures, as well as systems to deliver increased access to quality HIV Testing and Counselling services.

As we seek to diversify the testing efforts we wish to ensure that quality is maintained across all the settings of HIV Testing and Counselling. In view of this, NASCOP has identified a task force whose main objective is to ensure that quality goes along with implementation of HIV Testing and Counselling.

This document provides a broad policy framework of quality HIV Testing and Counselling and it is my belief that all implementing partners will be guided by this document, as they provide HIV Testing and Counselling in a manner that observes all the Standard Operating Procedures and Bio-Safety recommendations.

I encourage all HIV Testing and Counselling providers in HIV Testing and Counselling settings to study the quality details described here and embrace them with a view to ensuring that HIV Testing and Counselling service provision is guided by quality and not only driven by the need to see an increase in the numbers tested.

I would like to acknowledge all those who contributed to the success of this document: LVCT, SPEAK–JICA Project, Kenyatta National Hospital, National HIV Reference Laboratory, Jhpiego, Trinity Biotech for all the financial and technical support. In addition, I would like to extend my appreciation Dr. Miriam Taegtmeyer of Liverpool School of Tropical Medicine, Dr. Steven Kinoti of University Research Council and Dr. Rashad Massoud of USAID Healthcare Improvement Project, for their technical input in the development of this document.

Special acknowledgement is due to the editing team, for their very notable dedication and immense contribution. This team was coordinated by Carol Ngare and comprised of: Harriet Watindi, Joseph Gatimu, Paul Ngone, Silah Kimanzi, Irene Mwega, Peter Maingi, Catherine Gichimu, Angela Sila and Yuko Takenaka.

My heartfelt appreciation goes to the quality assurance and supervision division of LVCT, led by Harriet Watindi, for their role as the secretariat

in the whole process of developing the National Quality Management Guidance Framework document.

It is my sincere hope that this comprehensive HIV Testing and Counselling National Quality Management Guidance Framework will go a long way in helping to strengthen the provision of quality HIV Testing and Counselling services everywhere, which every Kenyan deserves and I look forward to a successful fulfilment of the objectives as set out in this guidance document.

Dr. Nicholas Muraguri
Head, NASCOP

Executive Summary

The delivery of quality HIV Testing and Counselling is critical, hence the need to manage it effectively and efficiently. The aim of the National Quality Management Guidance Framework is to provide a framework for quality HIV Testing and Counselling services. This document describes systematic approaches to assessing, monitoring, and improving the quality of services to consistently meet client needs.

Internal and external quality assessment measures should be conducted in all elements of HIV Testing and Counselling services which include: Testing, Counselling, Logistics, and Data Management.

Provision of quality HIV Testing and Counselling services is everyone's responsibility, from service delivery points up to the national level. Therefore, this document endeavours to ensure that quality becomes an integral part of HIV Testing and Counselling services in the diverse HIV Testing and Counselling approaches and settings, as provided for in the National HIV Testing and Counselling Guidelines in Kenya, i.e. community based and health facility settings.

This document advocates for a minimum package of HIV Testing and Counselling which includes pre-test information and post-test counselling. It further recommends the application of the core principals of HIV testing and counselling services summarized as the 3Cs: Consent, Confidentiality and Counselling.

Quality testing begins at the national level with the evaluation, approval, and registration of HIV test kits by the National Blood Safety Committee. Only HIV test kits that are provided for in the national

algorithm by the Ministry of Public Health and Sanitation will be used for HIV testing in Kenya. Provision of accurate HIV test results is important and this calls for continuous quality assessment through validation and proficiency testing.

This document gives guidance on quality logistics which include: realistic forecasting, procurement, distribution and storage of supplies. It also provides guidance on quality data management, which ensures accurate measures of current performance. National standardized tools shall be used for HIV Testing and Counselling data collection and management.

For this document to be utilized most effectively, NASCOP through the National Quality Management Team, via the decentralized structures at the provincial and district levels, will continue to provide leadership and direction. The government will continue working closely with development partners and implementing agencies to ensure provision of quality HIV Testing and Counselling services.

General Background

The rapid scale-up of HTC in Kenya dates back to the year 2000. Since then, HTC has expanded throughout the country, with the GOK advocating for universal accessibility, availability, and affordability of HTC services in Kenya.

Currently only 58% Kenyan females and 42% Kenyan males, aged 15-49 years, know their HIV status (KDHS 2009). Testing coverage needs to increase substantially to reach the national goal of HIV testing - 80% of all adults and adolescents by 2013 (KNASP III 2010).

HTC has evolved with time, since year 2000, with several models having been introduced in recent years. It started with VCT services in stand-alone and integrated VCT sites. CT models were then scaled up to include PMTCT, DTC, PITC, mobile VCT, 'moonlight' VCT, and door-to-door HTC, among others. All these HTC models and strategies still exist and complement each other through harmonized and standardized National HTC Guidelines.

HTC services are also offered to groups with special needs such as: young people, survivors of sexual violence, persons with disabilities, and Most at Risk Populations (MARPs) such as Sex Workers (SWs), Intravenous Drugs Users (IDUs), and Men Who Have Sex With Men (MSM).

Kenya has been a pioneer among countries using the provider initiated approach, as the inclusion and prioritization of this model in this guidance suggests. Integrated HIV Testing and Counselling in blood safety settings began as early as 1989, and early infant diagnosis (EID) using PCR was introduced in 2006.

Through the combination of all these models, Kenya currently conducts an average of 500,000 HIV tests per month (NASCOP M&E Report, 2010).

Rationale of the National Quality Management Guidance Framework

The main objective of the National Quality Management Guidance (NQMG) framework is to provide a framework for quality HTC service delivery in Kenya.

The framework is aimed at ensuring that quality becomes an integral part of HTC services, whether in public or private health facilities, mobile units or door-to-door testing services. Tackling quality is everyone's responsibility and therefore having a framework allows for a structured process of addressing quality.

This document will be suitable for use in all settings and covers all approaches of providing HTC services. All forms of HIV testing are expected to observe standard guiding core principles of HTC: Consent, Confidentiality, and Counselling. All forms of HIV testing should comprise of pre-test information, the actual test, a post-test session and appropriate referral. All this is intended to benefit the client being tested. Accurate HIV test results should be provided to the client regardless of the HTC settings and QA measures should be undertaken to assure this. The systems of referral, tracking and data management, are a critical component of HTC outcomes and are also part of the guidance document.

This document aims to promote 'local' (site and service provider) ownership of QI and to integrate this into a simple and effective QA system that benefits the entire health system.

Since HTC delivery is based on teamwork, the QM approach described in this document supports an inter-disciplinary team approach for identifying and working on quality-related problems. It therefore calls for involvement of care and support services within a health facility, not just the HTC services.

The target audience of this document includes, but is not limited to, HTC policy makers, managers, and service providers at all levels and settings.

Quality Assurance Background

The rapid scale up of Kenyan HTC services, that started in 2000, necessitated the formation in 2004 of NQAT; a sub-committee of the National VCT Taskforce. The main objective of this team was to oversee the quality implementation of HTC services in the country.

National QA strategy guidelines were developed, launched and disseminated and they became a basis of quality implementation of HTC services. All tools meant for registration, licensing and accreditation were part of the QA strategy, and roles and responsibilities of all players at all levels were spelt out.

This new NQMG framework document strives to compliment the previous QA strategy, with inclusion and considerations of various settings of HTC which have been adopted in the country.

Other strategies, that previously enhanced quality in the implementation of HTC, included the development and dissemination of a National HTC curriculum. This was developed and adopted by all stakeholders. It was a 3-week curriculum of HIV/AIDS information counselling theories and a testing component. Qualified TOTs across the country were identified and trained and only they were allowed to train VCT counsellors. In an endeavour to ensure quality trainings, a limited number of institutions outside the GoK were accredited to train counsellors and all certificates issued post training were signed by the Head of NASCOP. Refresher courses were highly recommended, and were based on

new HTC related emerging areas. These refresher trainings helped in maintaining quality of the VCT counsellors. This developed client confidence in the services, which is probably the single most important factor that has contributed to the high testing demand to date. Other mechanisms to ensure quality of HTC services included:

Counsellor Support Supervision

Counsellor support supervision is a forum where service providers reflect on their work with clients and learn from that reflection. This they do with the facilitation of experienced counsellor who takes on the role of a supervisor.

Counsellor support supervision for HTC providers dates back to the year 2002, when the first lot of 21 counsellor supervisors was trained at the national level. The integration of support supervision for counsellors was, and remains not only part of the quality assurance mechanisms for HTC services, but also an ethical requirement for practicing counsellors. The process entails a formal, mutually agreed upon arrangement for counsellors to discuss their work regularly with an experienced and competent counsellor supervisor, who is trained and is therefore familiar with the process.

HTC services in Kenya have evolved over the years with more health care workers being trained to offer HTC services. The demand for services has also risen over time with increased awareness; in turn this continues to put pressure on the health care workers and necessitates support supervision. Supervision further plays an important role of developing the providers' skills, knowledge and attitude towards service delivery. Support supervision strengthens providers adherence to organisational and professional policies, thus safeguarding the welfare of the client.

Administrative Support Supervision for HTC

Administrative support supervision was aimed at strengthening / improving management and administrative duties.

In accordance with the previous QA strategy, administrative support supervision was carried out at all levels. i.e. national, provincial, district and site levels. At the national level this happened twice a year and was facilitated by a team from NASCOP, while at provincial level this was facilitated by the PASCO and was undertaken quarterly. Administrative support supervision at district level was carried out monthly and was facilitated by the DASCO. This helped trouble-shoot the various quality issues, and on the job trainings took place in response to identified need. Supervisory reports were shared with the stakeholders and follow-up for sites that were not doing well was done through the PASCOs and the DASCOs.

Occasionally partners also supported their sites and the service providers, as additional support.

Observed Practice

Direct observed practice was introduced as a mechanism of providing instant feedback to counsellors on a counselling session they had just conducted. Observed practice was conducted by an experienced counsellor or counsellor supervisor, with the consent of the client. The observer, using laid down guidelines and a structured tool, sat through a counselling and testing session and gave feedback to the counsellor at the end of the session, based on what they had observed. This was used to check, among other things, whether the counsellor had conducted a client-centred session, remembered the key components of the pre- and post-test counselling protocols, helped clients deal with emotional reactions to the test result and developed a risk reduction plan etc.

Client Exit Interviews

Client exit interviews were structured questionnaires / interviews administered on clients that had received HTC services.

This approach was aimed at obtaining client views on the quality and satisfaction of VCT services they had just received. National tools were used.

These were introduced in 2005 through National QA Strategies. Information on the forms was collected by an interviewer identified from the community. This mechanism was however not widely applied in VCT sites due to lack of knowledge and skills on how to administer the tools, analyse the information captured and utilise the information for quality improvement. Other limitations attributed to limited utilization of the tool included lack of resources for engaging interviewers. However, from the few instances where it had been successfully utilized, it was found to be useful to capture client opinion on service standards and provider attitudes.

Provider Self Assessment

This was introduced along with the client exit interview. It was carried out by using national self administered questionnaires, focusing on some key aspects of a VCT session. Each aspect was rated on a scale from 1 to 4. Counsellors were required to fill at least one self assessment form per day. At the end of each month, counsellors summarized all filled assessment forms and discussed them with their supervisor, as they reviewed their performance.

Mystery Client

Mystery clients are trained people, usually community members, who visit programme facilities in the assumed role of clients, and then report on the experience with an aim of service QI (ref: *Using Mystery Clients; A Guide to Using Mystery Clients for Evaluation.* Pathfinder).

In Kenya, mystery clients were trained on HTC and observation skills. They visited various VCT sites across the country. The exercise was carried out in 2004 and 2005

with a view of assessing the quality of VCT services in Kenya against the quality of service stipulated in the National Quality Assurance Strategies, National VCT guidelines and steps and procedures prescribed by service delivery protocols. The exercise further established whether counsellors were adhering to the counselling code of ethics and practice. The exercise was promoted as a means of observing a counsellors interaction with a client, without the bias of a counsellor having to act in a particular way because of having an observer in the session.

Testing Quality Control (Validation)

This is a process or system that ensures testing SOPs meet predetermined specification and quality attributes.

QA samples, in form of DBS, were collected randomly from every fifth tested client. As the uptake of VCT services increased, this was reviewed and adjusted to every tenth tested client, in accordance with the National VCT Guidelines. Validation of DBS samples was processed at the NPHL. Feedback from the validation was sent back to the facilities through the DMLT and follow-up made where there were issues arising from discordant results.

With the launch of new HTC guidelines, DBS QA samples are now collected from the 20th tested client.

In 2008, PT was piloted by NHRL in some selected sites in different regions. This approach to assuring the quality of testing is currently being rolled out nationally.

Laboratory support supervisory visits were made by the national team in the regions and districts, in collaboration with the PMLTs, DMLTs and trained Laboratory supervisors on the ground.

Registration, Licensure and Accreditation

In 2001, NASCOP initiated a registration scheme that would

enable it to have an up-to-date register of all VCT sites in the country. Since September 2001, each VCT site in Kenya, that demonstrates compliance with minimum standards, has been issued with a unique site code.

Once registered, however, sites were not required to revalidate their registration, causing concerns whether these standards were continuously adhered to. Thus, NASCOP established a strengthened national quality assurance system. It consisted of registration of new sites, annual licensing of registered sites and voluntary accreditation.

NASCOP maintained a live national database, which indicated each site's current status - registered, de-registered (temporarily or permanently), licensed or accredited. In this way, NASCOP had a complete picture of the current status of all VCT sites throughout the country.

National accreditation started in 2005 and continued for 4 years, up to 2008. This was a voluntary exercise for sites that felt confident about offering quality services, over and above the national minimum standards. Sites adhering to guidelines stipulated in the National QA strategy applied to participate in the process. Upon receipt of the application, a team from the national level, the PASCO and the DASCOs visited these sites and administered the scoring tools, after which a report was shared with the National HTC TWG members and HTC stakeholders. The sites applying for inclusion increased every year, which was an indicator that more and more sites did not mind being exposed to the accreditation process. The best performing sites were motivated and given a wall plaque which indicated that they were offering quality services over and above the minimum guidelines.

National PASCOs and DASCOs Meetings

The NQAT work-plan included an annual PASCO / DASCO workshop which was organised by NASCOP

and stakeholders. The main objective of this meeting was to share best practices and discuss challenges around quality control and quality assurance for VCT service delivery. This started in 2005 and all the PASCOs, DASCOs and stakeholders came together to share lessons learnt and best practices. The best performing regions were asked to share their lessons with others and this acted as a way of improving quality across the country. During these meetings, the best performing sites, districts and provinces were motivated by being awarded trophies. The awards created healthy competition and everyone worked hard at their various levels to win the following year.

Data Audit

Data audit is a process of ascertaining the validity and reliability of produced HTC data.

Use of the Monthly and Quarterly VCT Data Form (MOH726/727) for reporting HTC services enabled NASCOP to audit data.

Quality Management (Definitions)

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Definitions

Quality Management

QM is considered to have three core components (QA, Quality Control and QI). It is an ongoing effort to provide services that meet or exceed clients' expectations.

Quality Management for Health Services

QM for health services is the concerted effort to provide health services to meet the needs of clients and providers, in an equitable and acceptable manner, within the resources available and in line with relevant stipulated guidelines.

QM of health services is an integrated organizational approach for meeting client expectations, by involving both managers/ administrators and providers. This approach works towards improving services using both quantitative and qualitative techniques.

It addresses the issues of accessibility, acceptability, equity, safety, effectiveness and efficiency of service delivery, which in turn contribute to the goal of producing better health in our communities. QM creates public confidence in the services we provide, which is particularly important for HTC service provision.

QM requires that there is clarity on the specific aspects of service provision that we wish to monitor. This therefore requires that QM teams are very clear on:

- Specific quality indicators to be monitored
- Where the relevant indicators will be found / collected from
- Data tools to be used to collect the required data

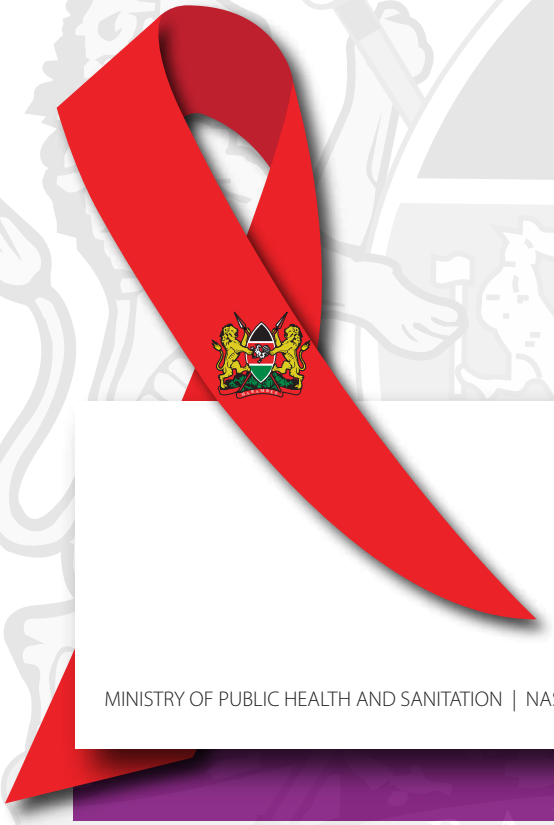
Quality Assurance

QA is a systematic and planned approach to monitoring, assessing and improving the quality of services on a continuous basis.

In QA, standards are set for services; managers and service providers ascertain that services are delivered in such a way that these standards are met consistently; and the client is therefore assured of the quality of the service.

QA and improved quality of services requires more than a technical approach of tools and methods. Sustained improvements often require both a change in attitude and sense of ownership of the quality of services provided by all.

HTC QUALITY ASSURANCE CYCLE



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Quality Management in HIV Testing and Counselling (HTC)

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Core Principles of QA in HTC Services

The following are the core principles of quality in HTC service provision;

1. **Focus on clients:** the goal is to meet the needs and expectations of both internal (service providers and managers) and external clients (consumers of the service including patients and the community).

2. **Focus on systems and processes:** involves understanding structures and procedures followed in delivery of quality HTC services.

3. **Focus on measurement:** Use of data to analyze HTC service delivery processes; identify problems, test solutions and measure performance.

4. **Focus on team work:** encourages a team approach to problem solving and quality improvement from HTC service delivery points to the national level.

HTC Quality Assessment

In order to monitor and improve on the quality of HTC services, it is important to measure/assess how processes and services correspond to current standards, as well as a patient's satisfaction with the care received. This can only be achieved if HTC standards and indicators are well defined and understood by all service providers and managers. (See table on HTC standards and indicators).

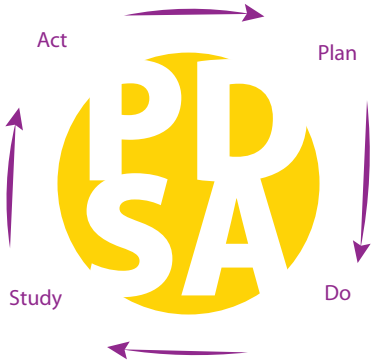
HTC Quality Improvement

QI is a key component of HTC service delivery. It is the concerted effort to continuously do things better, until they are done right at all times. It endeavours to reduce the gap between performance and set standards.

QI entails identifying quality related problems using various mechanisms. It advocates for analysing problems with a view to understanding the root causes and developing solutions based on the root causes.

QI requires that QM teams are very clear on expected outcomes or results of service delivery and continuously seek to determine if the outcomes are being achieved.

Plan-Do-Study-Act Cycle (PDSA-Cycle)



The PDSA is a component of the larger QA cycle (see page 28) and can be used to provide guidance on how to improve the quality of service delivery in small incremental steps.

1. **Plan:** Recognize an opportunity / area for improvement and plan a change. Define what issues need to be addressed, predict expected outcomes from

addressing the problem, the steps that will be undertaken to resolve the problem, including who will do what, where and by when the changes will be implemented and the resources needed to implement proposed changes.

2. **Do:** Test the change. Carry out a small-scale study.

3. **Study:** Review the outcomes of the implemented changes; analyse the results and identify what you've learnt.

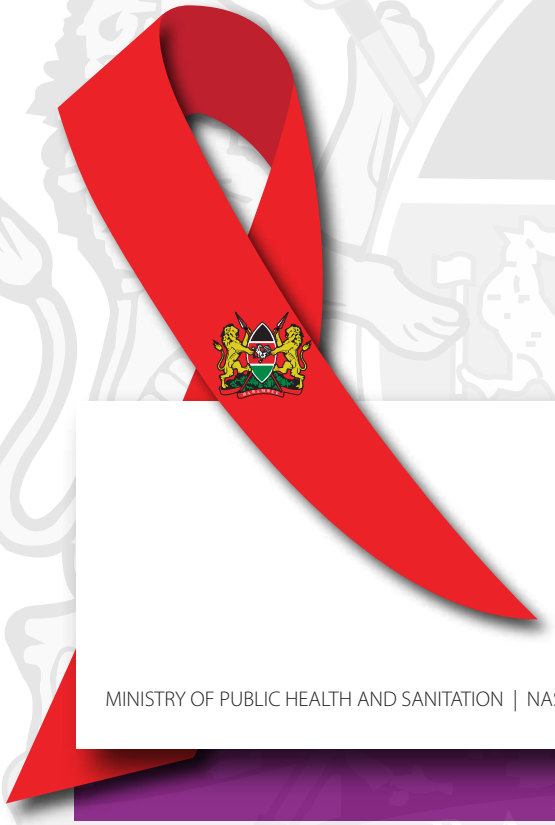
4. **Act:** Take action based on what you learned in the study step: If the change did not work, go through the cycle again with a different plan. However if the changes were successful, they can be incorporated into wider changes. They could further be documented as best practices and institutionalised.

HTC Quality Control

This process is employed to ensure certain levels of quality in a product or service e.g. in-built controls for rapid test kits.

HTC Quality Management

It should be noted that QM is an integral part of all HTC services and every effort must be made to ensure that service delivery is of the highest quality. This means that QM systems must be in place for all HTC components; testing, counselling, logistics, and data management. QM strategies should be operational at both the national and regional levels, and should be carried out at both the facility and individual site levels.



Basic Requirements for HTC Service Delivery in Kenya

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Implementation of Quality Management for HTC Services

HTC Personnel

All HTC service providers must receive training as stipulated in the national HTC curriculum. The providers are also required to access continuous mentorship and support supervision. HTC providers are further required to adhere to all the policies and standards as outlined in the national HTC guidelines. HTC service providers shall be provided with national level certification, after completion of the required HTC training

HTC Infrastructure

HTC service provision facilities/ sites/models shall make every effort to ensure privacy of HTC service provision. In health facility settings where services are provided at open spaces e.g. wards, OPD etc. screens will be availed to provide visual privacy for clients taking up services. However whenever possible, a room shall be identified and used for HTC service delivery.

HTC services provided in community settings shall be provided in a well ventilated VCT room, tent, van or home. All care will be taken to ensure that clients have privacy when receiving the services.

HTC Commodities

All commodities procured for HTC in Kenya shall be approved and registered for use by the ministries of health. The minimum commodities required for HTC are:

- Test kits and their accessories
- Consumables—gloves, cotton wool, spirit, jik/ disinfectant, lancets,
- Data recording tools
- Waste disposal containers

- Quality assurance package—filter papers, zip lock bags, glycine bags, serviettes, humidity indicators, desiccants, filter paper drying racks, cotton wool, alcohol swabs, detergents.

- Male and female condoms

- HTC service delivery protocols

Distribution of commodities will be coordinated from a central level, but the district level will distribute to the sites. At facility level, test kits and testing commodities should be stored by the laboratory in charge (where present) or by the officer in charge. All test kits and testing commodities will be stored in secured lockable cabinets and in accordance to manufactures instructions.

HTC commodities at the facility will be recorded in the laboratory inventory book and distributed to the service delivery points. The lab in charge or the person responsible will compile a monthly consumption report and order and submit it to the district medical lab technologist by the fifth day of every month in order to receive kits supplies in subsequent months.

Where possible, test kits will be supplied directly to the health facilities, but in other cases the kits will be delivered to the DMLT who will ensure they are delivered to every health facility that requires them.

HTC Data Recording Tools and Registers

To ensure accurate recording, timely reporting, and appropriate data entry . All Facilities offering HTC service should have HTC laboratory registers and national data reporting tools. All HTC facilities are required to ensure that HTC related data is kept confidentially and is only accessible to HTC service providers.

All facilities/districts will ensure that data is submitted in respective departments on time.

This will enhance good framework for data analysis and decision making at every stage of HTC implementation

Referral for Continuum of Care

Knowledge of HIV status is not an end in itself, but rather an entry point to prevention, care and treatment . For this reason all facilities/sites/ models providing HTC services, are required to maintain an up to date referral directory as well as a records of clients referred for other services. Additionally, HTC service providers should make every effort to track referred clients to establish whether they have taken up service's as well as if the referral systems are effective. Other records that facilities/sites/models are required to keep include upto date records of tracked clients.

Registration, Licensing and Accreditation of HTC Services

All VCT sites, regardless of whether they are stand-alone or integrated, should be registered, licensed, and accredited. PITC sites are however not required to go through a licensing or registration process This is because health facilities offering HTC services are already registered by the government, in the broader context of health care services. All HTC sites including health facilities and VCT sites, must notify NASCOP through their respective DASCO, of all HTC strategies e.g. mobile, door to door, etc, that they provide or intend to provide. A list of all sites providing HTC services as well as different approaches such as MHTC, Door-to-Door etc. Should be available at the different NASCOP administrative structures.

Registration

This is a mandatory process through which all new stand-alone and integrated VCT sites are evaluated and certified, using a standard tool with the specific objective of assessing whether they meet certain minimum set criteria to provide HTC services. This registration should be done by the DASCO and forwarded to

NASCOP. The registration is done by name and physical address. Only registered sites will have access to HTC commodities such as rapid HIV test kits, HTC laboratory registers, as well as condoms.

De-registration of Sites

Stand-alone and integrated HTC sites that do **NOT** meet the national minimum criteria for providing HTC services, thus posing a threat to clients through modification of standard operating procedures, lack of adherence to bio-safety measures or poor quality counselling services, may be temporarily or permanently removed from the NASCOP register. The process of de-registration will be conducted by the DASCO, in conjunction with the PASCO, and forwarded to NASCOP.

An official letter from NASCOP, copied to the PASCO and the DASCO, will be written to the de-registered site highlighting reasons for de-registration. Re-registration will **ONLY** be effected after the site has addressed all the concerns raised leading up to it's de-registration.

Annual Licensing

This is a process through which NASCOP grants permission to the stand-alone and integrated VCT sites to continue providing HTC services. An annual assessment visit will be made by the DASCO, on behalf of the DHMT, to determine whether the site continues to adhere to minimum set standards. A standard tool will be used to carry out this assessment. NASCOP will develop and place a national tool in all the registered sites, which will be used by the DASCO or any identified DHMT member, to license the sites annually. The DASCO, in cooperation with the DHRIO, will maintain and update the list of registered and licensed sites.

Accreditation

This is a formal process through which NASCOP, with members of NQMT, will evaluate the sites

that have applied for this exercise and determine which of them meet or exceed the minimum set standards for HTC service provision. A national standardized tool will be used for performance assessment in all site applications. This is a voluntary annual exercise initiated by the sites. NASCOP and partners will come up with a rewarding and recognition system, which may vary from year to year, for those that have been accredited.

The table below is a summary of the different registration, licensing and accreditation requirements for HTC approaches in health facility and community settings.

REGISTRATION AND LICENSING OF HTC SITES / FACILITIES

	Health Facility Setting		Community Setting	
Approach	CITC	PITC	CITC	PITC
Strategies	Static HTC	PITC	Static HTC, any mobile HTC services including workplace etc.	Door-to-door
	Integrated VCT	Public and private health facilities	Stand-alone VCT	VCT and health facilities
Registration	Yes	No	Yes*	Yes*
Annual Licensing	Yes	No	Yes*	Yes*
Accreditation	Voluntary for sites that feel they are performing above minimum standards			
HTC Signboard or Notice	Yes	Yes	Yes	Yes**
Certification of HTC Service Providers	Yes	Yes	Yes	Yes

* HTC services in the community settings such as MHTC, door to door etc., should be carried out by registered and licensed organizations. This must be reported to the DASCO.

** Service providers offering door-to-door must be identifiable by badges, backpacks, and authorizing letters from recognized MOH officials.

HTC Quality Management Structures

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The HTC QM structure outlines the implementation of quality HTC service provision from national level, down to the service delivery points.

National Quality Management Team (NQMT) for HTC Services

The NQMT is a sub-committee of the HTC Technical Working Group (TWG) at NASCOP. Its main objective is to provide leadership and advocacy for QM of all HTC services in Kenya. The NQMT is coordinated by NASCOP, whose membership comprises various organizations providing and supporting HTC services in Kenya.

The main role of NQMT is to make recommendations to NASCOP on the following issues of quality HTC service provision:

- Development of long and short term objectives for QM of HTC services in Kenya
- Development of an annual work plan for achieving the national QA objectives
- Review national progress on quality improvement
- Preparation of annual reports on quality of HTC services in Kenya
- Dissemination of information on quality of HTC services to stakeholders and partners

- Feedback to the relevant national systems, for facilitation of appropriate policy development
- National registration, licensing and accreditation of HTC sites as required
- Accreditation of HTC training facilities and trainers
- Maintenance of an up-dated inventory of certified and practicing HTC service providers
- Equitable and appropriate distribution of human resources and logistics for HTC services
- Assessment of priority areas for quality improvement and capacity needs plus continuous capacity building of HTC service providers
- Review and development of guidelines, standards, and standard operating procedures including national QA mechanisms, tools and approaches

Provincial Level

The Provincial Quality Management Team for HTC services will be coordinated by the PASCO, who is responsible for overseeing HTC alongside other HIV and AIDS related responsibilities in the province. The PASCO, who is an appointee of the Provincial Health Directors and a member of the PHMT, will work closely with NASCOP, HTC stakeholders at the provincial level and DASCOs in the province, to oversee provincial HTC quality issues.

District Level

The District Quality Management Team for HTC services will be coordinated by the DASCO, who is responsible for overseeing HTC, alongside other HIV and AIDS activities in the district. The DASCO and member(s) of the DHMT will work closely with the PASCO and HTC stakeholders at the district level. It is highly recommended that the DASCO works closely with other DASCOs within the province, to share best practices and lessons learnt to improve quality in HTC services provincially.

District Medical Laboratory Technologist

It is the responsibility of the DMLT to ensure the continuous availability of rapid HIV test kits and other QA commodities, including filter papers, at all HTC sites within the district.

District Medical Laboratory HTC Support Supervisor

The district medical laboratory supervisor who is a representative of the DMLT should be a certified HTC service provider. They should be responsible for quarterly laboratory support supervisory visits, counter check validity of test kits at district level, ensure SOPs are adhered to, etc. Their role also entails monitoring EQA participation in the district.

District Health Record and Information Officer

It is the responsibility of the DHRIO to ensure: quality of HTC data validation and management, submission of complete and accurate district HTC data sets to national level, and data usage plus feedback. It is highly recommended that the DHRIO works closely with the DASCO to exchange views of the HTC service provision in the district.

HTC Support Supervisor

The HTC Support Supervisor should be a practicing HTC service provider, trained in counselling supervision in accordance with the national curriculum. HTC Support Supervisors' roles at district level will be clearly outlined by the DASCO. It is important that HTC managers and all levels clearly understand the different roles played by support supervisors and administrative supervisors. The role of the supervisor is to:

- Assess level of quality of HTC service at service delivery points
- Provide support supervision for practicing HTC service providers, mitigate burn-out and address clients' needs
- Provide mentorship for continuous professional development
- Identify and address knowledge and skills gaps amongst service providers
- Give feedback on any observations regarding HTC service provision to the DASCO

There should be adequate trained supervisors in every district. It is recommended that all HTC sites have at least one supervisor. The HTC site manager should ensure each HTC service provider has access to support supervision at least once a month during site support supervision.

Facility Level

HTC QM is an integral component of the general QM in both public and private health facilities. It is recommended that the HTC QM team at the facility level be a sub-committee of the larger facility QM team. The HTC QM team will meet at least once a month. The HTC Support Supervisor and/or HTC Coordinator will be responsible for convening this meeting. Feedback from the meeting will be given to the overall facility manager, who will share it with the DASCO/DHMT.

Interdisciplinary HTC QM teams are the best mechanisms for driving the quality culture and the QM process. It is recommended that some team members have managerial decision making skills that can directly influence quality of service delivery. The HTC QM team should be responsible for implementing QM by:

- Promoting QM awareness for HTC services
- Continuously monitoring, assessing and improving quality
- Analyzing data to measure the level of quality of HTC services
- Developing and implementing QA change plans
- Working as an interdisciplinary QM team
- Involving the community and other stakeholders in QM

The minimum standards required for facilities to provide HTC services include:

- Trained HTC service providers
- Adequate private space
- Availability of an access system for test kits, testing commodities, and data collection tools
- Availability of relevant national policy guidelines e.g. National HTC Guidelines
- Maintenance of adequate stock levels of test kits and other HTC service related commodities

HTC Coordinator

An HTC Coordinator will be designated at each site, especially in health facilities. The HTC Coordinator will strive to be continually up-to-date with the latest HTC service provision requirements.

This position is recommended for all HTC sites, to support quality HTC services through the following functions:

- Ensure quality of HIV Testing and Counselling services
- Monitor and evaluate HTC services
- Organize HTC support supervision for HTC service providers
- Organize refresher trainings and mentorship, based on gaps identified by HTC service providers and supervisors
- Report on facility HTC data
- Ensure adequate site storage of HTC commodities
- Champion uptake of HTC services

HTC Service Provider

Responsibility for quality rests with each service provider. Ownership of the QM process by HTC service providers remains the secret for success in turning policy on quality of care, into practice. It requires individuals to internalize the concepts of quality improvement and assurance, and apply them in their daily work. The responsibilities of the HTC service provider on QM is inclusive of, but not limited to:

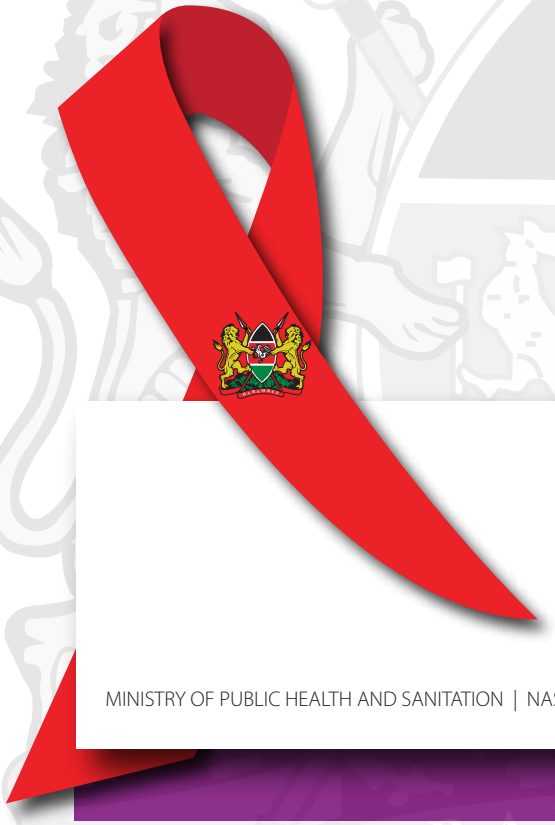
- Adhering to standard operating procedures and national guidelines on HTC
- Actively participating in EQA
- Actively participating in support supervision
- Maintaining accurate HTC records
- Monitoring own performance in counselling, testing and data management
- Managing, monitoring and maintaining HTC logistics and commodities
- Attending at least one observed practice session per year
- Attending continuous professional development (CPD) sessions at least once a month
- Reading and understanding relevant HTC policy guidelines and documents
- Accessing continuous mentorship to enhance competence in HTC service delivery

Community Involvement in QM for HTC Services

Community involvement is critical to the continued success and improvement of health services. HTC service providers and managers are encouraged to embrace participatory approaches to QM in the community. As much as possible, communities where services are provided will be involved in defining and participating in HTC QM activities. Various methods including FGDs, client / community feedback tools, etc., can be used to strengthen dialogue between communities and service providers. Health facilities are encouraged to invite local community volunteers to be part of facility QM teams.

Further, service providers and managers will strive to ensure that there is free information flow, both from service providers to the community and vice versa.

HTC QUALITY MANAGEMENT STRUCTURE



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Quality Management Measurements in HTC

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In order to adequately address quality, HTC services are divided into the following 4 components, under which QM is followed in each:

Quality Management in Testing

Quality HIV testing produces results that are accurate, reliable, reproducible, and timely. This involves proper identification of clients, appropriate infrastructure, proper testing commodities, qualified staff, and adherence to SOPs, proper documentation, laboratory support supervision, and participation in external quality assessment (EQA).

Measures to control quality in HIV testing are vital, because the consequences of either a false positive or a false negative result are dire. HIV testing in HTC should be conducted by trained professional staff as outlined in the national HTC guidelines. Only test kits and testing algorithims recommended by the NHRL will be used in the provision of testing services. Change in algorithm and or test kits can only be effected through a circular released by the Director of Medical Services.

Laboratory technicians and technologists are the only personnel authorized to perform laboratory machine-based HIV tests, such as standard Enzyme-Linked Immuno-Sorbent Assays (ELISA or EIA), Polymerase Chain Reaction (PCR), Western Blot (WB), or Viral Cultures. NHRL coordinates national HIV testing validation exercises.

Quality Management in Counselling and HIV Information Giving

Counselling for HIV testing involves the provision and clarification of information to the clients about the HIV test, facilitating informed decision-making regarding the results.

It also involves prevention counselling, focusing on the client's HIV infection risks and negotiated behaviour change for risk reduction. It further provides client support during appreciation of test results, reviews strategies for risk reduction with support, explores mechanisms of disclosure and partner or child testing, discusses appropriate treatment options or access to the same and makes appropriate referrals.

Quality Management in Logistics and Commodities

Quality Logistics involves integration of information, inventory, warehousing, material handling, and occasionally security. Logistics is a channel of the supply chain management, which adds the value of time and place utility. For ease of monitoring consumption patterns of test kits from the national level down to the facility level, all test kits procured by government and partners should be channelled through KEMSA.

Quality Management in Recording and Reporting Quality HTC data management

This involves the process of accurate recording, timely reporting, and appropriate data entry and storage, prior to its analysis and feedback. Harmonized HTC recording and reporting tools contribute to standardized HTC service data collection.

The following table outlines the components as well as the standards and indicators for HTC services and QM data collection processes.

HTC QUALITY MANAGEMENT MINIMUM STANDARDS

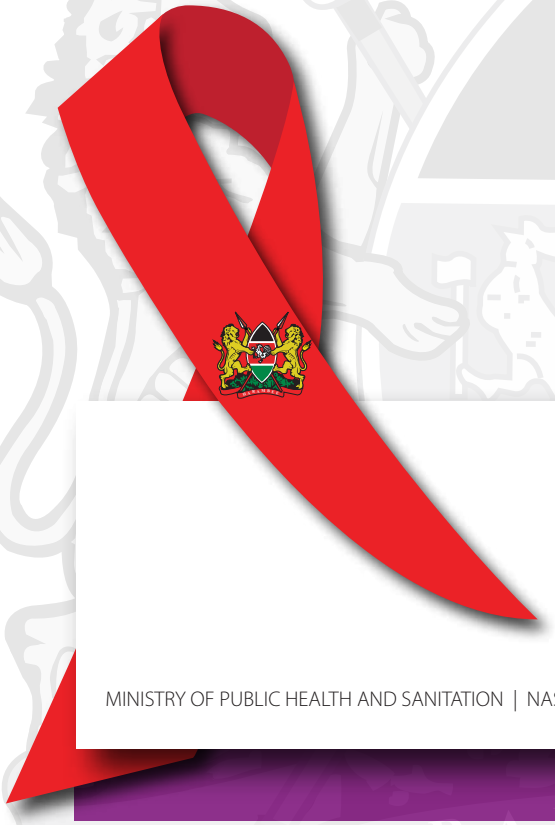
Standards	Indicator	Definitions & Clarifications	Data Collection		
			Source of data/ MOV (include tools)	Frequency of submission	Responsible organization/ person(s)
HTC service providers are competent to provide HTC services.	• No. of service providers trained in provision of HTC services • No. of providers receiving support supervision on provision of HTC services • No. of providers receiving quarterly administrative support • No. of HTC providers receiving laboratory support supervision	Training refers to new training or retraining of service providers in provision of HTC services, according to national standards	Program Training Reports MOH certification	Periodic	NASCOP/ MOH/ Implementing partner
		• Assess quality of HTC service provision by the trained service providers. • Conduct continuous mentorship	Facility support supervision reports	Once a month	Facility in-charge HTC coordinator / counsellor supervisor
		Assess how administrative managers are involved in the management of HTC services	Minutes of meetings, signed visitor books and/or reports	Monthly by facility managers, quarterly by district managers, biannually by provincial managers, annually by national team	National, provincial, district and facility in-charges
		Lab technologist provides technical support to the HTC service providers to ensure quality of HTC service provision by ensuring accurate blood sample collection, DBS and PT panel processing and discrepant results analysis	• Minutes or reports • Records of concordant and discordant samples • DBS collected and PT panels received and sent back to national reference lab. • Feedback received from HIV Reference Laboratory Log book for supervision	Quarterly	• Qualified laboratory technologists • HTC service providers

Standards	Indicator	Definitions & Clarifications	Data Collection		
HTC service providers are receiving continuous support to provide quality HTC services	No. of HTC providers attending continuous professional development (CPD)	All HTC providers should attend CPD programs at least once per month, should be HTC related and access counsellor support supervision to update their knowledge and skills. This would include updates on emerging issues in HTC service provision and HMIS	• Signed CPD record books • Client records • Presentations in conferences and meetings participation in • HTC related trainings • Records of counsellor support supervision	Monthly	National, provincial, district and facility in-charges
HTC conducted in accordance with the procedures outlined in the national HTC guidelines	• Presence of SOPs , national testing algorithm and manufacturer's instructions • Adhering to infection prevention policy guidelinestesting guidelines • Presence of waste management guidance at the site • Site segregation bins • Running water • PPE (personal protective equipment	To ensure accurate HIV results and compliance to infection prevention policy guidelines	Checklist of the following: • SOP for sample collection • Feedback reports from lab, regional and national reference lab • National HTC Laboratory Register • Infection prevention checklist	Continuously	National, provincial, district and facility in-charges
	Evidence of a complete and accurate HTC laboratory register	Assess levels of concordance with reference laboratory at all levels	Records of DBS collected and sent to the national reference laboratory Records of proficiency testing from the reference laboratory Feedback records from the reference laboratory	Continuously	National, provincial, district and facility in-charges
	No. of HTC providers recording all information in the HTC laboratory registers for each client	To ensure accurate, valid and complete data entry in the HTC laboratory register by all practicing HTC trained service providers	HTC Laboratory register	Monthly	National, provincial, district and facility in-charges

Standards	Indicator	Definitions & Clarifications	Data Collection		
HIV rapid test kits are managed as per the laid down guidelines	Proportion of test kits within expiry date	To ensure that all HTC service providers are using test kits that are under the expiry dates and stored as per manufacturers recommendations	Kits in stock within expiry dates Stock inventory register HTC laboratory register capturing the expiry dates for all the test kits Rapid test kits checklist	Monthly	Facility in-charge e.g. Med. Supt., nursing officer in-charge, senior health administrator, lab tech, HTC Coordinator and service providers
	Proportion of kits stored within appropriate temperature and humidity levels				
Functional HTC QA systems are in place as provided for in the national HTC guidelines	No. of QA meetings held at all levels to identify areas for HTC service improvement No of facilities with clear and well defined QA systems No. of client satisfaction surveys conducted No. of HTC providers undertaking self assessment	All HTC service providers at all levels e.g. national, provincial, district, facility, SDP should ensure that QA systems are in place to enhance quality of HTC services.	Minutes and reports from QA meetings Evidence of action taken on recommendations	Quarterly	National, provincial, district and facility in-charges
			M&E reports	Biannually	
			HTC national quality assurance tools	Monthly	
HTC services are carried out according to national counselling and testing protocols	No. of HTC sites adhering to nationally recommended counselling and testing protocols	All HTC services offered in accordance to nationally approved counselling and testing protocols and SOPs	Availability of HTC testing and counselling protocols	Annualy	National, provincial, district and facility in-charges

Standards	Indicator	Definitions & Clarifications	Data Collection		
A functional logistic system (an inventory plan) is in place and adhered to, conforming to the national guidelines	HTC sites with a functional inventory plan	Forecasting, requesting, receiving, storage, distribution or utilization and reporting of HTC commodities (see list below) undertaken as per national guidelines • Adequate stock at facility/site level of the following: test kits and non-pharmaceuticals commodities and materials e.g. gloves, serviettes, bleach, filter paper, zip lock bags, glycerine bags, humidity indicators, desiccants, racks, alcohol swabs, cotton wool, gloves, sharps disposal container, disinfectant, biohazard waste bag ,detergents, male and female condoms etc. *(at least one month buffer stock)	Nationally approved commodity registers used to record/report test kit consumption Activity plans showing projected quantities of commodities required including those for outreach activities such as cooler boxes, specialized bags, tents/shades	Monthly	National, provincial, district and facility in-charges
All HTC services recorded in accordance to national guidelines	Proportion of facilities using the testingHTC laboratory registers	All Facilities offering HTC service should have HTC laboratory Registers which captures all HTC services provided.	Updated stock records of the HTC laboratory Registers at all levels(national, provincial, district, facility)	Regularly	Facility in-charges
HTC promotional activities are in place at all testing facilities	No. of HTC services promoted through notices, posters, signboards, electronic and print media No. of health talks conducted to provide information to clients visiting sites/facilities No. of IEC materials available and placed at accessible points at the sites/facilities	All facilities providing HTC services to provide adequate and accessible HIV information, in order to increase quality of HTC uptake	Evidence of HIV information posters, sign posts and notices Records of health talks Records of community mobilization activities Media advertisements	Regularly	National, provincial, district and facility in-charges
Functional and operational referral system adhering to national and facility recommendations	Facilities with functional client referral and tracking No. of facilities with client referral and tracking forms	All HTC service providers/ facilities should ensure that clients are appropriately referred and tracked for additional support and care after an encounter with the service provider And further ensure that recommended referral and tracking tools are used.	Filled and filed referral and tracking forms/records. Facility referral inventory list Completed HTC laboratory register and records maintained for tracking/ Follow up	Continuous	National, provincial, district and facility in-charges

Standards	Indicator	Definitions & Clarifications	Data Collection		
Facilities / sites with specific targets for general and special populations based on the gaps towards achieving nationally defined targets	Facilities with targets for general and special population e.g. MARPS, Couples, etc.	All facility managers are encouraged to develop specific targets for general and special populations for their localities/geographical areas. This will be translated in the national endeavour to achieving 80% universal/ national target for HIV Testing and Counselling	Records/checklist of general or special population reached	Continuous	National, provincial, district and facility in-charges
Sets of HTC service data are counter-checked at each level	No. of service delivery points properly completing the HTC laboratory Register No. of data in-charges verifying data accuracy and completeness No. of facility Health Records & Information officer verifying completeness and accuracy of MOH 711A No. of DRHIOs verifying completeness and accuracy of MOH 711B	All facilities to ensure proper, sufficient , efficient and accurate data entry in all the fields of the HTC Laboratory Register, summary sheets, MOH 711A and MOH 711B at each category of requirement e.g. SDP, Data in – charge, DHRIO etc.	HTC Laboratory Registers Filed copies of HTC summaries MOH 711A forms MOH 711B forms HTC data in FTP	On-going	NASCOP/ MOH DMLT, M&E/ Records officers, HTC managers/coordinators/ service providers
All HTC reports submitted in a timely manner at all levels	No. of facilities /districts providing timely submission of MOH 711A and MOH 711B to facility in-charge/DHRIO/ NASCOP/HMIS	All facilities/districts to ensure that data is submitted in respective departments on time. This will enhance good framework for data analysis and decision making at every stage of HTC implementation	MOH 711A forms MOH 711B forms HTC data in FTP (File Transfer Protocol)	Monthly	NASCOP/ MOH DMLT, M&E/ Records officers, HTC managers/coordinators/ service providers
HTC data audit is conducted at least once a year	No. of HTC data audit conducted by HMIS/ NASCOP, district and health facility	Data audits are conducted to ensure transparency, ownership, accountability and concordance of HTC data generated at all levels to inform programming and planning.	Reports of data audit which include the results of data comparison.	Annually	NASCOP/ MOH DMLTs, M&E/ Records officers, HTC managers/coordinators



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Mechanisms for Strengthening Delivery of Quality HTC Services

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Quality Management Mechanisms

It is important to note that no one method or mechanism, can be used to monitor all the quality indicators that HTC programmes may require monitored. QM teams should be cognizant of the fact that different tools and methods have both strengths and weaknesses. For this reason it is recommended that different methods be used to monitor and assess the quality of services being delivered. QM data collection is however not an end in itself but rather a means of identifying quality issues. Collected data is only useful if it is used to inform QI. See annexes for a few draft QM data collection tools.

HTC Trainings and Continuous Professional Development

All HTC Service providers will be trained, using the national HTC curriculum. Trainings will either be carried out using full time taught model or an on job cascading model. Only training institutions or ToT's that are licensed and accredited by NASCOP-MoPHS are authorized to conduct trainings. The HTC trainees will also undergo observed practice as part of the training, after which they will be certified by NASCOP. Only those who meet the above minimum criteria will be allowed to practice as HTC providers.

Observed Practice for Practicing Service Providers

Direct observation of sessions i.e. observed practice will be carried out by a senior HTC provider or supervisor with a view to providing feedback, thus helping the providers attain more knowledge and skills. The observation will be done after obtaining consent of the client. The observer should be trained on the observed practice process and be able to appreciate the different

HTC settings. Appropriate guidelines for observed practice should be in place, while a checklist is used to assess specific areas of competency. It is recommended that newly trained HTC providers with an experience of one year and below, as well as those who do not practice consistently, undergo observed sessions twice a year.

Other more experienced providers are required to seek to undergo at least one observed practice session per year. Where capacity gaps are identified a number of corrective measures including immediate feedback, refresher trainings or other capacity building opportunities including mentorship can be employed and or organised as part of continuous professional development (CPD).

Internal and External Quality Assurance for Testing

Measures to control quality in an HIV testing site are vital, because the consequences of either a false positive or a false negative result are dire. A number of factors may affect the quality of rapid test results such environmental factors, decomposition of reagents or kits, interfering substances, service providers bias. Service providers may also make mistakes in the testing procedures or in their interpretation of the results, or even in their documentation. For this reason, it is important that external quality assurance mechanisms such as those listed below be employed.

Standard Operating Procedures

Adherence to standard operating procedures is paramount for obtaining quality and reliable results. Critical analysis of each step involved client identification, sample collection, testing, interpretation of results, recording, kit storage must be carried out to ensure that quality is controlled. Providing quality results will in¬crease the good reputation of the testing site and lead to an increase in demand for the service.

Discrepant Results

A tie breaker will be carried out for every discrepant result. Clients who test negative after the tie breaker should be advised to come back for re-testing after 3 months. Such clients will need to be provided with information on possible reasons why their test results were discrepant and further counselled on risk reduction to reduce the chances of getting infected or re-infected during the 3 months period.

Providers who get discrepant results are however required to re-examine all the steps they went through to carry out the tests including techniques, timing, reagents used etc to rule out human error. Should they note an error in the process followed, it is recommended that they re-test the client possible using test kits from a different batch number before carrying out a tie breaker test.

Dried blood Spots

It is recommended that every 20th client is sampled for quality control. Their blood will be collected and saved on filter paper as dried blood spots and stored in a dry and cool environment before being forwarded to the NHRL for validation

Proficiency Testing (PT)

PT is a quality control function used to compare concordance between NHRL and facility results. It starts with the NHRL preparing HIV positive, negative and indeterminate serum panels and distributing them to HTC sites/facilities . Facilities carryout tests using recommended algorithms and test kits and send results using standardised tools to the NHRL within a specified time for comparison with national results.

Laboratory Support Supervision

Laboratory support supervision, as a key mechanism of quality assurance for HIV testing, is aimed at building the capacity of HTC providers in a bid to ensure that testing is conducted in accordance with the national guidelines. Quarterly laboratory supervision should be undertaken to: provide sites with updates on HIV testing and related topics, evaluate and monitor adherence to standard operating procedures (SOPs), stimulate information exchange and networking among testing sites as well as re-train staff on-site, where need be.

A standardized laboratory supervision tool should be used by the district laboratory supervisors and the DMLT to ensure the testing is being conducted according to recommended standards. The provincial team should

accompany the district team biannually to undertake laboratory supervision, while the national supervisory teams should conduct at least 10% of laboratory supervision annually as an external quality assurance measure.

Support Supervision for HTC Service Providers

Counsellor Support Supervision

Supervision in the context of counselling is an ethical requirement as a mechanism for mitigating burnout among the practicing counsellors. HTC providers face burnout as a result of interacting with clients in the course of their work. It is in line with this that the National Guidelines for HIV Testing and Counselling in Kenya have provided for supervision to 'be made available to HTC providers on a regular basis'. Support supervision has been recognized as a key approach for strengthening the quality of all aspects of HTC service delivery (counselling, testing, logistics and data) through working with service providers to identify areas of improvement and continuous professional development. Counsellor Support Supervision aims to fulfil 3 key functions:

1. **Educative:** Identify and fill knowledge and skills gaps amongst service providers.
2. **Supportive:** Identify and address personal or professional issues that have an impact on service delivery.
3. **Administrative:** Addresses ethical and professional aspects of work.

Counsellor support supervision helps to maintain optimal provider performance and hence facilitating the delivery of high quality

services. Various forms of support supervision may be used, these include: self, group, peer and one-to-one supervision.

Group supervision provides the richest forum for providers to share their unique experiences and challenges.

Counsellor support supervision for service providers should be offered by supervisors who are trained in counsellor supervision using a recognised curriculum. Practising supervisors should seek their own supervision for continuous professional growth.

Administrative Support Supervision

Administrative supervision focuses on strengthening / improving management and administrative duties. It focuses on issues such as staffing, logistics and supplies, data management etc. It is important to recognize that there is a difference between support supervision for HTC providers and administrative support supervision by managers. The two types of supervision serve different purposes, but complement each other in ensuring quality of HTC services. HTC support supervisors should visit HTC sites/facilities to provide supervision on a monthly basis, while DASCOs should make quarterly visits. Supervision tools should be utilized to check and address all the service quality issues.

Recording and Reporting Support

The supervisor or the data person-in-charge at the facility should confirm timeliness, completeness, accuracy, and consistency of the data records including: the HTC Laboratory Register, the HTC Service Summaries, and the MOH711A. It is also the role of the facility supervisor or data person-in-charge to give feedback, on HTC data, to the HTC service providers and other HTC stakeholders at the facility.

All HTC records should be kept confidential and accessible only to authorized persons. There should be strict control of access to client information, including name and test results. These should only be released to other HCWs for purposes of referrals and other related post-test services, with the consent of the client. All test results must be entered in a standardized HTC Laboratory Register, that is stored in a lockable cupboard.

Data Auditing

Data auditing involves an evaluation to verify the effectiveness of the data system and processes, plus is performed to ascertain the validity and reliability of the HTC data produced.

Quality data auditing should not only report non-conformances and corrective actions but also highlight areas of good practice to enhance continual improvement.

HTC data audit should be done between: HMIS/NASCOP and district, district and the health facility, and HMIS/NASCOP and health facility.

Mentorship

Mentorship is a system of practical training and consultation that fosters ongoing professional development with an aim of yielding sustainable high quality HIV services (*National Mentorship Guidelines for HIV Services in Kenya 2009*). Mentorship in HTC aims at

promoting continuous professional growth and development amongst HTC service providers. The process seeks to ensure continuous transfer skills and knowledge to HTC service providers, consequently resulting in improved quality of HTC services.

Mentorship should be undertaken by experienced practising HTC service providers (mentors), with an objective of helping less experienced HTC service providers (mentees) apply theoretical knowledge acquired from different learning fora to practise, build their capacity and motivate them to continuously provide quality services. And further, to encourage the strengthening continuum of care.

Mentorship will be undertaken in accordance to the approaches and decentralised structures stipulated in the National Guidelines on Mentorship for HIV Services in Kenya.

Client Feedback

One of the key objectives of providing quality services is to ensure that the client's needs are met. Satisfied clients are more likely to listen, comply with treatment and / or advise, and provide complete and accurate information in relation to their concerns and / or illness (*A Practical Handbook for Quality Improvement in HIV Testing and Counselling Services 2010*).

Client feedback interviews / questionnaires provide an opportunity for HTC service providers and managers to assess client perceptions on the services they have received.

Client feedback data should be collected periodically, analysed and used to inform. Different QI mechanisms can be used to obtain this feedback. These include structured questionnaires, self or interviewer administered, suggestion boxes, FGDs etc.

Continuous Professional Development

As part of maintaining quality, service providers are encouraged to actively seek CPD. Service providers working in health facilities are required to participate in the facility CME's while those working in the community will access the same during monthly site support supervision and other skills and knowledge building fora. NASCOP in collaboration with other stake holders has developed a CPD scheme to provide guidance on accreditation of service providers following CPD.

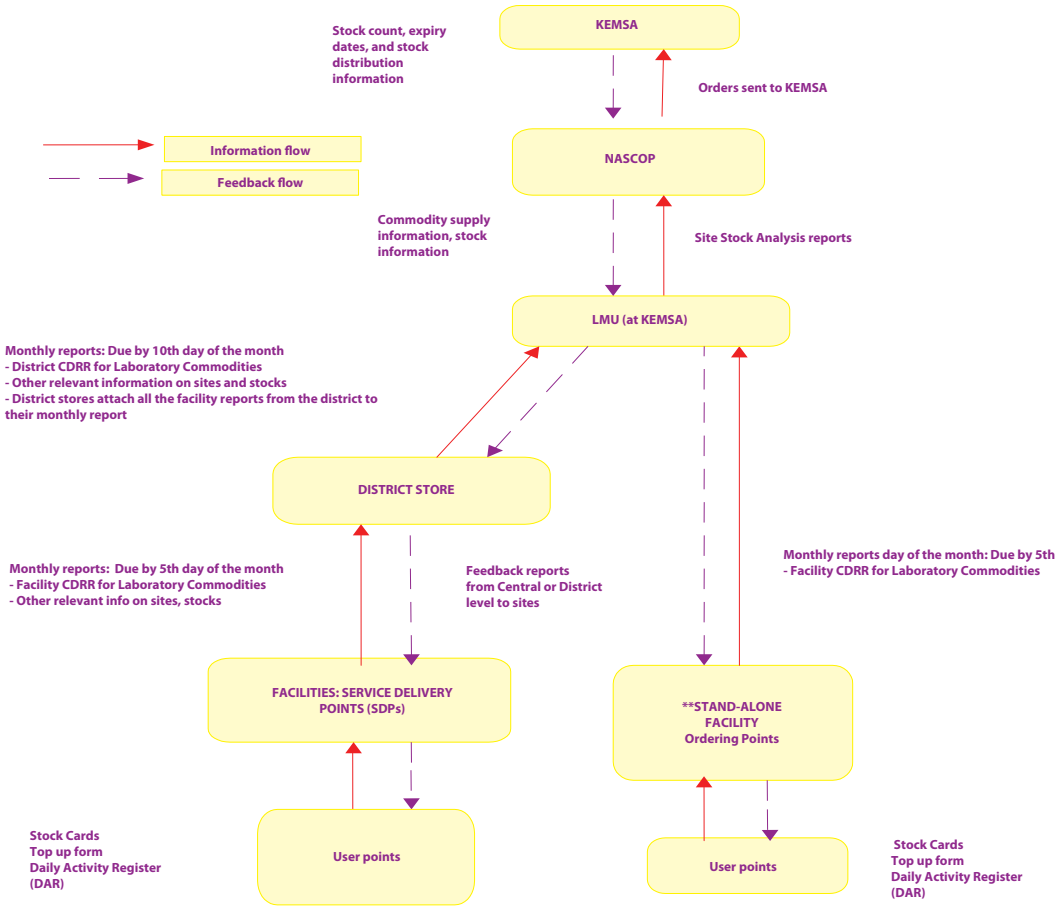
Annexes

Guidance of approximate time taken to conduct a rapid HIV test

Procedures	Screening Test	Confirmatory Test	Tiebreaker test
Swabbing process	1 min	1 min	1 min
Pricking, harvesting and dropping blood onto the test device	3 min	3 min	3 min
Waiting to read the results	Specific to test kit in use, e.g. Determine -15 min	Specific to test kit in use, e.g SD Bioline-10 min	1 Specific to test kit in use, e.g. UniGold-10min
Reading the test results	2 mins	2 mins	2 mins
Clearing and disinfecting the desk	2 mins	2 mins	2 mins
Minimum time required for testing if above test kits are used	23 minutes	18 minutes	18 minutes

* The time stated above does not include pre-test information giving and post counselling time.

HTC Commodity Information Flow Pipeline



KEY:
SDP: Service delivery point
CDRR = Consumption Data Report & Request form, DAR = Daily Activity Register, SDP =
** Facility Orderingordering points include: Provincial General Hospitals (PGHs), Regional Blood Transfusion centre's (RBTCs), the 2 Referral Hospitals, NASCOP VCT centre, DoD clinic.

HTC Recording and Quality Monitoring Tools

MOH642: Daily Activity Report (DAR)

MOH 642

REPUBLIC OF KENYA

MINISTRY OF HEALTH

S/ No.

DAILY ACTIVITY REGISTER FOR LABORATORY REAGENTS AND CONSUMABLES

Facility Name:…… Bench/Section…… Commodity……

Date	Shift	Unit of issue	Beginning Balance	Quantity received	Origin	Batch. No.	Expiry Date	No. of Tests Done	Quantity Used	Losses/ Adjustment	Ending balance	Remarks	Name	Sign
TOTAL														

MOH643: Facility Consumption Data Report and Request Form for Laboratory Commodities

MOH 643

Original

REPUBLIC OF KENYA

Serial No.

MINISTRY OF HEALTH

FACILITY CONSUMPTION DATA REPORT AND REQUEST FORM FOR LABORATORY COMMODITIES

Table applicable to HIV Test Kits only

Type of service	No. of tests
VCT	
PMTCT	
PITC/ Clinical Diagnosis	
Blood Screening	
Other (please specify)	

Province:…….....…

District:…….....……..

Name of Facility:…….....……

Affiliation: GoK☐ NGO☐ CBO☐ FBO☐ Other☐

Reporting period: Beginning (dd/mm/yyyy) ..... / ..... / ..... Ending (dd/mm/yyyy)..... / ..... / .....

Commodity Name	Unit of Pack /Issue	Beginning Balance	Quantity Received	Quantity Used	Tests Done	Losses	Adjustments	Ending Balance Physical count	Quantity expiring in< 6 months	Quantity Requested
Haematology reagents										
Normal control										
Abnormal high control										
Abnormal low control										
Grouping anti-sera- anti A										
Grouping anti-sera- anti B										
Grouping anti-sera- anti D										
Grouping anti-sera- Anti Human Globulin (AHG)										
Haemocue cuvettes										
Pathological control										
Normal control										
ALT(SGPT)										
AST(SGOT)										
Alkaline phosphatase										
Gamma GT										
Serum protein kit										
Serum Amylase test kit										
Albumin										
Urea										
Creatinine										
Electrolytes										
Total Cholesterol										
HDL Cholesterol										
Triglycerides										
Glucose test strips										
Pregnancy test strips										
Multistix										
EDTA Vacutainer Stabilizer tubes										
EDTA Vacutainer tubes										
Plain Vacutainer tubes										
Vacutainer needles G21										
Vacutainer needles G23										
Yellow tips										
Blue tips										
Carbol fuchsin powder										
Methylene Blue										
Giemsa Stain										
Methanol										
Glycerol										
Oil Immersion										
Universal bottles										
Culture Plates										
AFB Polypots with lids										
Stool Polypots										
Applicator sticks										
Microscope slides										
Slide storage boxes										
Latex Gloves										
Potassium Cyanide										
Potassium ferri cyanide										
Sodium Hydrogen Carbonate										
HIV-RELATED LABORATORY COMMODITIES										
Rapid HIV 1+2 Test Kit (**Determine**)										
Rapid HIV Test ½ SD (**Bioline**)										
Rapid HIV 1+ 2 Test Kit (**Unigold**)										
Hepatitis B Surface Antigen Haemmaggl Kit (**Hepanostika**)										
Hepatitis C (ELISA) Test (**Murex HCV**)										
ELISA HIV/AIDS 1 and 2 Test Kit (**Vironostika**)										
ELISA HIV/AIDS 1 + 2 Test Kit (**Murex HIV 1/2 Plus O**)										
HIV Test Kit (**Murex Ag/Ab combination**)										
Rapid Syphillis Test (**RPR**)										

Explain losses and Adjustments: _____

Filled by: _____ Tel:_____ Designation:_____ Sign:_____ Date:_____

Approved by: _____ Tel: _____ Designation: _____ Sign:_____ Date:_____

MOH644: District Consumption Data Report and Request Form for Laboratory Commodities

Original

MOH 644

REPUBLIC OF KENYA

Serial No.

MINISTRY OF HEALTH

DISTRICT CONSUMPTION DATA REPORT AND REQUEST FORM FOR LABORATORY COMMODITIES

Province:……..……

District:……..……

Full store name:……..……

Table applicable to HIV Test Kits only

Type of service	Aggregated No. of tests
VCT	
PMTCT	
PITC/ Clinical Diagnosis	
Blood Screening	
Other (please specify)	

FACILITY REPORTING RATES		
Expected Reports	Received Reports	Reporting Rate

Reporting period: Beginning (dd/mm/yyyy) ..... / ..... / ..... Ending (dd/mm/yyyy)..... / ..... / .....

Commodity Name	Unit of Pack /Issue	Beginning Balance	Total Quantity Received	Total Quantity issued to Sites	Losses at District Stores	Adjustments at District Stores	Physical count at District Store	Total Quantity Consumed at Sites	Total Tests Done	Total Physical stock (all sites)at end of period	Quantity expiring in< 6 months	Total Quantity Requested
Haematology reagents												
Normal control												
Abnormal high control												
Abnormal low control												
Grouping anti-sera- anti A												
Grouping anti-sera- anti B												
Grouping anti-sera- anti D												
Grouping anti-sera- Anti Human Globulin (AHG)												
Haemocue cuvettes												
Pathological control												
Normal control												
ALT(SGPT)												
AST(SGOT)												
Alkaline phosphatase												
Gamma GT												
Serum protein kit												
Serum Amylase test kit												
Albumin												
Urea												
Creatinine												
Electrolytes												
Total Cholesterol												
HDL Cholesterol												
Triglycerides												
Glucose test strips												
Pregnancy test strips												
Multistix												
EDTA Vacutainer Stabilizer tubes												
EDTA Vacutainer tubes												
Plain Vacutainer tubes												
Vacutainer needles G21												
Vacutainer needles G23												
Yellow tips												
Blue tips												
Carbol fuchsin powder												
Methylene Blue												
Giemsa Stain												
Methanol												
Glycerol												
Oil Immersion												
Universal bottles												
Culture Plates												
AFB Polypots with lids												
Stool Polypots												
Applicator sticks												
Microscope slides												
Slide storage boxes												
Latex Gloves												
Potassium Cyanide												
Potassium ferri cyanide												
Sodium Hydrogen Carbonate												
HIV-RELATED LABORATORY COMMODITIES												
Rapid HIV 1+2 Test Kit (**Determine**)												
Rapid HIV Test ½ SD (**Bioline**)												
Rapid HIV 1+ 2 Test Kit (**Unigold**)												
Hepatitis B Surface Antigen Haemmaggl Kit (**Hepanostika**)												
Hepatitis C (ELISA) Test (**Murex HCV**)												
ELISA HIV/AIDS 1 and 2 Test Kit (**Vironostika**)												
ELISA HIV/AIDS 1 + 2 Test Kit (**Murex HIV 1/2 Plus O**)												
HIV Test Kit (**Murex Ag/Ab combination**)												
Rapid Syphillis Test (**RPR**)												

Explain losses and Adjustments: _____

Filled by: _____ Tel:_____ Designation:_____ Sign:_____ Date:_____

Approved by: _____ Tel: _____ Designation:_____ Sign:_____ Date:_____

MOH363: HTC Laboratory Register

"Serial No."	Client Name	Sex	Age	Strategy	Marital statues	Disability	MARPs	Consent	Client tested as	"Date Tested"	HIV Test-1	HIV Test-2	HIV Test-3	Final Result	Final Result Given	Tester	Couple Discordant	DBS Collected	DBS Result	Tested before	The test result	TB Screening	Referral: CCC	Referral: TB	Referral: Others	Remarks
											Kit Name	Kit Name	Kit Name													
											Lot No.	Lot No.	Lot No.													
											"Expire Date / /"	"Expire Date / /"	"Expire Date / /"													
a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r	s	t	u	v	w	x	y	z	aa
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												
											N P I	N P I	N P I	N P ID												

Page Summary

# Tested:						Test Kits Performance			
	<15	15-24	25-49	>/=50	Total	N:	N:	N:	N:
Male						P:	P:	P:	P:
Female						I:	I:	I:	ID:
Total						Total:	Total:	Total:	Total:

Supervisor: Signature: Date:

HTC SERVICE SUMMARY

HTC Service Delivery Point:

Reporting Month: 20

HTC Strategy:

- Health Facility including Integrated VCT
- Static in Stand Alone VCT
- Outreach (door to door)
- Outreach (mobile and others)

Service Up-take

	<15 yrs		15-24 yrs		25-49 yrs		50 yrs+		Total
	M	F	M	F	M	F	M	F	
# offered									
# tested and received their test results									
# never tested									
# tested but do not know their status									
# positive									
# referred									
# tested as couple									
# tested as couple with discordant results									

Test Kits Performance Summary

	HIV Test			Final Result of Client
	1	2	3	
Negative (Non-reactive)				
Positive (Reactive)				
Invalid				
Indeterminate				
Westeage				
Total				

HTC Segment of MOH711 proposed by NASCOP

In Health Facility incl. Integrated VCT	<15 yrs		15-24 yrs		25-49 yrs		≥ 50yrs		Total
	M	F	M	F	M	F	M	F	
# offered									
# tested and received their test results									
# never tested									
# tested but do not know their status									
# positive									
# tested as couple									
# tested as couple with discordant results									
Static in Stand Alone VCT	<15 yrs		15-24 yrs		25-49 yrs		≥ 50yrs		Total
	M	F	M	F	M	F	M	F	
# offered									
# tested and received their test results									
# never tested									
# tested but do not know their status									
# positive									
# tested as couple									
# tested as couple with discordant results									
Door to Door	<15 yrs		15-24 yrs		25-49 yrs		≥ 50yrs		Total
	M	F	M	F	M	F	M	F	
# offered									
# tested and received their test results									
# never tested									
# tested but do not know their status									
# positive									
# tested as couple									
# tested as couple with discordant results									
Mobile and Other Outreaches	<15 yrs		15-24 yrs		25-49 yrs		≥ 50yrs		Total
	M	F	M	F	M	F	M	F	
# offered									
# tested and received their test results									
# never tested									
# tested but do not know their status									
# positive									
# tested as couple									
# tested as couple with discordant results									
Health Facility Performance	OPD	IPD							
% of individuals seeking health services who tested for HIV in health facility									

Mentees Logbook

Name of Mentee:_____Designation:_____
Date:_____

Name of Mentor:_____

NOTE:

In order to be certified as having completed the Mentorship Program the mentees must demonstrate proficiency through direct experience in the following areas:

Activity	Demonstration done (Yes/No)	Proficient/ skilled (Yes/No)	Comments	Mentees Signature & Date	Mentors Signature & Date
Counselling					
Contracting					
Appropriate use of counselling skills					
Correct and updated HIV&AIDS information					
Adherence to counselling protocols					
Testing					
Adherence to Testing Standard Operating Procedures (SOP's)					
Good Laboratory Practice (GLP)					
Adherence to nationally approved HIV testing algorithm					
Participation in External Quality Assessment (Validation and Proficiency testing)					
Data Management					
Proper data entry and recording					
Proper data summary and reporting					
HTC data utilization including presentation, analysis and interpretation					
Logistics					
Proper Testing commodities and data tools procurement procedures					
Procurement of other relevant HTC materials i.e. IEC materials					
Cross cutting					
Proper planning for efficient HTC service delivery					
Quality management systems and processes in place					
Community mobilization for increased HTC service utilization					
Availability and awareness of HTC related guidelines and policies					
Reporting					
Timely reporting to the various HTC managers (Facility – District)					

Overall comments

Mentors signature:_____ Date:_____

Mentees signature:_____ Date:_____

Mentors Observation Checklist

Name of Mentee:_____Designation:_____
Date:_____

Name of Mentor:_____

Grading

Not done or done incorrectly	Acceptable	Good (done beyond expectation)
0	1	2

Skills/knowledge	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Average score
Counselling							
Explained to client what to expect during the session							
Used appropriate counselling skills							
Gave correct and up to date information regarding HIV&AIDS							
Performed risk assessment							
Did a condom discussion and demonstration							
Helped client attain risk-reduction plan							
Discussed disclosure of test results							
Discussed referral options with client							
Testing							
Preparation of testing area complete with all required testing commodities							
Performed adequate Finger-pricking							
Adequately collected clients blood sample							
Adhered to HIV testing procedures							
Adhered to HIV testing algorithms							
Adhered to testing standard operating procedures (SOPs)							
Disaggregated and disposed waste appropriately							
Appropriately collected samples on DBS for EQA							
Participated and adhered to the NHRL Proficiency Testing procedures							
Data Management							
Timely, accurate and complete entry of client data using the national data collecting tools							

Skills/knowledge	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Average score
Summarized data accurately, timely and completely using the national data reporting tools							
Submitted timely, accurate and complete data reports to the district level by 5th of the following month							
Utilized generated data for continuous quality improvement of HTC services							
Logistics							
Timely procured test kits, other test commodities, consumables and other EQA materials							
Stored Test kits and other testing commodities as per the manufacturers specifications							
Reporting							
Timely submission of reports to the different HTC managers (facility- district)							
Total score							

Overall comments

Mentors signature:_____ Date:_____

Mentees signature:_____ Date:_____

National HTC (CITC) Registration Survey Tool

Assessment for registration of new sites

Registration is compulsory for all sites planning to provide HTC services. The registration assessment focuses on adequacy of existing structures (human resources, guidelines, infrastructure, safety issues and information systems) for delivery of HTC services.

This tool is to be used by NASCOP to register and give site codes to new stand alone and integrated CITC Sites

Facility Name:	**Date:**
District:	**Time started:**
Province:	**Time finished:**
Facility Type: (please circle) **Stand Alone/ Integrated**	**Managing Agency:**
Assessors: 1. 2. 3.	
Staff interviewed: 1. 2. 3. 4. 5.	

Purpose:

To ensure compliance with minimum national HTC standards for registration

Objectives:

1. Assess availability of trained personnel
2. Assess adherence to HTC and safety guidelines
3. Assess physical infrastructure for HTC service delivery.

a) STAFF SITE PROFILE

Please complete table for each member of staff working on HTC in the facility.

Name	Position (supervisor, counsellor, lab technician, receptionist, etc.)	Completed training (certification, registration, license)	Full Time (F/T) Part Time (P/T) (on HTC services)	Employment Status (permanent contract paid volunteer, etc.)
1				
2				
3				
4				
5				
6				
7				
8				
9				

b) SITE OPENING HOURS

Days of the Week	Opening Hours
Monday – Friday	
Saturday	
Sunday	
Public Holidays	

c) SCORING SYSTEM

Yes	**Minimum standard met**
No	**Minimum standard not met**

Critical criteria questions must score 100% (10/10) and all other questions ≥ 75%

	Critical Criteria	Yes	No
1	Trained HTC provider available?		
2	Trained lab technician or counsellor able to do rapid tests available?		
3	Secure lockable cupboard/cabinet for storing client records available (counsellor access only)?		
4	Provision for storing test kits at appropriate temperature (fridge required if above 30 degrees)?		
5	Sharps container available for disposal of lancets and needles?		
6	Gloves and gowns available?		
7	Separate, lined bin in testing room for disposal of contaminated waste (gloves, cotton wool etc.)?		
8	Pit, incinerator or contractual arrangement in place for disposal of contaminated waste?		
9	HTC Laboratory register/ log book available		
1	Running water available in testing room?		
	Human Resources	**Yes**	**No**
1	Site/facility manager or in-charge available?		
1	Trained HTC Trained HTC supervisor available?		
1	Trained laboratory supervisor available?		
	Policy, Standards and Guidelines	**Yes**	**No**
1	National HTC guidelines easily accessible?		
1	HTC counselling protocols available and on display?		
1	HTC testing protocols available and on display?		
1	Safety guidelines available and on display (including advice on needle stick injuries)?		
	Infrastructure	**Yes**	**No**
1	Adequate sign posting and directions for HTC room/s?		
1	Fee charges prominently displayed and ≤ 100 KShs?		
2	Door tags available (please enter/counselling in progress)?		
2	Adequate counselling room/s available (well lit, spacious, ventilated, private)?		
2	Room/s adequately equipped with 3 chairs, 1 table and separate testing area?		
2	Adequate waiting area (chairs and space)?		
2	Room/s and waiting area well maintained and clean?		
2	Penile model available and on display?		
2	Condoms freely available and on display?		
2	Accessible clean toilets with hand washing facilities?		
2	Arrangements in place for sustainable supplies (gloves, lancets, soap,. disinfectant etc.)?		

	Records and Information System	Yes	No
2	System for confidential client information records in place		
3	Stock register available		
3	Accident/incident book available?		
3	Referral system in place or being developed?		
3	Quality assurance system for testing in place or being developed?		
3	Quality assurance system for counselling in place or being developed?		

I hereby make a commitment to adhere to current HTC guidelines or any other guideline that may be introduced by NASCOP in future.

_____ _____

On -site supervisor / in-charge Witnessed by assessor

Overall Remarks: (Please comment specifically on each item that has scored a 'no')

Critical Criteria (Must score 100%)	**Total Yes**		**Total No**		**Score Y/(Y+N) x 100**	%	
All other questions (Must score ≥ 75%)	**Total Yes**		**Total No**		**Score Y/(Y+N) x 100**	%	
Recommendation for Registration	**PASS**	**RE-ASSESSMENT WITHIN**			**MONTH/S**		**FAIL**

ASSESSORS:

Name:	**Name:**
Signature:	**Signature:**

National Annual (CITC) Licensing Tool

Annual licensing is mandatory for all stand-alone and integrated CITC sites providing HTC services. The annual licensing assessment focuses on adequacy of existing structures (human resource, guidelines, infrastructure, safety issues and information systems) and key processes for delivery of HTC services.

This tool is to be used to assess stand alone and integrated CITC sites for licensing.

Facility Name:	**Date:**
Province:	**Time started:**
District:	**Time finished:**
Facility Type: (please circle) **Stand alone/ Health facility based**	**Managing Agency:**
Assessors: **1.** **2.** **3.**	
Staff interviewed: **1.** **2.** **3.** **4.** **5.**	

Purpose:

To ensure compliance with minimum national HTC standards and guidelines

Objectives:

Assess availability of staffing levels

Assess adherence to protocols

Assess availability of health education materials and condoms

Assess availability and use of record keeping formats

Assess availability of test kits and medical consumables

Assess adherence to staff roles and responsibilities

Assess general aspects of site operations

a) STAFF SITE PROFILE

Please complete table for each member of staff working on HTC in the facility.

Name	Position (supervisor, counsellor, lab technician, receptionist, etc.)	Completed training (certification, registration, license)	Full Time (F/T) Part Time (P/T) (on HTC services)	Employment Status (permanent contract paid volunteer, etc.)
1				
2				
3				
4				
5				
6				

b) SITE OPENING HOURS

Days of the Week	Opening Hours
Monday – Friday	
Saturday	
Sunday	
Public Holidays	

c) SCORING SYSTEM

Yes	**Minimum standard met**
No	**Minimum standard not met**

Critical criteria questions must score 100% (15/15) and all other questions ≥ 75%

	Critical Criteria	YES	NO
1	At least one HTC trained counsellors available?		
2	Trained lab technician or counsellor able to do rapid tests available?		
3	Secure lockable cupboard/cabinet for storing client records available (counsellor access only)?		
4	Kits within expiry date?		
5	Kits stored at an appropriate temperature (fridge required if above 30 degrees centigrade)?		
6	Protective clothing available and used for testing (gown and gloves)?		
7	Sharps containers used for disposal of lancets and needles		
8	Separate, lined bin in testing room for disposal of contaminated waste (gloves, cotton wool etc.)?		
9	Safe site storage of contaminated waste until disposal?		
10	Pit, incinerator or contractual arrangement in place for disposal of contaminated waste?		
12	HTC Laboratory Register available and maintained daily?		
14	Approved testing algorithm used?		
15	Running water available?		
I	**STRUCTURE**		
1.	**Leadership & Supervision**	**YES**	**NO**
1.1	Trained HTC supervisor supervising counsellors?		
1.2	Trained laboratory supervisor supervising systems for testing?		
2.	**Human Resource Management**	**YES**	**NO**
2.1	HTC site-manager or in-charge available?		
3.	**Policy Standards and Guidelines**	**YES**	**NO**
3.1	National HTC guidelines easily accessible?		
3.2	HTC counselling protocols available and on display?		
3.3	HTC testing protocols available and on display?		
3.4	Safety guidelines available and on display?		
4.	**Infrastructure**	**YES**	**NO**
4.1	Facility registered to provide HTC services?		
4.2	Adequate counselling room/s available (well lit, spacious, ventilated, private)?		
4.3	Room/s adequately equipped with 3 chairs, 1 table and separate testing area?		
4.4	Penile model available and on display?		
4.5	Room/s and waiting area well maintained and clean?		
4.6	Adequate waiting area (chairs and space)?		
4.7	Accessible clean toilets with hand washing facilities?		
5.	**Supplies and Storage**	**YES**	**NO**
5.1	Uninterrupted and adequate supply of non-pharmaceuticals (gloves, lancets, condoms, spirit, cotton wool, chlorine, detergent, disposable syringes)?		
5.2	Uninterrupted and adequate supply of rapid test kits in stock?		
6.	**Referral System**	**YES**	**NO**
6.1	Referral system in place and functioning?		
6.2	Designated referral site for care and support?		
7.	**Records and Information System**	**YES**	**NO**
7.1	Uninterrupted and adequate supply of HTC Laboratory Registers?		

7.2	System for confidential client information records in place and functioning?		
7.3	Easily retrievable copies of quarterly reports sent to DHMT available?		
7.4	Stock register available and up to date?		
7.5	Accident/incident book available and used?		
8.	**IEC Materials**	**YES**	**NO**
8.1	Signboards, signs, labels and directions for HTC room/s?		
8.2	Opening hours prominently displayed?		
8.3	Fee charges prominently displayed and ≤ 100 KShs?		
8.4	Door tags used for privacy (please enter/counselling in progress)?		
8.5	Adequate supply of condoms freely available and on display?		
II	**PROCESS**		
9.	**Adherence to Guidelines/Client-Provider Interaction**	**YES**	**NO**
9.1	HTC services available on advertised days?		
9.2	Informed consent (signature) obtained before testing the client for HIV?		
9.3	Condoms supplied where appropriate?		
9.4	Same day blood testing conducted on site?		
9.5	HTC laboratory registers/log books are checked for missing items at the end of each day?		
9.6	All counsellors attending regular support supervision?		
10.	**Continuous QI**	**YES**	**NO**
10.1	5% of blood samples sent for quality control to a certified laboratory?		
10.2	All discrepant results and filter papers sent to a certified laboratory?		
III	**RESULTS**		
11.	**Performance (Are the following indicators calculated on a quarterly basis?)**	**YES**	**NO**
11.1	Breakdown of clients by age, sex and test result		
11.2	Levels of concordance with reference laboratory		

Overall Remarks: (Please comment specifically on each item that has scored a 'no')

Critical Criteria (Must score 100%)	**Total Yes**		**Total No**		**Score Y/(Y+N) x 100**	**%**	
All other questions (Must score ≥ 75%)	**Total Yes**		**Total No**		**Score Y/(Y+N) x 100**	**%**	
Recommendation for Registration	**PASS**	**RE-ASSESSMENT WITHIN**			**MONTH/S**		**FAIL**

ASSESSORS:

Name:	**Name:**
Signature:	**Signature:**

National Accreditation (CITC) Tool

Accreditation is voluntary for sites providing HTC services. The accreditation assessment focuses on adequacy of existing structures (human resources, guidelines, infrastructure, safety issues and information systems), key processes and results in the delivery of HTC services.

This tool is for accreditation assessment of stand alone and integrated HTC sites.

Facility Name:	**Date:**
Province:	**Time started:**
District:	**Time finished:**
Facility Type: (please circle) **Stand Alone / Integrated**	**Managing Agency:**
Assessors: **1.** **2.** **3.**	
Staff interviewed: **1.** **2.** **3.** **4.** **5.**	

Purpose:

To ensure continuous quality improvement systems are in place for assuring compliance with national HTC standards and guidelines

Objectives:

1. Assess availability of staffing levels
2. Assess adherence to protocols
3. Assess availability of health education materials and condoms
4. Assess availability and use of record keeping formats
5. Assess availability of test kits and medical consumables
6. Assess adherence to staff roles and responsibilities
7. Assess general aspects of site operations

a) STAFF SITE PROFILE

Please complete table for each member of staff working in the facility.

Name	Position (supervisor, counsellor, lab technician, receptionist, etc.)	Completed training (certification, registration, license)	Full Time (F/T) Part Time (P/T) (on VCT services)	Employment Status (permanent contract paid volunteer, etc.)
1				
2				
3				
4				
5				
6				
7				

b) SITE OPENING HOURS

Days of the Week	Opening Hours
Monday – Friday	
Saturday	
Sunday	
Public Holidays	

c) SCORING SYSTEM

Yes	**Minimum standard met**
No	**Minimum standard not met**

Critical criteria questions must score 100% (15/15) and all other questions ≥ 75%

	Critical Criteria	YES	NO
1	At least one HTC provider available?		
2	Trained lab technician or HTC provider able to do rapid tests available?		
3	Secure lockable cupboard/cabinet for storing client records available (HTC provider access only)?		
4	Kits within expiry date?		
5	Kits stored at an appropriate temperature (fridge required if above 30 degrees centigrade)?		
6	Protective clothing available and used for testing (gown and gloves)?		
7	Sharps containers used for disposal of lancets and needles		
8	Separate, lined bin in testing room for disposal of contaminated waste (gloves, cotton wool etc.)?		
9	Safe site storage of contaminated waste until disposal?		
10	Pit, incinerator or contractual arrangement in place for disposal of contaminated waste?		
11	HTC Laboratory Register available and maintained daily?		
12	For discrepant results, tiebreaker test performed or referred to laboratory?		
13	Approved testing algorithm used?		
14	Running water available?		

I	**STRUCTURE**		
1.	**Leadership & Supervision**	**YES**	**NO**
1.1	Regular site meetings taking place?		
1.2	Regular QA site meetings taking place?		
1.3	Named District HTC coordinator (DASCO) making regular supervisory visits?		
1.4	Trained HTC supervisor supervising counsellors?		
1.5	Trained laboratory supervisor /DMLT supervising systems for testing?		
2.	Human Resource Management	YES	NO
2.1	List of HTC staff available including registration, qualifications etc.?		
2.2	Job descriptions of HTC staff available?		
2.4	Site/ facility manager or in-charge available?		
3.	**Policy Standards and Guidelines**	**YES**	**NO**
3.1	National HTC guidelines available and easily accessible to providers?		
3.2	HTC counselling protocols available and on display?		
3.3	HTC testing protocols available and on display?		
3.4	Safety guidelines available and on display?		

4.	**Infrastructure**	**YES**	**NO**
4.1	Facility registered to provide HTC services?		
4.2	Adequate counselling room/s available (well lit, spacious, ventilated, private)?		
4.3	Room/s adequately equipped with 3 chairs, 1 table and separate testing area?		
4.4	Penile model available and on display?		
4.5	Room/s and waiting area well maintained and clean?		
4.6	Adequate waiting area (chairs and space)?		
4.7	Accessible clean toilets with hand washing facilities?		
5.	**Supplies and Storage**	**YES**	**NO**
5.1	Uninterrupted and adequate supply of non-pharmaceuticals (gloves, lancets, condoms, spirit, cotton wool, chlorine, detergent, disposable syringes)?		
5.2	Uninterrupted and adequate supply of rapid test kits in stock?		
6.	**Safety**	**YES**	**NO**
6.1	All HTC staff received Hepatitis B Immunisation?		

7.	**Referral System**		**YES**	**NO**
7.1	Referral system in place and functioning?			
7.2	Referral directory/list available?			
7.3	Designated referral site for care and support?			
7.4	Post-test support available (PTC, PLWHA etc.)?			
8.	**Records and Information System**		**YES**	**NO**
8.1	Availability of the HTC Laboratory Register?			
8.2	System for confidential client information records in place and functioning?			
8.3	Easily retrievable copies of quarterly reports sent to DHMT available?			
8.4	Stock register available and up to date?			
8.5	Accident/incident book available and used?			
8.6	DBS and PT from NRL easily accessible?			

9.	IEC Materials		YES	NO
9.1	Signboards, signs, labels and directions for HTC room/s?			
9.2	Opening hours prominently displayed?			
9.3	Door tags used for privacy (please enter/counselling in progress)?			
9.4	Uninterrupted and adequate supply of HTC leaflets or posters?			
9.5	Information leaflets on display and available for clients?			
9.6	HTC posters prominently displayed?			
9.7	Adequate supply of condoms freely available and on display?			
10.	**Financial Management**		**YES**	**NO**
10.1	Fee charges prominently displayed and ≤ 100 KShs? (if FREE skip 10.2, & 10.3 & circle N/As)			
10.2	Records of accounts available?	N/A		
10.3	Clear policy and measures in place for clients unable to pay?	N/A		
II	**PROCESS**			
11.	**Adherence to Guidelines/Client-Provider Interaction**		**YES**	**NO**
11.1	HTC services available on advertised days?			
11.2	Informed consent (signature) obtained before testing the client for HIV?			
11.3	Condoms supplied where appropriate?			
11.4	Same day blood testing conducted on site?			
11.5	HTC Laboratory Register checked for missing items at the end of each day?			
11.6	Community mobilisation activities being conducted?			
11.7	HTC Providers accessing regular supervision?			
11.9	HTC providers' working scheduled hours (not assigned to other non HTC services)?			

12.	**Continuous QI**		**YES**	**NO**
12.1	Regular monitoring and analysis of HTC data conducted (summary sheets, graphs)?			
12.2	QA tools used for systematically monitoring quality of service provision (client exit interviews, counsellor self assessment or other alternatives)?			
12.3	QA meetings identify areas for improvement and plan accordingly?			
12.4	5% of blood samples sent for quality control to a certified laboratory?			
12.5	All discrepant results and filter papers sent to a certified laboratory?			
III	**RESULTS**			
13.	**Performance (Are the following indicators calculated on a quarterly basis?)**		**YES**	**NO**
13.1	Breakdown of clients by age, sex and test result			
13.2	% Clients given condoms			
13.3	% Counseled clients who take HIV test			
13.4	% HIV +ve Clients referred for care & treatment?			
13.5	% Test results given same day			
13.6	% Test results indeterminate			
13.7	Levels of concordance with reference laboratory			
13.8	Timely submission of monthly/quarterly reports			
14.	**Client**		**YES**	**NO**
14.1	Mechanisms for client feedback in place (exit interviews, suggestion box, complaints procedures, community meetings etc)?			
14.2	Client satisfaction improved over time?			
15.	**Provider**		**YES**	**NO**
15.1	HTC providers' attitude, motivation, job satisfaction and professional improvement is assessed and monitored over time (annual appraisal)?			

Overall Remarks: (Please comment specifically on each item that has scored a 'no')

Critical Criteria (Must score 100%)	**Total Yes**		**Total No**		**Score** Y/(Y+N) x 100	%	
All other questions (Must score ≥ 75%)	**Total Yes**		**Total No**		**Score** Y/(Y+N) x 100	%	
Recommendation for Annual License	**PASS**	**RE-ASSESSMENT WITHIN MONTH/S**					**TEMPORARY CLOSURE**

ASSESSORS:

Name:	**Name:**	**Name:**
Signature:	**Signature:**	**Signature:**

Laboratory Supervision Tool

This a supervisory tool for the external assessment of testing procedures in integrated and stand-alone HTC sites.

Facility Name:	**District:**
Date:	**Province:**
Facility Name:	**Site type:**
Designation of External Assessors:	
Time started:	**Time ended:**
No. of Testing Personnel Present:	

Purpose:

To ensure that quality testing is maintained in all HTC sites

Objectives:

To assess the following:

1. Testing facility
2. Availability and use of test kits and disposal receptacles
3. Test kit storage
4. Skills in sample collection and testing
5. Interpretation of results
6. Adherence to testing protocols
7. Availability and use of disinfectants
8. Practice safety measures
9. Availability and proper records in the HTC Laboratory Register
10. QA measures in place from training to operations.
11. General staff interaction with regard to testing

a. SCORING SYSTEM

1	**Minimum standard not met; no demonstrated efforts; only excuses**
2	**Minimum standard not met; demonstrated efforts; visible commitment to improve**
3	**Minimum standard met; acceptable compliance with maximum standard**
4	**Minimum standard met; demonstrated effort to surpass the standard; visible commitment to do even better in future; maximum standard met in most aspects**
5	**Maximum standard met; hardly possible to improve any further; demonstrated positive trends over a longer period of time (to be agreed upon)**

Key: 1=bad; 2=fairly bad; 3=fair; 4=good; 5=excellent

Note: Some of the items to be assessed require either 'yes' or 'no' as answers. In such cases score 5=YES and 1=NO. Minimum standard is based on the location of the facility, the general layout, environment, and its general organization. The assessor may describe this at the end of the session.

TESTING STAFF PROFILE

Please complete table for each member of staff performing tests in the facility

Name	Position (laboratory technician or technologist, counsellor or both)	Completed 3 days training on testing	Comments
1			
2			
3			
4			
5			
6			

I STRUCTURE

1. Supervision

		1	2	3	4	5
1.1	Named laboratory supervisor available?	☐	■	■	■	☐
1.2	List of staff performing tests available, including qualifications?	☐	☐	☐	☐	☐
1.3	Code numbers of staff performing tests available?	☐	☐	☐	☐	☐

2. Infrastructure

		1	2	3	4	5
2.1	Adequate testing room/space available?	☐	☐	☐	☐	☐
2.2	Adequate illumination of testing area?	☐	☐	☐	☐	☐
2.3	Room adequately furnished (1 table, 3 chairs)?	☐	☐	☐	☐	☐
2.4	Room properly organized for testing?	☐	☐	☐	☐	☐
2.5	Lockable cabinet for storing kits available?	☐	■	■	■	☐
2.6	Lockable cabinet for storing records?	☐	■	■	■	☐
2.7	Lockable cabinet for storing filter papers samples?	☐	■	■	■	☐
2.8	Safe water supply in testing room?	☐	☐	☐	☐	☐

3. Supplies and Storage

		1	2	3	4	5
3.1	Monthly status-report on testing accessories (S&S 903 filter papers, gloves, spirit, cotton wool, lancets, soap, disinfectant)	☐	☐	☐	☐	☐
3.2	Uninterrupted and adequate supply of accessories?	☐	☐	☐	☐	☐
3.3	Stock-out experienced since last visit?	☐	☐	☐	☐	☐
3.4	Kits within expiry date?	☐	☐	☐	☐	☐
	3.4.1. Determine	☐	■	■	■	☐
	3.4.2. Bio-line	☐	■	■	■	☐
	3.4.3. Uni-Gold	☐	■	■	■	☐
3.5	Stock at hand No of kits:	☐	☐	☐	☐	☐
	3.5.1. Determine	☐	☐	☐	☐	☐
	3.5.2. Bio-Line	☐	☐	☐	☐	☐
	3.5.3. Uni-Gold	☐	☐	☐	☐	☐
3.6	Kits stored at an appropriate temperature?	☐	■	■	■	☐
3.7	Uninterrupted and adequate supply of QC/QA materials					

(filter paper, humidity indicator cards, zip-lock bags)? ☐☐☐☐☐

	4. Safety in sample collection	**1 2 3 4 5**
4.1	Disposal receptacle for non-contaminated dry waste available?	☐■■■☐
4.2	Disposal receptacle for contaminated solid waste available?	☐■■■☐
4.3	Disposal receptacle for sharp instruments available?	☐☐☐☐☐
4.4	Adequate amount of working strength disinfectant available?	☐☐☐☐☐
4.5	Facility for final waste disposal in place (incinerator or pit or contract)?	☐☐☐☐☐
4.6	Addresses of contact people posted on wall visible to all staff?	☐■■■☐
4.7	Staff trained on post exposure prophylaxis (PEP)?	☐☐☐☐☐
4.8	ARVs available for PEP for testing staff?	☐☐☐☐☐

	5. Records	**1 2 3 4 5**
5.1	Official or equivalent 'laboratory' logbooks available?	☐☐☐☐☐
5.2	Records of expiry date and lot numbers of test kits available?	☐☐☐☐☐
5.3	All test results recorded?	☐☐☐☐☐
5.4	All test anomalies recorded?	☐☐☐☐☐
5.5	All repeated tests recorded?	☐☐☐☐☐
5.6	Records of filter paper samples collected available?	☐☐☐☐☐
5.7	Records of filter paper samples submitted to referral laboratory available?	☐☐☐☐☐
5.8	Accident/Incident record book available?	☐■■■☐

II PROCESS

(To be completed for each service provider observed)

Name of Service Provider: _____

HTC Providers Name: _____

	6. Sample Collection and Client Care	**1 2 3 4 5**
6.1	All requirements within reach?	☐☐☐☐☐
6.2	Initial rapport developed with client to explain whole process? (Confirm consent)	☐☐☐☐☐
6.3	Test devices opened (and labelled) in the presence of client?	☐☐☐☐☐
6.4	QC/QA appliances set and labelled in the presence of client?	☐☐☐☐☐
6.5	Client asked to make choice of finger?	☐☐☐☐☐

6.6	Proper swabbing of finger with spirit (alcohol) done?	☐☐☐☐☐
6.7	Fingerstick done correctly (check on site, orientation of lancet, depth)?	☐☐☐☐☐
6.8	First drop of blood wiped off (dry cotton wool used)?	☐☐☐☐☐
6.9	Massaging of finger done correctly?	☐☐☐☐☐
6.10	Sample collected correctly?	☐☐☐☐☐
6.11	Bleeding stopped correctly (dry cotton wool used)?	☐☐☐☐☐
6.12	Client reassured all through the process?	☐☐☐☐☐
7.	**Testing Procedures**	**1 2 3 4 5**
7.1	Standard Operating Procedures (SOPs) for testing displayed in testing area?	☐☐☐☐☐
7.2.1.	Two drops of whole blood added to the test device using a pipette?	☐☐☐☐☐
7.2.2.	One drop of Chase buffer added?	☐☐☐☐☐
7.2.3.	Minimum of 15 minutes allowed for results to develop?	☐☐☐☐☐
7.2.4.	Results interpreted correctly?	☐☐☐☐☐
7.3	Bio-line	
7.3.1.	One drop of whole blood added to the test device using a dropper ?	☐☐☐☐☐
7.3.2.	4 drops of assay diluents?	☐☐☐☐☐
7.3.3.	Minimum of 15 minutes allowed for results to develop?	☐☐☐☐☐
7.3.4.	Results interpreted correctly?	☐☐☐☐☐
7.4	Uni-Gold	
7.4.1.	Two drops of whole blood added using pipette?	☐☐☐☐☐
7.4.2.	Two drops of Wash solution added?	☐☐☐☐☐
7.4.3.	Time of 15 minutes allowed for results to develop?	☐☐☐☐☐
7.4.4.	Results interpreted correctly?	☐☐☐☐☐
8.	**Handling of filter paper**	**1 2 3 4 5**
8.1	Gloves assessed for presence of powder before starting preparation?	☐☐☐☐☐
8.2	Circles on filter paper not touched?	☐☐☐☐☐

8.3	Filter paper labelled correctly (Client code, date, counsellor code)?	☐☐☐☐☐
8.4	Filter paper placed in the horizontal orientation?	☐☐☐☐☐
8.5	Three (3) or more circles properly charged with blood?	☐☐☐☐☐
8.6	Location set aside for drying is adequate and convenient?	☐☐☐☐☐
8.7	Dried blood spots packaged in zip-lock bags with desiccant?	☐☐☐☐☐
8.8	DBS stored at RT or at 4oC before transmission to reference lab?	☐☐☐☐☐
9.	**Safety Precautions**	**1 2 3 4 5**
9.1	Working surfaces cleaned before work commenced?	☐☐☐☐☐
9.2	Arrangement of working surface in order?	☐☐☐☐☐
9.3	A new pair of gloves used per client?	☐☐☐☐☐
9.4	Disposal of all waste done promptly and correctly?	☐☐☐☐☐
9.5	Hands washed correctly after completion of process?	☐☐☐☐☐
10.	**Continuous Quality Assessment**	**1 2 3 4 5**
10.1	Regular peer evaluation done within the facility (monthly)?	☐☐☐☐☐
10.2	Does peer evaluation meeting identify weak points?	☐☐☐☐☐
10.3	20% of all blood samples collected on filter paper?	☐☐☐☐☐
10.4	For discrepant results tie breaker test performed or refereed to the laboratory?	☐☐☐☐☐
10.5	Blood collected on filter paper for all discrepant result?	☐☐☐☐☐
10.6	Blood collected on filter paper for all discordant results?	☐☐☐☐☐
10.7	All filter paper samples sent for quality assurance to reference laboratory?	☐☐☐☐☐

III RESULTS

11.	**Continuous quality assessment**	**1 2 3 4 5**
11.1	Reported cases of invalid results obtained	☐☐☐☐☐
11.2	Levels of concordance with reference laboratory	☐☐☐☐☐
11.3	Type of discrepancy obtained facility (+ve) Lab(-ve)] _____Total/month	
11.4	Type of discrepancy obtained [facility(-ve) Lab(+ve)] _____Total/month	
11.5	Number of transcriptional errors obtained _____Total/month	

General comments:

1 2 3 4 5

Final score ☐☐☐☐☐

HTC DIRECT OBSERVATION FORM

Observation date(s): __/___/___ Name of the HTC Provider: _____

Venue: _____ Observer: _____

Please score as follows: 0 = not done, 1= attempted with little success, 2 = achieved fairly, 3 = achieved successfully, N/A = not applicable.

Aspects of HTC service being assessed	Score	Comments
Explained to the client what to expect?		
Appropriate skills applied?		
Gave client adequate room to talk?		
Assessed HIV risks?		
Helped client develop a risk-reduction plan?		
Explained and demonstrated correct condom use?		
Discussed other reproductive health methods and options		
Discussed disclosure of test results and availability of social support?		
Obtained adequate finger-prick?		
Obtained consent (verbal/written) from client to test him/her?		
Correctly used correct device (Pipette/ Capillary/dropper) to harvest adequate blood sample?		
Explained clearly meaning of test result to the client?		
Read the results at the correct timing after incubation/ processing?		
Gave correct results to the right client?		
Helped client handle his/her emotional reaction?		
Gave core conditions to the client throughout the session?		
Gave adequate time to the client?		
Discussed referral options and referred client appropriately?		
Conducted client-centred session		

Session: Start time _____:_____ Stop time_____:_____

OFFICIAL STAMP DATE:_____ OBSERVER'S SIGNATURE_____

HTC Provider Self Reflection Form

Score range: 0-4; 0=very poor; 1=unsatisfactory; 2=satisfactory; 3=good; 4=excellent

1. Did I explain to the client what to expect in the session?
2. Did I perform a risk assessment?
3. Did I help the client come up with a risk reduction plan?
4. Did I discuss proper condom use with the client?
5. Did I explain to the client how to interpret their results?
6. Did the client understand the meaning of the test results?
7. Did I assess the availability of the clients' social support?
8. Did I discuss disclosure of test results with the client
9. Did I discuss referral options with the client?
10. Did I give adequate time to the client?

Summary Sheet: Counsellor Self-Reflection Form

Facility Name:		**District:**	
From: dd/mm/yy		**To:** dd/mm/yy	
Aspects of service being assessed	**Number Completed**	**Total Score**	**Mean Score (total score/number completed)**
1. Explained what to expect			
2. Performed a risk assessment			
3. Helped client attain risk reduction plan			
4. Discussed proper condom use			
5. Explained how to interpret results			
6. Client understood meaning of results			
7. Assessed availability of social support			
8. Discussed disclosure of test results			
9. Discussed referral options			
10. Gave adequate time to the client			

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