Ministry of Public Health and Sanitation

National Guidelines for HIV Testing and Counselling in Kenya

National AIDS and STI Control Programme (NASCOP)
Ministry of Public Health and Sanitation
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Content

List of Abbreviations

AHI	Acute HIV Infection
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Clinic
ARS	Artesunate (Malaria Treatment)
ART	Antiretroviral Therapy
CACC	Constituency AIDS Control Coordinator
CBO	Community-based Organisation
CDC	United States Centers for Disease Control and Prevention
CHEW	Community Health Extension Worker
CITC	Client-initiated Testing and Counselling
CORP	Community Owned Resource Person
CSW	Commercial Sex Worker
DASCO	District AIDS and STI Coordinator
DBS	Dried Blood Spot
DHSF	District Health Sector Forums
DMOH	District Medical Officer of Health
DTC	Diagnostic Testing and Counselling
EID	Early Infant Diagnosis
ELISA	Enzyme-linked Immunosorbent Assay (Test)
EQA	External Quality Assessment
FBO	Faith-based Organisation
FP	Family Planning
GOK	Government of Kenya
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
IDU	Injecting Drug User
IEC	Information, Education and Communication (Materials)
IPC	Inter-Personal Communication
IRB	Institutional Review Board
KEMSA	Kenya Medical Supplies Agency
KNASP	Kenya National HIV/AIDS Strategic Plan
KNH	Kenyatta National Hospital
LVCT	Liverpool VCT, Care and Treatment
M&E	Monitoring and Evaluation
MC	Male Circumcision
MCH	Maternal and Child Health
MOH	Ministry of Health
MSM	Men Who Have Sex with Men
MVCT	Mobile Voluntary Counselling and Testing
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Programme
NBTS	National Blood Transfusion Service
NHRL	National Reference Laboratory
NGO	Non-Governmental Organisation
NHSSP	National Health Sector Strategic Plan
OI	Opportunistic Infection
OVC	Orphans and Vulnerable Children
PASCO	Provincial AIDS and STI Coordinator

PCR	Polymerase Chain Reaction (Test)
PITC	Provider-Initiated Testing and Counselling
PLWHA	Persons Living With HIV or AIDS
PMCT	Prevention of Mother-to-child HIV Transmission
PWD	Persons with Disabilities
PMO	Provincial Medical Officer
PWP	Prevention with Positives
QA	Quality Assurance
RRI	Rapid Response Initiative
RTC	Routine Testing and Counselling
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNGASS	United Nations General Assembly Special Session on AIDS
VCT	Voluntary Counselling and Testing
WB	Western Blot (Test)
WHO	World Health Organization
WTC	Workplace Testing and Counselling

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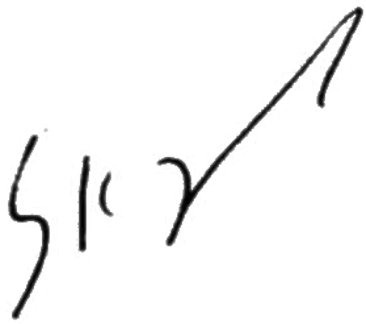

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Foreword

The Ministry of Health (MOH) acknowledges the development of the new National Guidelines for HIV Testing and Counselling in Kenya as an important step for Kenya in keeping pace with international guidance and recommendations. These guidelines have been updated in response to recent scientific evidence, programmatic achievements, available technologies, and the changing dynamics of the HIV epidemic in Kenya.

As the main entry point to HIV prevention, care, support, and treatment services, HIV testing and counselling (HTC) is central to all HIV programmes nationwide and is closely linked with other health services. It is therefore in the interest of the MOH to facilitate the provision of optimal HTC services in all settings by regularly updating, disseminating, and implementing the guidelines put forth in this document.

The publication of these guidelines is also very timely, as they coincide with a period of increased efforts by the Government of Kenya (GOK), with support from various partners, to increase knowledge of HIV sero-status among all Kenyan citizens. Kenya has made significant progress in recent years towards achieving the goal of 'universal access' to HIV testing and counselling services through the scale-up of voluntary counselling and testing (VCT) and Provider Initiated Testing and Counselling (PITC) services. Still, in order to reach the 'universal access' goal of 80% of Kenyans knowing their HIV status by the year 2010, much work remains to be done.

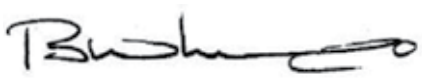
In accordance with current trends and international recommendations, the MOH emphasizes that while certain core elements of HTC remain largely unchanged, such as the '3Cs' of confidentiality, counselling and consent, the publication of this document also introduces novel approaches to HTC that will reduce the number of missed opportunities for providing HTC services. Among the innovations discussed here are door-to-door testing for HIV, self-testing, national HIV testing campaigns, added emphasis on couple and family testing, and infant and child HIV diagnosis, to mention a few. With a diversified approach and the continued prioritization of HTC, along with referrals to follow-up services, we are confident that Kenya is moving towards achieving its 'universal access' goal.

In this era of increased funding for addressing HIV/AIDS globally, and with more widely available care and treatment services, we are called to remember the critical role of HTC and other HIV prevention programmes in reducing further spread of HIV infection in Kenya.

Through linkages with care, treatment, and support programs HTC contributes to lessening the impact of the HIV epidemic on children, adults, families and communities. These updated guidelines demonstrate that HTC is a critical priority for Kenya, and resources should be strategically utilized to accelerate and strengthen implementation of HTC approaches in the context of the current policy environment.

Guided and inspired by previous success stories and milestones, we are confident that the implementation of these guidelines at all levels, with an emphasis on the provision of quality, targeted HTC services in varied settings, will empower the people of Kenya to learn their HIV status.

Finally, I encourage HTC service providers throughout Kenya, including health care workers providing HTC in clinical settings, VCT counsellors at stand-alone, outreach and other sites, administrative and support staff, and all others who contribute to HTC service provision to read, absorb, and hereby implement the guidelines put forth in this document.



Hon. Beth Wambui Mugo, M.P.
Minister for Public Health and Sanitation

Executive Summary

HIV testing and counselling (HTC) is the main entry point to prevention, care and treatment. Kenya has adopted the UNAIDS concept of Universal Access by 2010. The achievement of these ambitious targets will hinge on the successful expansion of HTC programs in the country. These guidelines are the basis for this expansion.

The phrase HIV testing and counselling, which is introduced in these guidelines, is the essence of the strategy to bridge the gap between two distinct HTC approaches in Kenya. Many Kenyans are familiar with Client-initiated HTC, which is also known as voluntary counselling and testing (VCT). Health workers are also familiar with Provider-initiated HTC (also called PITC), which was previously known as Diagnostic HIV testing and counselling. Unlike DTC which targets sick people PITC targets all patients and clients in the health facility.

In general both provider and client-initiated HTC have similar values and guiding principles, but the settings vary slightly. Client-initiated HTC is provided in community-based settings, and can be conducted by non-health personnel. PITC is mostly provided in health settings, although provided in the community. Further, the emphasis of client-initiated HTC is early HIV diagnosis, HIV prevention and social support, whereas in PITC the focus is linkages to care and treatment. However, both approaches are associated with important HIV prevention, care and treatment outcomes. These are general rules which are not exclusive.

These guidelines were developed in the context of existing Kenyan laws and policies, especially the HIV and AIDS Prevention and Control Act (2006). They support the provision of HTC to children, youth, and adults, according to the circumstances described herein. The guidelines retained key policy issues that were in previous guidelines, but they have outlined some of the emerging evidence based approaches and lessons learnt in the implementation of HTC in the last eight years. The issue of quality has been highlighted as critical in HTC. There are quality issues in both counselling as well as testing. The attainment of high quality services is dependent on a good work force, in this case made up of health care workers, professional and lay counsellors. Quality testing leans on a well functioning national laboratory infrastructure and network. Effective support systems must also be in place, including test kit logistics and monitoring, and timely reporting.

Some of the new principles and concepts that are introduced in these guidelines include special focus on referrals and linkages to comprehensive HIV prevention, care and treatment. This will happen through introduction of name-based, confidential testing in all HTC settings; and shifting the emphasis from pre-test counselling to post-test counselling and strengthening integration. The guidelines also introduce a concept known as the HTC service package. This implies that HTC services are to place premium on integrating other health services into HTC. The key and urgent ones include clinical staging and tuberculosis screening. Others include opportunistic infection screening and referral, STI screening, nutritional education and stronger prevention support. As part of integration and linkage, other health services should also integrate HTC into their core activities.

For these guidelines to be utilized most effectively, the Ministry of Health through the National AIDS/STI Control Program (NASCOP) and through the decentralized structures will continue to provide leadership and direction. The government will continue working closely with development partners and implementing agencies.

Chapter 1
Introduction

Background

HIV testing and counselling (HTC) has experienced very rapid growth since it was launched in 2001. HTC has contributed significantly to the reduction of stigma associated with HIV/AIDS, and the promotion of behaviour change. It has also facilitated access to prevention, care and treatment for people living with HIV/ AIDS.

The program started with three pilot sites that were established in government health facilities. Lessons from these sites provided a strong basis for the development of the national guidelines and standards, which in turn led to the rapid growth that was observed in the first three years if implementation. In line with international commitment and a declaration from the Joint United Nations Programme on HIV and AIDS (UNAIDS), Kenya has renewed this pledge of 'universal access' by setting the goal of 80% knowledge of HIV status by 2010 (NACC, Draft Report).

Approaches to HTC in Kenya have shifted over the years from primarily client-initiated models, to the broad scope of approaches that are currently in place. By the end of 2007, there were at least 900 VCT sites in Kenya, most of which were situated in health facilities (hence called integrated sites). About 15% of these sites are in community settings, hence referred to as 'stand-alone' sites. Other models of HTC have been introduced in recent years, including mobile, 'moonlight', and door-to-door HTC, among others. Many service providers also provide HTC services to groups with special needs such as the youth, rape victims, people with disabilities, and persons engaged in high-risk behaviour such as commercial sex workers (CSW), injecting drug users (IDU) and men who have sex with men (MSM).

Hospitals and health centres in Kenya have begun incorporating provider-initiated HIV testing and counselling (PITC) as part of routine health care to all patients and clients. The PITC approach reflects the recognition that many HIV positive clients are symptom free and the health facility provides an opportunity where they can learn their HIV status. Therefore, these guidelines recommend an expansion of the DTC approach that was introduced in Kenya in 2004 to full PITC.

Policy Guidance

It is the mandate of the Kenya Ministry of Health (MOH) to deliver quality, affordable health care to all citizens of Kenya. Various strategic documents have outlined plans towards achieving this goal, including the Second National Health Sector Strategic Plan (NHSSP II, 2005-2010) and the Kenya National AIDS Strategic Plan (KNASP, 2005-2010). These documents form the basis of all HIV prevention and care programmes, including HIV testing and counselling.

In addition to the documents mentioned above, various other policy documents were consulted during the preparation of these guidelines. These guidelines derive their validity from and conform to certain items of legislation, which

include but are not limited to the following Acts:

- HIV and AIDS Prevention and Control Act, 2006
- Sexual offences Act, 2006
- Children's Act, 2001
- Medical Laboratory Act, 1999
- Science and Technology Act, 1980
- Public Health Act (Cap 242)

This document also harmonizes specific policy issues from other MOH documents regarding HIV/AIDS, such as the National Guidelines for the Prevention of Mother-to-Child HIV/AIDS Transmission (PMCT), National Tuberculosis (TB) and Leprosy Guidelines for TB and HIV collaborative activities, the National Guidelines on Blood Transfusion in Kenya, and the National Quality Assurance Strategy for Voluntary Counselling and Testing (VCT). International policy documents were also referenced during the preparation of this guidance, including the UNAIDS and WHO Guidance on provider-initiated HTC in health facilities, the WHO and CDC Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing, WHO guidance on the early detection of HIV infection in infants and children, and UNAIDS and WHO guidance on encouraging beneficial disclosure, ethical partner counselling and appropriate use of HIV case-reporting.

Justification

As stated above, HTC is the entry point to HIV prevention, care and treatment. The rapid expansion of care and treatment services has increased the need for HTC. Different components of the population require different HTC approaches in order to enhance access to available care and treatment services.

Recent scientific and programmatic evidence, have contributed to the development of these guidelines. Some of these key areas include

- The need to prioritize couples
- Testing for HIV-infected persons and their family members,
- Paediatric HIV testing,
- Strengthening quality assurance systems, and
- The introduction of oral HIV test kits for possible self-testing.

This document upholds the basic rights of individuals and families as enshrined in statutes. These include rights to knowledge of HIV status in a proper environment, which is the basis for informed decision making including knowledge of the HIV status of their sexual contacts or persons with whom needles are shared. It also includes the right to comprehensive HIV prevention, care and treatment services.

Policy Review Process

In May 2007 an HIV prevention summit was held in Kenya which among other things emphasized the need to scale up HTC services. After this summit, an HTC stakeholder meeting was called in June 2007. The focus of this meeting was the review of the HTC program in Kenya. There was discussion about current HTC approaches and key achievements to date, gaps in existing policy and operational documents. Out of this stakeholders' meeting a working committee

of experts from the Ministry of Health, bilateral agencies, and non-governmental organisations was formed, and was assigned the task of revising Kenya's national HTC guidelines.

The HTC Guidelines Working Committee held weekly meetings from June to December, 2007 to discuss the key HTC issues in greater depth. Experts in specific fields were invited to give presentations highlighting the most recent evidence in areas such as monitoring and evaluation (M&E), logistics, laboratory, and target populations. The minutes from these meetings formed the basis for these guidelines, which then received a peer review by local, regional and global experts from the World Health Organization (WHO), U.S. Centers for Disease Control and Prevention (CDC), Liverpool School of Tropical Medicine (LSTM), and Family Health International (FHI). Additional review of the guidelines was provided by stakeholders during a two day consultation meeting in November, 2007.

The purpose of these guidelines is to provide national standards for all institutions, organisations and individuals to adhere to regarding the provision of high quality HIV testing and counselling services in Kenya.
This document is a policy document, and provides a framework for all HTC programmes in Kenya. This is not an operational document per se. However some operational elements of HTC may be addressed for clarity and cohesion. These updated policy guidelines will be followed by updated operational guidelines for HTC, as well as revision of existing training materials, job aids, monitoring and evaluation tools, and quality assurance standards as appropriate.

Chapter 2
Types of HIV Testing and Counselling

This document suggests a broad definition of HIV testing and counselling (HTC) that can be initiated by the client, patient, or health care provider in any setting. Further explanation of the terms client-initiated HIV testing and counselling and provider-initiated HIV testing and counselling are provided below, as well as other types of HTC.

Client- Initiated HIV Testing and Counselling

Client-initiated HTC refers to a situation whereby an individual, couple, or group actively seeks out HIV testing and counselling at a site where these services are provided and/or accessible. Previously in Kenya this took place primarily in the context of voluntary counselling and testing (VCT); however HTC may be initiated by clients in settings other than VCT sites such as health facilities, mobile sites, or in people's homes.

The client-initiated approach to HTC requires that persons wishing to know their HIV status take it upon themselves to request an HIV test. Clients may seek HTC services to guide personal life decision making, plan for one's future or the future of their family, and understand symptoms one is experiencing, or support personal HIV prevention efforts. Typically, client-initiated HTC puts emphasis on tailored risk reduction counselling to help the client or couple identify a plan for the prevention of HIV transmission or acquisition.

Provider-Initiated HIV Testing and Counselling

Provider-initiated HIV testing and counselling refers to a situation in which the HTC service provider, who may be a health care worker or other type of HTC service provider, offers an HIV test to a client or patient regardless of their reason for attending the facility.

> It is important to note that PITC is significantly different from DTC. Whereas DTC targets patients with HIV-related signs and symptoms, PITC opens up HTC to all patients in the health facility. PITC therefore makes HTC part of routine care in health facilities in Kenya. Failure to offer HTC when symptoms or signs of HIV are present is substandard care and is not acceptable

In the context of health facilities, HIV testing should be treated in a similar manner to other methods for laboratory diagnosis, and should ideally take place as part of routine medical care before the onset of HIV related symptoms. For persons who are ill, provider-initiated HTC can facilitate the identification of HIV associated disease so that they may more readily access comprehensive care and treatment services. In much of Kenya, because a high proportion of hospital patients have HIV infection, it is recommended that HIV testing be offered to all patients.

Prior to receiving an HIV test, the health care provider will explain the procedure and the reasons for requesting the test to the client or patient. Upon the recommendation of the health care provider, if the client or patient agrees to

learn their HIV status s/he will receive an HIV test and will be informed of their results.

Wherever possible, health care providers should provide both counselling and testing at the point of care. If this is not possible for various administrative and logistical reasons, clients or patients may be referred to another HTC service provider or to laboratory for testing. The crucial issue is that clients or patients must receive their test results, whatever the system used. This provision of results should be accompanied by appropriate post-test counselling. Efforts should be made to provide HTC services in the same room or location nearby to where the patient is receiving other medical care.

While HTC should be offered to all clients or patients attending any health facility as part of routine care, failure to offer HTC in the following situations is unacceptable and will be considered negligent:
- Maternal and child health services
- Adult and paediatric inpatient facilities
- Tuberculosis (TB) clinics
- Sexually transmitted infection (STI) clinics
- Post rape patients
- Occupational exposure clients
- Promotion health services (i.e. family planning)
- General outpatient services

Other Types of HIV Testing and Counselling

Self-testing for HIV

Recent advances in testing technologies have availed several non blood-based HIV tests. Some of the common examples include oral fluid and urine based testing. It is anticipated that other simple non blood will become available in the coming years.

These technologies have made self testing possible. The basic principle of self testing is the conducting of an HIV test upon one self. This principle has been used before for other non invasive tests, such as in pregnancy test. In all these situations, clients can access test kits from pharmacies and other approved suppliers.

Self testing is different from the traditional HTC strategies. For example in self testing the client does not have a chance to receive basic HIV/AIDS education, or pre-test counselling. But in order to strengthen support systems for self testing, there is need for basic standards. These standards include:

- Test kits must be evaluated and approved for use in Kenya;
- Test kits must be used before the expiration date
- Storage conditions must be adequate;
- Test kits must pass quality control standards in Kenya;
- Pharmacists must be trained and approved to dispense, counsel, and demonstrate the use of the test kit to clients and patients as the need arises;
- Follow up and referral services, including services for confirming positive test

results, must be accessible for clients and patients.

Persons accessing an HIV test kits from a pharmacist or other health care provider must have some basic training, to enable them provide basic information to clients. The vendor should be able to provide the client with step-by-step instructions for

1. How to conduct the test;
2. How to correctly interpret the test results; and
3. Where to access follow-up and support services in the surrounding area.

Persons must also be informed that the results of the self-test are not confirmed until a second, confirmatory test is conducted. This information should also be made available on a package insert, to be included on all HIV tests sold or distributed in Kenya, along with the minimum standards mentioned above.

Pharmacist and other suppliers of self test materials should undergo HTC training and be certified by the Ministry of Health. They must provide a private room for clients who may need further information, counselling and social support. Utmost care should be taken to avoid cases of misuse of test kits, as well as to prevent cases of negative social outcomes.

Required HIV testing

HIV testing may be performed without specific consent in certain specific settings, such as during military recruitment and specialized employment. HIV testing may also be ordered by a court of law.

In all cases of required testing, services must be confidential, and performed with adequate counselling. Persons receiving an HIV test in these settings shall be informed of the test and must have access to the results in an appropriate setting, in addition to being provided with the necessary referrals.

HIV testing of blood and tissue donations

As indicated in the Policy Guidelines on Blood Transfusion in Kenya, all blood for transfusion must pass the infectious disease screening tests agreed upon by the MOH before being made available to the recipient. This includes testing for HIV, as well as other transfusion or tissue transmissible infections.

All blood and tissue donors should be given general information about HIV testing, and should have access to their results. Blood donor services will also work with other sections of the Ministry of Health to ensure that other HIV/AIDS services are provided for blood donors, so that those who need more information and further support can be assisted.

HIV testing for research and surveillance

Research in Kenya may only be conducted the research protocol has been cleared by the relevant ethical review committee (or board). In general, written informed consent is required for all research participation, and this should include consent for HIV testing if necessary. Except in very exceptional circumstances, all study subjects should receive their test results with appropriate post-test

counselling. Such exceptional circumstances if any will have been cleared by ethical committees.

All HIV testing conducted as part of research must be accompanied by appropriate counselling in line with the policies outlined herein.

Sentinel surveillance in Kenya has been based on unlinked anonymous testing of pregnant women attending antenatal clinics and of patients attending STI clinics. Anonymous testing should be complemented with the provision of HIV services, including information and confidential HTC.

Chapter 3
Settings

HIV testing and counselling (HTC) provided in a variety of settings. While clientinitiated HTC typically takes place in community based sites and provider-initiated HTC in health facilities, these rules are flexible. For example the use of a mobile VCT truck for a medical outreach program. In this case, both client and provider initiated HTC will be provided in the facility.

The diverse HTC approaches in Kenya are premised on the need to expand the options that are available, so that clients can select the approach that suits their interests and conveniences. And yet out of all the options that are currently available in Kenya, promotional HTC campaigns and home based HTC are the two approaches that have the potential to dramatically increase coverage of HTC services in a short time, and achieve population level impact. In the coming years, more focus will be placed upon these two approaches, without loosing the momentum that has been attained in the other approaches over time.

It is recommended that organisations providing HTC via stand-alone or fixed sites attempt to diversify their service provision settings to include other outreach services, as these different methods have been shown to be cost-effective for reaching different types of clients (Menzies, et al).

Community Based Settings

Emphasis on community based sites for the provision of HTC is in line with the Ministry of Health (MOH) Community Strategy (Kenya MOH, Health Sector Reform Secretariat) and the National Health Sector Strategic Plan-II, which recognize the contribution of community health workers deployed by the MOH for meeting Kenya's health care needs. When properly trained and certified, non-health care personnel may provide HTC in community based settings. The focus of HTC in these settings is generally on strengthening the social elements of HTC for prevention, family level counselling, and links to support groups.

Some examples of community based sites are:

Stand-alone HIV testing and counselling centres

Stand-alone HTC centres are facilities within the community that are not attached to other specific health services. Generally these sites are operated by nongovernmental organisations (NGOs), faith-based organisations (FBOs), or other community-based organisations (CBOs), though the Government of Kenya (GoK) does provide support to some stand-alone HTC sites. Stand-alone HTC centres target the general population, or can also be tailored to populations with specific needs such as HTC for the deaf, youth-friendly HTC centres, and sites specifically available for commercial sex workers (CSW) and injecting drug users (IDU).

Outreach HIV testing and counselling

Outreach HTC refers to services offered outside of a fixed site, such as mobile or workplace HTC. Some of the current means that are used for providing outreach HTC services in Kenya include:

- Vehicle with private counselling rooms
- Using tents as counselling rooms
- Utilizing pre-existing community facilities such as a church, school, university, or market building
- In the workplace
- In a client or patient's home
- Camel or bicycle, or other mobile outreach mechanism

Outreach HTC can be conducted at night to reach working populations, including taxi and truck drivers and sex workers who are more available for HTC at night.

This is sometimes referred to as Moonlight HTC.
Organisations conducting outreach HTC activities must register with NASCOP to ensure appropriate quality control measures are in place, and must adhere to the guidelines and policies put forth in this document.

Home-based HIV testing and counselling

Background

Home Based HTC is one of the new HTC approaches that have been introduced in Kenya recently. It was first piloted in Suba district of Nyanza province, where it was well received by the community, which translated to high acceptance rates. Other pilots in Kenya, as well as experiences from other countries have shown that HBCT is feasible and acceptable in the community. The goal of HBCT is interruption of HIV transmission and increase in access to care and treatment, because of the high level of coverage that is achieved (public health impact)

Description

Home-based HTC refers to a situation whereby the HTC service provider physically goes to the home of a potential client or known patient to offer HTC. HTC in this setting is initiated by the service provider, but the client has a right to refuse the test. There are currently two broad categories of HBCT. IN one approach, counsellors visit all the homes in a specified geographical area. Sometimes this is referred to as door-to-door HTC. The other type is where counsellors only visit the homes of patients in a care and treatment (index clients) to provide HTC to their families. Home-based HTC of family members of ART patients has been shown to be cost-effective (Menzies et al) and is associated with uptake rates above 95%.

This approach also leads to identification of many previously undiagnosed HIV infected patients, particularly among children, and high rates of HIV discordance within couples (Were, 2006). Benefits of home-based HTC are maximized when couple members are tested together rather than as individuals and when HTC is provided to children of HIV-infected or deceased mothers.

In the pilot in Suba and Nandi, the program was well received by the community, and the acceptance was high (above 90%) Home-based HTC may be incorporated as a programmatic strategy by organizations and agencies with sufficient capacity, appropriately trained staff, and high quality control standards. Organisations wishing to do home-based testing must register with NASCOP to ensure appropriate quality control measures are in place, and must adhere to the guidelines and policies put forth in this document.

Benefits of HBCT

HBCT has tremendous benefits, chief among which are:

- Providing HTC for couples, leading to enhanced social support and disclosure
- HTC for especially HIV exposed children is feasible
- Most clients and families find HBCT to be confidential, because they don't have to be seen going to the VCT
- Increased knowledge of HIV status among family members improves attitude towards the disease and may promote social support e.g. for adherence to medication, and emotional support
- Anecdotal evidence from the pilots in Kenya suggests that clients find HBCT to be less costly and convenient
- HBCT increases access to community based social support structures including the church and other community initiatives
- HBCT reduces HIV stigma and as such many clients are better able to proceed to the places where they have been referred. This stigma reduction is partly due to the fact that HBCT has high acceptance and coverage, therefore almost everyone in the community knows their HIV status.

Workplace HIV testing and counselling

HTC programmes in the workplace may be introduced by employers or organizations who wish to ensure their employees have access to quality HTC services. These have been carried out successfully by many companies as a means of encouraging employees at all levels to learn their HIV status, to learn more about how to prevent transmission and acquisition of HIV, and to provide a link to care and treatment programs as necessary.

Workplace HTC programmes may follow a variety of different methods, sometimes beginning with educational services to inform employees of the benefits of HTC and providing referrals to HTC centres near the workplace. Some employers can make special arrangements with nearby HTC centres to ensure services are provided at low or no cost to the employees. Alternatively, HTC may also be offered in the workplace itself if employees are interested in accessing this service on-site.

When workplace HTC is offered on-site, as with any type of HTC, the core principles of confidentiality, consent, and counselling must be adhered to and referrals for care and treatment must be made as needed. Workplace HTC services must be voluntary and workers shall not be required to be tested by their employer.

Personal data relating to a worker's HIV status or other personal information may not be disclosed to the employer unless the employee specifically provides consent to do so. In cases where health care is provided by the employer, it may be suitable for the employee to disclose his or her HIV status to the employer in order to receive treatment for HIV related symptoms and disease.

It is recommended that businesses and organizations throughout Kenya incorporate HTC as part of their welfare strategy for employees. An organization's management staff should be involved in the process of incorporating HTC into their workplace policy, and may opt to provide follow-up care and treatment to employees as needed.

Health Facility Settings

HTC can be initiated from any service delivery point in all sections of a hospital or health facility for any person. In settings experiencing generalized epidemics, HIV prevalence has been shown to be high across all in and out-patient settings in major health facilities (Wanyenze 2008). HTC in the health facility generally requires the direct participation and engagement of the health care worker in providing the service. Trained health care workers are encouraged to provide HIV testing to patients themselves, when possible, rather than referring the patient to the laboratory for testing, as this can provide a stronger link to care and treatment programmes for HIV positive clients. Health care workers should feel empowered to test all patients except those that opt out and others that may be available for testing – spouses or other sex partners, children, parents, or other family members. HTC in the health facility setting places emphasis of posttest counselling and, if indicated, linkage into appropriate care and treatment services.

Some examples of HTC sites in health facilities are:

Integrated HIV testing and counselling centre

Integrated HTC sites are co-located on the grounds of a health facility such as a hospital or a health clinic. The sole function of an integrated HTC centre is the provision of HTC services; other health services are generally not offered, though some related services such as family planning (FP) may be offered. The integrated HTC site may be a separate facility on the grounds of a functioning health facility, or it may be attached to the health facility such as a group of rooms in a specific ward.

Hospital or health clinic

An example of HTC in the hospital or health clinic setting is PMCT or HTC in the context of maternal and child health care (MCH). HTC may occur for pregnant women, infants and children in antenatal, maternity, or postnatal units. For children, HTC may also occur during routine immunizations or check-ups in the paediatric unit. HTC for TB patients may occur in the TB unit and for STI patients in the STI clinic. HTC may also take place as part of general outpatient or inpatient services.

Chapter 4
Eligible Populations

In the interest of achieving Kenya's goals for universal access to HIV prevention, care and treatment services, HIV testing and counselling (HTC) services should be offered to persons of all age groups. Kenya is still experiencing a generalized HIV epidemic, with high HIV prevalence among the general population, not just among specific groups. With this in mind, it is recommended that all persons in Kenya take preventive measures to protect themselves from acquiring HIV, including learning their HIV status, and the HIV status of their sexual partners.

Special groups within the general population may require specific consideration due to their potential for increased risk of HIV. Persons within these special populations might have an elevated HIV risk because of their socio-economic situation, because personal limitations and barriers created by their environment make them especially vulnerable, because they do not have access to HTC services, or because they participate in especially high risk behaviour.

General Population

Adults

HIV testing among HIV-infected persons has been associated with a 60% reduction in transmission risk behaviour in multiple settings (Crepaz, 2006; Bunnell, 2008). HTC also contributes to prevention of HIV transmission through individual and couples risk reduction counselling.

All adults should be offered HTC in order to know their HIV status, to prevent transmission to others or acquisition of HIV. HIV testing and counselling has significant benefits to HIV positive clients, particularly in the wake increased availability of care and treatment services in Kenya.

Youth including adolescents

Data shows that adolescents and young adults are at significant risk of acquiring HIV infection as they begin to engage in behaviors that may place them at risk, such as becoming sexually active; the majority of new infections are identified among persons aged 20-29 (KDHS, 2003).

Educational messages and materials that address the prevention of HIV should be developed specifically for adolescents and young adults, and youth-friendly HTC should be made available to them.

Youth, including children at risk of HIV, may be encouraged to bring a parent, guardian, or caretaker to attend the HTC session to ease disclosure and for more adequate linkages to care or treatment services if necessary.

Youth over age 16 may donate blood, and represent a population with low HIV prevalence on whom the National blood service relies for a significant amount of blood donations throughout the country. Youth between the ages of 16-18 must have the consent of their parent, guardian, or caretaker in order to donate

blood, and as their blood will be tested for HIV, to receive their HIV test results in a confidential and appropriate setting.

Post-test counselling must be done to ensure persons have the appropriate prevention messages to keep them safe from HIV, and to ensure that HIV positive clients are appropriately referred for services and know how to protect others from infection.

The Ministry of Health will collaborate with the National Blood Transfusion Services and other partners to strategize for how blood donor services may partner with other HTC service providers to return CT results to young clients in a respectful and client-centered manner.

Infants and children

Children with unknown HIV status presenting at health facilities should be offered an HIV test regardless of what brings them into the facility.

HIV testing and counselling should be offered to guardians and parents, who should also give written consent for their children to be tested. Where appropriate, children can also be offered counselling and other emotional support.

For all infants, testing should be offered to the parents and the child at the earliest opportunity. This may occur at an antenatal clinic (ANC), maternal and child health clinic (MCH), inpatient ward, or in any other setting as described in Chapter 3 of this document. Early infant diagnosis, using PCR or any other appropriate technology, should be offered to all infants who are exposed to HIV. Where PCR facilities are not available, rapid tests may be used in order to determine the child's exposure status and facilitate early entry into care and treatment programmes. Attempts should be made to reach beyond the index child to other children as well.

An algorithm for early infant diagnosis has been developed by the MOH, and should be consulted for further information on HTC on infants.

Child immunization campaigns may also be used as an opportunity to disseminate information about HTC, and can be an opportunity to test children (and adults) of unknown HIV status.

Special Populations

Couples

HIV transmission rates with discordant couples are high, with 10-12% of HIVnegative partners sero-converting each year (Quinn et. al. 2000, NEJM). Prevalence of HIV discordance is high in Kenya, with 50% of married or cohabitating HIVinfected persons having an HIV-negative spouse (KDHS 2003). HIV-negative partners within discordant couples are Kenya's largest risk group, numbering over 450,000 (KDHS 2003). Couples HTC has been associated with large reductions in HIV transmission risk within discordant couples (Allen et. al.; Sweat et. al.)

In Kenya, HTC service providers should encourage couples, including those intending to marry, to receive HTC together. This is to facilitate disclosure and

adequate referrals, to prevent HIV transmission within discordant couples, and to provide social support.

During couples HTC, each partner should be given an equal opportunity to talk and ask questions. Couples should be supported to openly disclose their results to other family members, although counsellors should screen for potential domestic violence risk and make referrals as needed. Information about prevention of mother-to-child transmission (PMCT) and family planning (FP) services should be provided to couples when appropriate.

Families of patients receiving HIV/AIDS care and treatment It is recommended that the families of patients receiving care for HIV/AIDS related illnesses should also be offered HTC. Family members include children, spouse(s) or other sexual partners, and may also include close relatives such as grandparents and caregivers of the patient.

It is recommended that health care providers encourage patients receiving care or treatment for HIV to bring their family members to the health care facility to be tested on site. However, uptake rates of facility-based referrals are generally low and programs should consider developing outreach programs to provide community or home-based HTC services for family members. If the patient prefers to take his or her spouse or sexual partner to be tested at a VCT site, the health care provider should emphasize that if the partner is also HIV positive they should both return to the health care facility for follow-up care or treatment.

Persons with disabilities (PWD)

This category includes persons with physical, sensory, or mental limitations who may be deemed disabled not solely because of a diagnosable condition, but also because they may not have equitable access to information, education, and other public services. Disability is an evolving concept that results from the interaction between persons with impairments and attitudinal and environmental barriers that hinders their full and effective participation in society on an equal basis with others (United Nations, 2006).

Provisions should be made for persons with disabilities (PWD) to access HTC services in a manner that meets their specific needs. This means incorporating approaches such as local sign language, wheelchair accessible spaces, providers who specialize in issues of mental handicaps, and flexibility on the part of HTC service providers in reaching clients where they are most accessible. In some cases, providers may attend to the client or patient in the home or another appropriate setting. HTC service providers should have the skills to determine if a person is mentally fit to receive their HIV test results, and should know where to refer a client to for further care and support when needed. If the provider is uncertain, the client or patient may be referred to the nearest health facility

Populations abusing alcohol and other drugs

Evidence has shown that there is a strong association between alcohol use and HIV infection (South Africa and Malawi studies; LVCT and Population Council, 2007). HTC providers should use their skills and training to determine if clients have drinking habits that may put themselves or others in danger. Individuals who are evidently intoxicated should be counselled and in this case HTC should be deferred to an appropriate time. In these circumstances alcohol information and

counselling should be integrated into pre- and post-test procedures. Appropriate referrals for alcohol counselling should be made, and alcohol and drug abuse support facilities should be part of HTC referral services.

With increasing evidence that injecting drug use is on the rise in some parts of East Africa, special attention should be paid to the risks associated with this behaviour and HIV acquisition, and efforts should be made to provide HTC services to injecting drug users (IDU).

Additional populations

There are additional populations that may also be vulnerable to HIV infection. A concerted effort should be made to ensure that these populations have equitable access to HIV testing and counselling. Where appropriate, these persons should also be encouraged to be tested with their sexual partners. These groups include, but are not limited to:

- Prisoners
- Long distance truck drivers, taxi drivers, and bus drivers
- Commercial sex workers (CSWs)
- Men who have sex with men (MSM)
- Orphans and other vulnerable children (OVCs)
- Families and children living on the street
- Children living in a group home
- Children 7-12 years
- Adults older than 50 years
- Refugees, displaced persons and migrants
- Persons separated from their spouses because of employment
- Servicemen/women and their families

CHAPTER 5
HIV Testing and Counselling Service Package

The three primary components of HIV testing and counselling (HTC) are the pretest session, the HIV test, and the post-test session. These three elements make up the minimum service package of HTC.

Pre-Test Session

Individual or group pre-test session

The pre-test session introduces basic HIV information to the client or patients wishing to receive an HIV test, and may be provided to an individual, a couple, or a group. Group information is not a substitute for individual or couples counselling, however. Whether attending as an individual, a couple, or a group, all persons should be given time to ask questions and receive personalized information, and should give consent for receiving HTC services.

The minimum services that should be provided during a pre-test session for HTC include:

Information on the benefits of knowing one's HIV status
Benefits of couple testing
An explanation of the HIV testing process
The need for consent for the HIV test

Other topics that may be discussed during the pre-test session, depending on the needs of the client and the setting, include:

A summarized version of risk assessment
Referral to support, care and treatment
Importance of disclosure to partners and other family members

HIV Testing

In majority of settings, licensed rapid tests will be done on the spot by the HTC service provider. Anyone receiving an HIV test should be encouraged to receive their HIV test results. In some instances at a health facility, patients or clients may be referred to another on-site HTC service provider or laboratory for the test; however, it is important to emphasize that clients should be offered their results, regardless of where the HIV test is conducted.

All HIV positive test results must be confirmed by at least one other test.
Serial testing algorithm (Figures 1) must be used by the HTC service provider as per the current National Algorithm. (see Annex: the current algorithm)

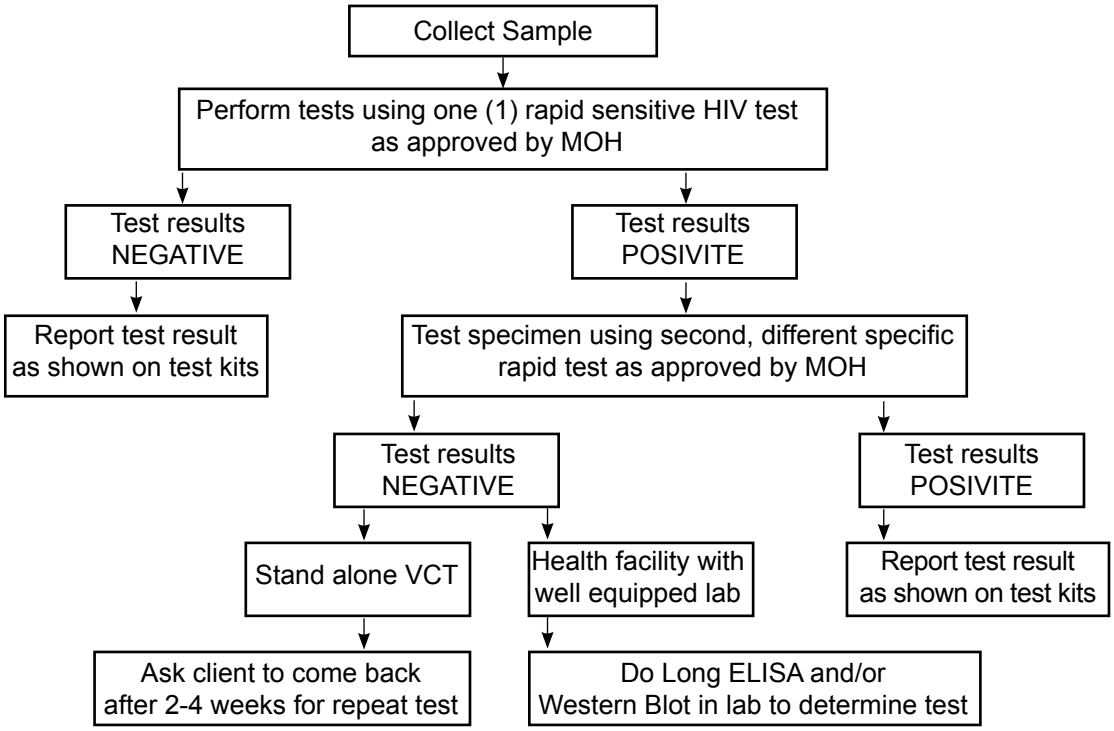


Figure 1 Serial algorithm for rapid HIV testing

In the event of discrepant test results, a nationally approved tie-breaker kit may be used to determine the client's HIV status. However, recent evidence on the relatively high prevalence of acute HIV infection (AHI) in persons with discrepant rapid test results (Wawer, et al.) suggests it may be most appropriate to advise these persons that their true HIV status cannot be known due to the discrepant test results, and that they should return for another test in 2-4 weeks to determine their true HIV status, or else be referred to a laboratory or other facility for p24 or RNA testing.

Persons advised to return for retesting in 2-4 weeks or referred to a laboratory should be counselled that they may be HIV positive or HIV negative, and that they should use strict preventive measures to protect themselves and those around them from HIV acquisition or transmission

Post-Test Session

Emphasis in these guidelines is being placed on post test counselling. After the HIV test is complete, the HTC service provider must offer post-test counselling to the client or patient based on the results. Risk reduction information and emotional support should be provided at this time based on the individual's personal risk factors, and referrals to appropriate follow-up services should be given.

Comprehensive referrals

HTC is an entry point for HIV/AIDS prevention, care, and treatment services (see Figure 2). The goal of comprehensive care is health, social and emotional wellbeing for people living with HIV/AIDS.

All HTC providers should have a directory of available HIV/AIDS services in the vicinity to which they will refer clients and patients. These referral points include community based care and support groups, as well as health facilities. For referral to be effective and standardized, HTC services should have standard referral forms.

Name-based referrals

Previously, HTC services in Kenya were anonymous. These guidelines now allow for name-based referral whether in client or provider initiated HTC. It is expected that provision of name-based referrals will facilitate referral and follow up.

Clients or patients who present with specific diseases and conditions should be referred for appropriate services, such as tuberculosis (TB) management, prevention of mother-to-child transmission services (PMCT), STI management, or comprehensive care. When appropriate, HIV positive clients and patients may also be referred for additional counselling services that are beyond the scope of the HTC service provider.

Figure 2 Comprehensive referral options for persons receiving HTC

Apart from referral to care and treatment services, further preventive interventions are recommended for both HIV positive or negative clients and patients. HIV positive clients should also be offered care and treatment services for the primary illness. As much as possible, services should be provided in the same place where the HIV test is given, so as to reduce loss to follow up (see Chapter 8). If these care and treatment services are not available close to the HTC services, other innovative efforts should be employed to facilitate referral. Client/patient escort has been used successfully in some places.

The following post-test services should be made available to HIV positive adult clients or patients, either by referral or direct provision of services

- HIV literacy and psychosocial support
- Clinical assessment including WHO staging
- Management of common opportunistic infections (OIs)
- Provision of cotrimoxazole prophylaxis
- Antiretroviral treatment
- Prevention with Positives interventions
- Provision of condoms
- PMTCT including family planning and infant feeding
- TB screening and referral
- Malaria prevention and treatment
- STI management
- Palliative care and symptom management
- Safe drinking water interventions
- Nutritional advice and support when necessary

(WHO Guidance: Core Package of evidence-based care and prevention interventions for HIV infected persons)

For all the services listed above, protocols will be developed by the MOH to specifically address the needs of HIV discordant couples and concordant HIV positive couples, as well as other groups with special needs as they arise.
The following services should be offered to HIV negative adult clients or patients, either by referral or direct provision of services:

- Prevention counseling
- Partner testing and disclosure
- Emotional support
- Referral to additional prevention services as needed e.g Male circumcision
- Needle exchange for injecting drug users (IDUs)
- Condoms education and distribution
- Post-exposure prophylaxis (PEP)

Other topics that may be discussed during the post-test session for either HIV positive or HIV negative clients, depending on their needs and the setting, include:

- Supported disclosure
- Family member testing
- Prevention with positives
- Maternal and child health services
- Family planning services

While the services above should be provided to clients and patients as they receive HTC services, additional effort should be made to promote wide acceptance for people living with HIV/AIDS.

Chapter 6
Core Principles of HIV Testing and Counselling

Consistent international policy and technical standards, the Ministry of Health (MOH) emphasize that all HTC services Kenya should be conducted with the best interests of the clients or patient. HTC should never be coercive or mandatory. Three core principles—consent, confidentiality, and counselling—otherwise known as the '3Cs', are central to HTC in Kenya. These fundamental principles are described in more detail below:

Core principles of HTC:
- Persons receiving HTC must give informed consent, therefore HIV testing should be based on sufficient, accurate information, and is voluntary.
- HTC services are confidential, meaning the anything that is discussed between the HTC provider and client or patient will not be disclosed to third parties. There are exceptions to this rule as described in Chapter 7.
- HIV testing must be accompanied by pre-test information and post-test counselling, including referrals to appropriate services.

Consent

Generally, all persons receiving an HIV test must give informed consent prior to being tested. The rules guiding consent are derived from the HIV and AIDS Prevention and Control Act (2006), which states that "no person shall be tested without their consent". This legislation provides for those who are not able to give consent. In these unique cases, HTC providers are allowed to test without consent.

Consent can either be written or verbal, and the HTC should provide adequate information to clients for proper decision making. Consent should be voluntary and not coercive. Children may be tested with the consent of a parent or guardian, or may give their own if they are symptomatic, pregnant, married, a parent, or engaged in behaviour that puts them at risk of contracting HIV.

A person with a disability that prevents them from giving consent may be tested with the consent of the guardian, parent, partner or family of the person being tested, or other caretaker.

The only circumstances where consent for an HIV test is not a requirement are: 1) when a person is required to be tested for HIV under the provisions of a written law; and 2) when a person is unconscious and unable to give consent, and the test is medically necessary for a clinical diagnosis.

Under no circumstances may persons be required to have an HIV test for purposes of employment, marriage, education, travel, or for the provision of health care, insurance cover, or any other service.

Confidentiality

Confidentiality in the context of HTC refers to the privacy of the interaction between the client and the HTC provider. Client information may not be shared except with the consent of the client. Previously, client records were coded (anonymous) but names can now be used in client or patient records, in order to facilitate referral to other services.

As mentioned in Chapter 8, these guidelines will seek to better integrate HTC with other health and social services. The standards of confidentiality will therefore be in keeping with the spirit of integration. Confidentiality must be maintained when conducting all types of HIV testing. All HTC sites must ensure that the policies, training and infrastructure needed to uphold patient confidentiality and to protect patient privacy are in place.

In the past anonymous testing was preferred by clients with the belief that this ensured confidentiality. However recent evidence suggests that changing from anonymous to confidential HTC does not negatively affect uptake of HTC services. In fact, the shift from anonymous to confidential HTC may improve the service provider's ability to provide enhanced care to the client or patient (Baryarama, 2005). In such situations the health care provider must ensure confidentiality of the test results as they provide confidential referrals for the appropriate care services.

Counselling

Counselling refers to the confidential interaction between an HTC provider and a client or patient. This interaction will make the client or patient have better understanding of their condition and the best way of managing it. It is the role of the provider to provide the client or patient with adequate information in a conducive environment, that facilitates this interaction.

Everyone who wishes to have an HIV test is entitled to adequate information before and after the test. The length and scope of the counselling session will depend on the specific needs of the individual client. In this era of increased awareness about HIV, pre-test counselling can be shortened, with more emphasis being placed on post-test counselling. In all situations, HTC service providers need to sensitively respond to individual, couple or family counseling needs.

A personalized risk reduction assessment, which consists of a discussion between the HTC service provider and the client or patient about their partners' HIV status and specific behaviours that may put the client or patient at risk for transmitting or acquiring HIV, is a critical component of all HTC sessions. For all types of HTC, discussion of personalized risk reduction plans for individuals and couples should occur during post-test counselling when HIV test results are known. In this way the detailed risk assessment may be tailored to meet the specific needs of the client based on the test results.

Everyone who wishes to have an HIV test is entitled to adequate information before and after the test. The length and scope of the counselling session will depend on the specific needs of the individual client. In this era of increased awareness about HIV, pre-test counselling can be shortened, with more emphasis being placed on post-test counselling. In all situations, HTC service providers

need to sensitively respond to individual, couple or family counseling needs.

Groups may be gathered for the initial pre-test session that provides basic information to HTC clients or patients; however, individuals or couples should still have the opportunity to ask questions or share personal information with the HTC service provider in private before the test is conducted.

Chapter 7
Disclosure

Disclosure is the process of informing patients or clients about their HIV test results. This may be to the primary client or to an approved third party. As described below, a person's HIV test results may only be disclosed to a third party if the person being tested gives formal consent, or in specific circumstances as outlined below. Counsellor-assisted disclosure, in which the counsellor is present during the disclosure process and assists in clarifying HIV-related information, is a new and effective approach for supporting disclosure, particularly in challenging situations such as discordant couples and paediatric disclosure.

Disclosure to the Client or Patient

The results of a person's HIV test are confidential, and should be offered to the person being tested as soon as they are available, followed by post-test counseling as indicated in Chapter 5. If the person being tested has given consent for the HIV test, the HTC service provider should not withhold that person's HIV test results from them for any reason. In some instances, a person may refuse to receive their own HIV test results; however, in the interest of HIV prevention, this should not be advocated. Clients and patients should be prepared and supported to receive their HIV test results during the pre-test session as indicated in Chapter 5.

Youth and adolescents who provide their own consent for HIV testing should be offered their test results as indicated above.

Where HIV testing is required by a court of law, the person being tested should be given basic information about the test, and should have access to the results in an appropriate, confidential, and supportive setting.

Disclosure to a child

Children should be informed of their HIV status in an appropriate and supportive environment. Parents, guardians, and caretakers must use their own judgment to determine when a child can safely receive knowledge of their HIV status. HTC providers, parents, guardians, and caretakers must be sensitive to the needs and emotional capacity of the child and should attempt to introduce age-appropriate information about HIV as early as possible, so as to reduce stigma associated with the disease.

HTC service providers should support parents, guardians, and caretakers in decisions about age of appropriate disclosure to a child, and should offer to assist with disclosure in case difficult questions arise. HTC service providers should also be available to provide ongoing support and counselling for the family as necessary.

Disclosure to youth and adolescents

Youth and adolescents should be offered their HIV test results in consultation with their parents, guardians, or caretakers except for emancipated minors.

Post-test counselling should be offered to both parties together, after which the youth or adolescent should be offered individual post-test counselling by the HTC service provider, as indicated in Chapter 5.

If they are not already receiving care and treatment for their HIV infection, children and youth who test HIV positive should be referred to a health care facility for follow-up care and possible treatment.

Disclosure to a Third Party

As mentioned above, disclosure of a person's HIV status to anyone other than the person being tested may only occur with written consent of the person tested, or in specific circumstances, such as when the person tested is not able to give consent on their own.

If an HIV test is ordered by a court of law, the result of the HIV test should be provided to the person being tested as mentioned in Chapter 7, as well as the person or body legally entitled to receive the test results, such as the court.

In the case of disclosure of a child's HIV status to persons outside of the child's family, parents, guardians, and caretakers, together with the child, must use their own judgement to determine when it is appropriate to disclose the child's status. HTC providers should provide support and ongoing counselling when persons are making these decisions, and should be available to assist with disclosure or general HIV education in schools and other settings, in case there are questions the parent, guardian, or caretaker is not able to answer.

Disclosure to a sexual partner or other person at risk

HTC workers should encourage and support clients and patients to disclose their HIV status to their sexual partners and other persons are at risk. If efforts to encourage the client or patient to disclose their HIV status fail, and the client or patient is placing a sexual partner or other person at risk, a medical practitioner may disclose someone's HIV status to their sexual partner or other person at risk. However, persons must be given a reasonable opportunity to disclose their HIV status to sexual partners or other persons at risk on their own, before a medical practitioner intervenes.

Health workers and other HTC providers should make every effort to encourage disclosure. This is critical for prevention HIV transmission and for improving social support for people living with HIV/AIDS. Disclosure of an infectious disease is necessary for public health and is enshrined in the laws and policies of the country, such as the Public Health Act and the HIV and AIDS Prevention and Control Act.

Refusal to notify a sexual partner that one is HIV positive is an infringement on the right to health and wellbeing of the sexual partner. It is clear that there is a high rate of HIV discordance among couples in Kenya, and in many cases the partner of an HIV positive person can remain uninfected for quite a long time.

As indicated in Chapter 5, all HIV post-test counselling should include strong efforts to support HIV positive persons to return with their sexual partners so that they may also be tested, and in order to facilitate the disclosure process.

This may be done through couples HTC, where both partners learn their results together in the HTC setting. Disclosure may also be done, as indicated, in a medical setting where one partner is being attended medically and the opportunity can be used to offer them HIV testing together. Settings and methods of disclosure should take into account possible risks of violence and social instability, and counsellors should be prepared to address the unique challenges that may arise during couples HTC.

Disclosure to Health Care Workers

A health care worker who provides an HIV test or other related assessments for a patient is permitted to disclose information concerning the results of those tests to other health care workers who are directly involved in the management of that patient. Personal information that has been shared with the initial health care worker that is not relevant to the diagnosis, care, or treatment of that patient should be treated as confidential information. This means it may not be shared with other health care workers, unless it becomes relevant to the patient's medical diagnosis, care, or treatment.

Disclosure on death certificates

The law requires proper completion of death certificates with accurate reporting of reason for death. AIDS related deaths should be truthfully and accurately reported on these statutory documents.

Chapter 8
Integration of Services

Due to the potential benefits, it is highly recommended that all HTC providers incorporate other health services into the primary HTC service and vice versa. This relationship will lead to early detection of HIV/AIDS and better health care for people living with HIV/AIDS. Some services that may benefit from this dual incorporation strategy include:

- Family Planning
- Tuberculosis services
- PMTCT / Antenatal care
- STI testing and treatment
- Antiretroviral therapy clinics
- Male Circumcision
- Post rape care

Integration of services may require new staff to be hired to provide these additional services directly at the site, as opposed to referring clients and patients elsewhere (i.e. health care workers, HIV test counsellors).

Family Planning

Empowering women and men with knowledge of their HIV status may increase their ability to make informed decisions about their future, including family planning. The integration of family planning and reproductive health services into HTC presents an opportunity for persons receiving HTC to make decisions regarding the number, spacing, and timing of pregnancies, and the use of contraceptive methods (UNAIDS and WHO, 2007). Evidence has also shown increased contraceptive use among women receiving HIV positive test results, who were offered HIV care and access to family planning after learning their HIV status (Hoffman, et al). Services that specifically provide family planning or other reproductive health services are encouraged to offer HTC as part of their routine standard of care as well.

Maternal and Child Health Care

As stated in the National Guidelines for the Prevention of Mother-to-Child HIV/AIDS Transmission (PMCT), all pregnant women and their sexual partner(s) should be encouraged to learn their HIV status. HIV testing of pregnant women should occur before delivery, however if it is not done before delivery it may be offered during delivery or as a routine standard of care immediately following delivery. Knowledge of HIV status is necessary both for the health care worker to make appropriate recommendations regarding health care, and for the pregnant woman and her partner(s) to make appropriate decisions about their health. Therefore, HTC should be integrated into antenatal and maternal and child health care (ANC and MCH, respectively).

Tuberculosis Services

According to the National Tuberculosis and Leprosy Guidelines, all confirmed TB patients and those who are being who have TB like symptoms and are

being evaluated for TB (sometimes referred to as TB suspects) should receive an HIV test. Likewise, all persons receiving HIV positive test results should be screened for TB and referred for appropriate follow-up care. It is the goal of TB-HIV collaborative activities to integrate HIV/AIDS activities into the core TB functions, and also to integrate TB activities into core HIV/AIDS functions like HTC. It is recommended that HTC service providers be trained to provide initial TB screening, and TB clinic personnel be trained to provide HTC.

> Failure to screen for TB in an HIV-infected individual is sub-standard care and is not acceptable.

STI Management

Due to the strong correlation between HIV and sexually transmitted infections (STIs), incorporating STI services into HTC and offering HTC at STI clinics is highly recommended. All persons who test positive for an STI should be offered an HIV test, and persons who receive HTC may be offered STI treatment or referred for STI services if they are not available on site.

Male Circumcision

The Ministry of Health has published policy guidance on male circumcision and HIV prevention. As it relates to HTC, it is important to note that when male circumcision (MC) is implemented it should be coupled with HTC. HIV testing should however not be a precondition to access male circumcision services. Likewise, male clients receiving HIV negative test results from an HTC service delivery point should have the benefits of male circumcision explained to them, and should be referred to an appropriate MC site if they wish to undergo the procedure.

Condoms

HTC service providers should promote use of condoms and should ensure that they have enough in stock for clients who may need them. They should also facilitate referral for other reproductive health services. Condom distribution should be coupled with demonstration of the proper use of a condom, and HTC service providers should encourage clients and patients to ask questions regarding their use.

Other Health Services

HIV testing and counselling should be offered as a routine standard of care in all health facilities, and should be integrated into all medical, surgical and paediatric services. Likewise, an HTC service provider may choose to incorporate other health services into their repertoire of service provision in order to meet the needs of their clients.

Failure to screen for TB in an HIV-infected individual is sub-standard care and is not acceptable.

Chapter 9
Personnel

The critical role of human resources in the provision of high quality HTC can not be overemphasized. These guidelines have clearly described the different settings where HTC services are provided. Despite the few differences in approach and emphasis, the core principles and values of HTC must be maintained in all HTC services. For this to be achieved there will be standardized and coordinated training, mentorship and supervision. HTC providers will also be supported and exposed to the changing disease trends and new testing technologies. This will be done through pre and in service training and also through continuous professional development.

Who Can Provide HTC Services?

HTC services are implemented by HTC providers who include health workers, professional or lay counsellors. Some of the cadres of health workers who provide HTC include doctors, clinical officers, nurses and laboratory staff. Provide majority of these health workers provide HTC as part of their regular duties, but counsellors are mostly full-time.

It is desirable that health care workers provide HTC services in health facilities, but in some health facilities the assistance of well trained and certified lay counsellors may be required. All HTC service providers must receive adequate training, mentorship and supervision, and must adhere to the required policies and standards outlined in these guidelines. HTC service providers shall be provided with national level certification after attainment of the required HTC training. Standards for training shall be determined by the Ministry of Health (NASCOP) and are outlined in Chapter14.

Qualified laboratory technicians and technologists are required in performing laboratory machine-based HIV tests such as standard enzyme-linked immunosorbent assays (ELISA or EIA), polymerase chain reaction (PCR), western blot (WB), or viral culture. Laboratory personnel may require further training and supervision to conduct such tests, as well as the care and maintenance of the equipment. This training should be widely available to laboratory professionals and may be certified by the Kenya Medical Training College (KMTC), the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), National Public Health Laboratories and Universities.

What Training do they Require?

One national HTC training curriculum will be adopted immediately after the completion of these guidelines. This umbrella document will incorporate all the HTC approaches. It will be modular in structure, with core modules and other program specific modules that can be incorporated as necessary.

It is recommended that all training institutions incorporate HTC into pre-service curricula. Further, all employers of health workers should provide more training and support to enable the provision of the highest quality HTC services in Kenya. These short courses are geared towards updating HTC workers on areas such as new policies, procedures or technologies.

There are other categories of workers who will support the HTC service providers and services. These may include programme managers and administrative staff, data personnel, community mobilizers, and others that may be required from time to time to support the HTC programme at different levels.

How are HTC Providers Certified?

For one to be trained as an HTC provider, one needs to have the minimum qualification of a certificate level training in social sciences, health services or other related area. It is however desirable that in the near future this standard will be raised to a diploma level. Training programs for health care workers are encouraged to integrate HTC training into their pre-service curricula In order to receive certification to provide HTC in Kenya, HTC service providers must receive appropriate training approved by Ministry of Health (MOH)/NASCOP.

How are HTC Providers be Supervised and Supported?

Professional growth for HTC service providers shall be monitored through a Continuous Professional Development (CPD) scheme in line with the relevant professional body. The Ministry of Health will encourage professional bodies to include HTC as part of the minimum requirements for annual licensure. Mentorship for providers shall be facilitated through a comprehensive capacity building package that will be developed shortly after the completion of these guidelines.

It is recognized that HTC can be challenging not just for the client, but also for the service provider, and appropriate support services must be in place for HTC service providers. A number of steps may be taken to prevent burn out and to care for the care givers. These include support supervision by senior counsellors, refresher trainings and group meetings. Such measures also act to ensure that the quality of services is maintained.

Tools will be developed and used to regularly assess and monitor the quality of counselling provided to clients and patients. The HTC site manager shall be responsible for ensuring the quality of counselling and testing services. Care for the care givers should also include regular supervision and access to continuous professional development.

Management of HTC Services

In order to ensure adequate planning, staffing deployment and management, monitoring and evaluation of services and quality, every HTC facility must have personnel who are responsible for HTC services, and tasks should be clearly outlined and understood by all personnel.

Chapter 10
HIV Testing and Counselling Support Services

Logistics

Procurement

HTC commodities are centrally procured in accordance with existing Ministry of Health (MOH) procurement regulations, and in consultation with the relevant programs. Distribution of these commodities is also coordinated from the central level, but the district level distributes to the sites.

Test kits and other HTC commodities should be stored and managed properly to ensure high quality of HIV testing. Recommendations for the storage of test kits will be further outlined in the operational guidelines that will follow this document.

Commodities

All commodities procured for HTC in Kenya shall be approved and registered for use by the Ministry of Health. Standards for HIV test kits defining the appropriate specificity and sensitivity levels shall be defined by a committee of experts appointed by the MOH. Only HIV test kits that are approved by this committee and registered with the MOH shall be utilized for HTC in Kenya.

Supply chain management

The Kenya Medical Supplies Agency (KEMSA) is the agency primarily responsible for procurement and distribution of HIV test kits in Kenya. KEMSA shall distribute test kits to the district level, which is then responsible for distributing the test kits to HTC sites. In addition, KEMSA will maintain a stock of rapid HIV test kits for back-up distribution when needed. An annual audit of the supply chain management systems for HIV kits will be undertaken to prevent stock-outs.

Reports on consumption of commodities will coordinated by Ministry of Health personnel at all levels, in collaboration with implementing partners.

Laboratory

The laboratory plays an important role in the provision of HIV testing and counselling in Kenya. The laboratory service has been intimately involved in the HTC programme since its inception, especially in the development of training materials and the adoption of new testing technologies. This complementary relationship will continue to be enhanced in the future so that HTC services in Kenya are of the highest quality. The role of the laboratory service in supporting HTC in Kenya is outlined below:

Capacity building

Training

Laboratory personnel will support training of HTC service providers, especially in the testing component of HTC. The support that the laboratory services will

provide includes:
- Curriculum development
- Training of personnel,
- Certification of competency at the end of training,
- The development of standard operating procedures (SOPs) and
- Ensuring safety precautions are upheld

Mentorship

Laboratory personnel will participate in mentorship for new HTC service providers. This involves supporting staff that are newly trained in HTC to commence and maintain high standards in the delivery of HTC.

Adoption of new technologies

The laboratory service will provide leadership in the adoption of new HIV testing technologies as they become available. They will analyze current literature associated with new technologies, assess their efficacy in Kenya, and provide recommendations for their use. Once the process of evaluating new technologies is finalized, the laboratory will conduct training with both trainers and service providers. Some examples of new technologies include the use of oral fluid testing and urine testing. Oral testing for HIV has been determined to be acceptable for use in Kenya based on a 2003 acceptability study, and oral test kits have been introduced for HTC in some parts of the country.

Support supervision

Laboratory personnel are part of a team that provides support supervision for HTC services in Kenya. The team has different areas of expertise, and is expected to participate in the accreditation of HTC services, support supervision and quality assurance procedures. Laboratory personnel will also work to strengthen the testing component of HTC services.

Regulation of HIV test kits

Evaluation of HIV test kits

The laboratory service evaluates and approves all HIV test kits for use in Kenya. This is done by a committee of national experts appointed by the MOH. Before approval, the test kits are subject to a rigorous process of evaluation in national level laboratories. No test kit will be allowed for use in Kenya unless it has been approved by this committee.

Post-market surveillance

The laboratory service also carries out a periodic random assessment of the HIV test kits that are used in the country. This ensures that test kits being used in the field are of the highest quality.

Validation of testing

Test kit validation will be conducted by either re-testing a proportion of HIV tests, by the use of proficiency panels, or by both methods performed in tandem. In the past, re-testing HIV tests has been the preferred method of test kit validation, with HIV positive samples and 10% of HIV-negative samples re-tested using dried blood spots (DBS). It is recommended that both methods be used where

the setting and the resources permit.

Infection control

Sharps should be disposed of in designated sharps containers. Used test kits and other contaminated waste should be placed in separate closed containers and incinerated, or should be disposed of according to bio-safety guidelines. HTC providers and support staff involved in handling and disposing hazardous waste should be adequately trained on infection prevention procedures

CHAPTER 11
Promotional Activities

Promotional activities are an essential component of HTC services in Kenya. Some of the common examples of promotional HTC activities include: mass HIV testing campaigns (such as the HIV testing days), media campaigns, targeted community mobilization, and the development and distribution of information, education, and communication (IEC) materials such as pamphlets and posters.

Promotional activities are necessary for mobilizing communities to understand and access HTC services, and for ensuring they have access to accurate information regarding HIV prevention, care and treatment, including HTC. Currently 33% of Kenyans know their HIV status (KAIS 2007). In order to attain Universal Access (80%) by 2010 promotional activities must be utilized not only to raise awareness, but to enhance uptake of services.

Promotional strategies should be reviewed and updated regularly so that they can adequately reflect current scientific and technological advances, national, regional, and site-specific trends, and strategic plans. Promotional activities may target the general population as a whole, or specific sub-populations, and materials should be adapted with the target population in mind.

> All promotional HTC services should highlight the need for couple HTC, given the high rate of discordance in Kenya

Other important aspects include scaling up testing of children and other high risk groups.

The Ministry of Health, working with stakeholders will develop a comprehensive HTC communication strategy. This will be used to guide the promotional activities.

Mass HIV Testing and Counselling Campaigns

An HTC campaign aims at providing HTC to a large number of people over a short duration. This is achieved by intensifying the different HTC approaches, more so the community based interventions like mobile and outreach. Apart from increasing uptake of HTC services, campaigns also improve the visibility of the program thus enhancing knowledge and attitude about HTC. In HTC campaigns, some of the principles and procedures are modified, so as to achieve the targets. Caution is taken not to compromise quality and standards.

Some characteristics of a mass campaign include:

- Intensified community and mass mobilization
- May conduct more group sessions, because you are testing more people in one day
- Need to add more temporary outreach sites to augment the existing static Sites
- All promotional HTC services should highlight the need for couple HTC, given

the high rate of discordance in Kenya
- May be required to work longer, more flexible hours to provide service during this campaign
- Should target specific groups that are not usually reached by HTC

The United Nations General Assembly (UNGASS) has endorsed international HIV testing day as a means of increasing access to and awareness of HTC services.

In response, the Government of Kenya has incorporated National HIV testing and counselling events into its calendar of events. These HTC events may take place over a one day, week, month or even longer. They can also take place at a lower level, such as in one government ministry or department, in one given district or division, in an institution or among a specific community

Quality assurance measures should be adhered to in HTC campaigns. They should be designed to minimize the impact of high client flow, long working hours, limited space and unfamiliar facilities and surrounds. Mass testing should provide the same high standard and levels of accountability as HTC services offered in any other setting.

Mass Media Campaigns

Mass media campaigns are meant to communicate key messages about HIV testing and counselling to an entire population or to specific segments of it.

Mass media campaigns to promote HTC may include billboards, television or radio campaigns. They may also use newspapers, depending on the readership.

These campaigns should provide accurate, approved messages, which should be culturally sensitive. Furthermore, the campaigns should include key messages that meet professional and ethical standards.

The messages, graphics, and logos put forth in all mass media campaigns should be approved by the Ministry of Health (NASCOP).

Community Mobilization

Communities may be mobilized to learn their HIV status via peer educators and community health workers and by engaging leaders and influential community agents to publicly advocate for HTC.

Community mobilization is part of all community based HTC strategies, and in some cases might be appropriate for health-facility based HTC as well.

All HTC service providers should be regularly involved in community mobilization activities within their catchment area. These are necessary to promote HTC services and to keep the community aware of the available services.

Information, Education and Communication Materials

The production and distribution of educational leaflets, pamphlets and posters are beneficial for people who want to carry information about HTC to share with family members or friends. This could be especially effective at health facilities

where clients or patients may have significant time in a waiting room and could benefit from visual educational materials.

Information, education, and communication (IEC) materials addressing all elements of the HTC service package should be made available at all HTC service provision sites.

IEC materials should be developed in multiple languages and with appropriate illustrations and graphics.

Chapter 12
Quality Assurance

In 2005 the National Quality Assurance Team (NQAT) produced the National Quality Assurance (QA) Strategy for Voluntary Counselling and Testing (VCT) to ensure that "a consistent and coherent approach on how to monitor, assess and improve quality can be agreed, promoted and adhered to by all VCT service providers and managers" (NASCOP, National Quality Assurance Strategy for VCT).

While the QA guidelines outlined in the National Strategy were specifically directed at VCT, it must be noted that QA 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 QA systems must be in place at all levels, including testing, counselling, logistics, and data management. All HTC service providers and managers must have a systematic and planned approach to monitor, assess and improve the quality of their services on a continuous basis.

Why are Quality Assurance Systems Important?

- They are essential for coherent and functioning service delivery at all levels
- They help ensure that the needs and expectations of clients and communities are being met
- They focus on how we work, and how we can work better
- They employ standards to ensure an acceptable level of quality
- They emphasize the use of data to assess whether services are delivered in accordance with set standards, and allow for improved reporting mechanisms
- They encourage a multidisciplinary team approach to problem solving and quality improvement

QA strategies operate at both the national and regional levels, and are carried out at the facility and individual levels. At the national level, the NQAT is led by NASCOP and is tasked with formulating and updating QA strategies in Kenya. This includes addressing human resource and logistics issues, registering, licensing, and accrediting HTC services and approving training institutions and curricula.

At the regional level, QA teams are responsible for overseeing the implementation of QA strategies. HTC facilities should have their own QA systems in place in accordance with national and regional guidance. This means that in every HTC facility it must be very clear which person or persons are responsible for monitoring and improving the quality of HTC services at the service delivery level. Furthermore, individual HTC service providers are also responsible for ensuring delivery of high quality HTC services to their clients and communities, according to the defined standards.

NASCOP working with other stakeholders is upgrading the existing QA strategies to suit the broader HTC program, including both client and provider-initiated HTC. Whenever possible, QA for HTC services in health facilities should be integrated into other ongoing QA activities at the health facility.

Testing Quality Assurance

Testing QA begins at the national level with the evaluation, approval, and registration of HIV test kits by the National Blood Safety Committee. In an effort to provide HIV testing in accordance with national and international standards, and to avoid duplication of efforts, the Blood Safety Committee will consult with international HIV test kit approval lists and evaluations performed by internationally accredited laboratories in the region when deciding to approve and register HIV test kits for use in the country. Only test kits are approved and registered by the Blood Safety Committee, they may be used for HIV testing in Kenya.

Another element of QA systems for HIV testing includes the development of, and adherence to, standard operating procedures (SOPs). Every HTC facility must have SOPs available on site, and HTC service providers must read, understand and follow these SOPs. SOPs should be updated on a regular basis to reflect the most current testing procedures, and informational inserts found inside HIV test kits should always be consulted for changes in test kit protocols.

Rapid testing algorithms have been described in detail in Chapter 5. Strict adherence to nationally approved HIV testing algorithms is an important QA measure. If a serial testing algorithm is followed, tests must be used in the order specified by NASCOP or the NHRL so as not to give out false results, and only tests specified for use in a parallel testing algorithm may be used with this approach.

Another important aspect of QA for HIV testing is **reporting and confidentiality**. Results of all HIV tests should be systematically recorded, and records books must be kept confidential and in a lockable storage location that is only accessible to HTC providers and health care providers when necessary.

Regular, ongoing **supervision** of HIV testing procedures and personnel is also critical for ensuring quality service. The NQAT laboratory supervision tool (National QA Strategy for VCT) is used by regional supervisors to assess testing procedures in VCT sites, and may also be adapted for the health care facility and other HTC settings.

Other **external quality assessment (EQA)** measures include the collection of dried blood spots for all persons with discrepant test results and 5-10% of all other HTC clients and patients. These dried blood spots, collected and stored on filter paper, are sent to a regional reference laboratory for validation using ELISA and rapid tests. After validation of the test results, the regional reference laboratory sends feedback regarding the EQA results to the persons responsible for QA at the HTC facility, who then make adjustments as necessary to improve the quality of HIV testing at their facility.

Proficiency testing has also been implemented as a form of EQA by the NHRL. The NHRL creates blood or serum samples of pre-known HIV status, sends a panel of different samples to regional laboratories and HTC sites for testing, which then send the results back to the NHRL for analysis. The purpose of this method of EQA is to compare concordance between national and regional laboratories

and HTC facilities. Feedback is sent to the HTC facility on whether their results are concordant with the NHRL, and adjustments are made as necessary to improve testing quality. At least one method of EQA must be employed by all sites performing HIV testing.

Conducting HIV testing in an **appropriate and adequately equipped physical space**, as well as **proper storage of test kits** that are not in use, will reduce the risk of mistakes or accidents when testing. This means having a clean, organized, well lit and well ventilated working space with an environmental temperature that does not exceed that required by the test kit. Every HTC facility must have available and must adhere to **procedures for the safe handling of biohazardous material.** This should include instructions on use of gloves, closed footwear, hand washing, handling and disposing of sharps, how to clean up a spill and disinfect HIV testing areas, and proper disposal of used test kits. In general, there should be no eating, drinking or smoking in the same place where HIV testing is conducted, and unauthorized persons should not be allowed in the HIV testing area. There must also be procedures in place for how to respond in the case of an accidental exposure to biohazardous material.

Counselling Quality Assurance

The counselling component of HTC provides the basis for HIV prevention, care and treatment. It prepares clients and patients to receive their test results and to make necessary adjustments. It is therefore imperative that counselling services in HTC are comprehensive and effective. The prerequisites for comprehensive and effective counselling are quality training and supervision. The two issues have been adequately addressed in the previous chapter.

The length of actual counselling sessions may vary depending on the specific needs of the client or patient (see Chapter 5 and 6). However, every HTC session should involve open, non-judgemental interaction between the HTC provider and the client(s) or patient(s) which seeks to provide emotional and social support for clients or patients. All persons providing HTC services in Kenya must be trained and certified, as outlined in Chapter 9, and should receive continuous support for ongoing training opportunities as necessary to strengthen the quality of their interactions with clients or patients.

Counselling support supervision is important for preventing 'burn out' of individual HTC service providers and maintaining high quality communications between providers and clients or patients. Supervision is an opportunity for HTC service providers to come together with other HTC service providers and at least one trained HTC supervisor to discuss and process issues that arise during HTC sessions (see Chapter 9). Supervision should be made available to HTC service providers on a regular basis. Counsellors may also wish employ the use of **selfreflection tools** or forms to monitor the quality of their own service provision over time.

HTC facilities should also regularly administer **client exit interviews** to gauge the quality of their service delivery from the client's perspective. Questions may be brief, and community members may be employed on a voluntary basis to help administer the interviews, which may address topics such as waiting time, cleanliness, counsellor attitude, and overall satisfaction with the service. Feedback from client exit interviews should be shared with HTC service providers,

and adjustments should be made to improve the quality of HTC service provision accordingly.

Observed practice is when, with the consent of the client(s) or patient(s), an HTC service provider requests to be observed – either in person or by videotaping the HTC session – by a more experienced HTC service provider or supervisor. Feedback is given directly to the HTC service provider by the observer, who should use a checklist to indicate whether the provider has followed all the necessary steps and protocol with the client(s) or patient(s). Observers should keep in mind that this is meant to be a supportive activity that HTC service providers can learn from if they receive constructive feedback.

Quality Logistics Management

Quality logistics includes realistic forecasting for HIV testing supplies (including test kits), procuring supplies in good time, maintaining adequate stocks that are not out-of-date, storing supplies properly, having strong accountability systems in place, and ensuring HIV testing supplies are delivered to HTC facilities in the right quantities and condition, and on time.

Logistics QA occurs at the national level in terms of forecasting, procurement, and distribution processes, and relies on accurate reporting and records keeping regarding the distribution, use, and storage of test kits at the regional and HTC facility level. Every HTC facility must identify a person or persons to be responsible for ensuring accurate and timely procurement of HIV testing supplies, appropriate storage of supplies including accurate stock rotation, and records keeping and reporting. Supervision for logistics QA will be provided at the regional level.

Quality Data Management

Proper data management is one of the most important elements of ensuring the provision of quality HTC services. In order to improve the quality of services that are provided, accurate measures of current performance must be maintained. This refers to data that may be collected regarding any aspect of HTC service provision, from data forms, client cards, and client and laboratory registers to stock registers and accident and incident logbooks. Quality data management requires active engagement of stakeholders at national, regional, and HTC service delivery levels.

Key elements of quality data management include: accurate recording or data collection by trained HTC service providers; timely reporting by HTC supervisors to regional and national offices; appropriate data entry at both the service delivery and regional levels; accurate and confidential data storage; and finally, data analysis and the provision of feedback to relevant stakeholders and individuals.

Standardized tools for HTC data collection and management shall be used, as described in Chapter 13. Regular data audits may be performed by NASCOP or the NQAT at the service delivery level to ensure quality data management.

Chapter 13
Monitoring and Evaluation

Monitoring and evaluation (M&E) involves data collection, analysis, interpretation and report writing at all levels of the HTC structure. This information is essential for the effective management and improvement of HTC services. Whereas monitoring involves the regular, routine assessment of ongoing activities, evaluation is episodic and examines large scale impact and achievements to answer specific management and epidemiologic questions that will guide future actions, planning, and decision making regarding HTC. Both monitoring and evaluation are critical components of Kenya's National HIV/AIDS Monitoring and Evaluation Framework (NACC, 2005).

All HTC service providers should be actively engaged in M&E processes, and are encouraged to utilize their own programme level data to improve and strengthen their operations.

Importance of Monitoring and Evaluation

Up-to-date monitoring of HTC allows for prompt identification and resolution of the challenges (and successes) of an HTC programme. M&E allows for observation of a programme's trends, which can guide priority setting and resource allocation at the local and national level. Finally, M&E data can be used to answer critical questions about Kenya's HIV epidemic in a regional, national, or international context. Scientific inquiries and surveillance documents such as the Kenya Demographic and Health Survey (KDHS) or the Kenya AIDS Indicator Survey (KAIS) also utilize data collected during standard M&E procedures.

Information from HTC service delivery points should be treated with the same level of confidentiality that all medical records are given. Only authorized officers should be permitted to handle client-level data.

Roles and Responsibilities

The National Health Management Information System (HMIS) provides a working framework for M&E of HTC programmes in Kenya. The HMIS ensures that specific indicators are collected at the service delivery level using a standard HTC data form. The HMIS also conducts a regular review of existing M&E systems to ensure that current procedures correspond with national and international priorities and the scientific and policy environments.

It is the responsibility of all HTC personnel to contribute to accurate and current record keeping, and staff should be provided with adequate internal or external training and tools to be able to provide quality management of M&E procedures.

Currently all HTC service providers collect routine data daily, which is compiled and submitted to the districts. The districts compile the facility data and submit to the National AIDS and STI Control Programme (NASCOP) for national compilation. The district also provides data to the provincial level.

HTC implementing partners who wish to use HTC data for their own purposes should seek prior approval from the Ministry of Health (MOH).

The flow of HTC data from the service delivery to the national level is depicted in Figure 3 below. A key element of the data flow chart is the provision of feedback from NASCOP to the provincial and the district levels, from provincial to district level, and the district to the service provision level.

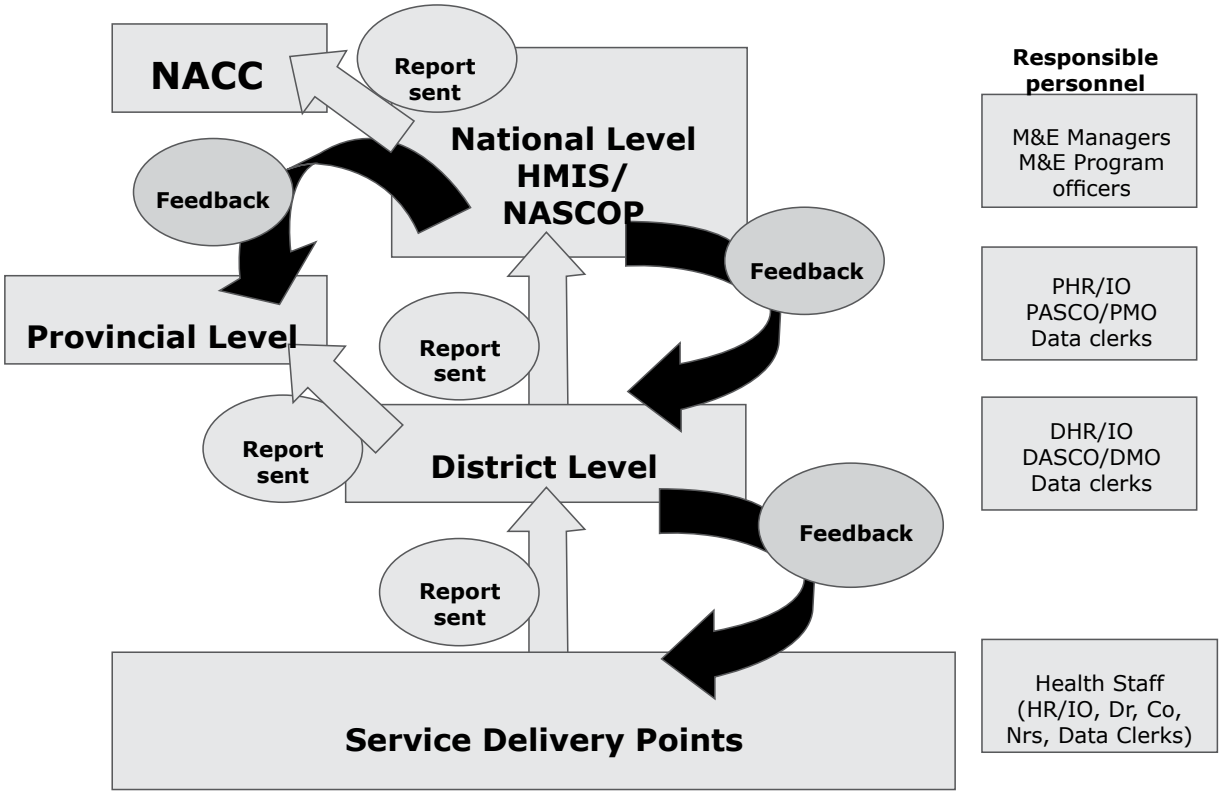


Figure 3 Flow of HTC Data

Data Management and Use

The National HIV/AIDS M&E Framework provides information on the key indicators that are required for national level HTC data collection. As these indicators are updated to correspond with national and international priorities, HTC service providers will be informed of changes to national reporting tools and requirements and provided with appropriate training.

HTC service providers should be aware of all data collection tools and reporting requirements. It is highly recommended that all HTC service providers use one standardized client form with standardized variables and harmonized data reporting tools with the same indicators.

Data should be analyzed at all levels from service delivery points to national level and utilized for programme design and future planning. Trends will be used for quality improvement and planning.

Chapter 14
Implementation Framework

National Level

The National AIDS Control Council (NACC) provides overall coordination of the multi-sectoral response to HIV and AIDS in Kenya.

The Ministry of Health (MOH), through the National AIDS and STI Control Programme (NASCOP) coordinates implementation of technical programs in Kenya, including HIV testing and counselling (HTC).

NASCOP convenes an HTC taskforce on a regular basis, with technical experts from bilateral and multilateral agencies, international and national non-governmental organisations (NGOs), and academia. The taskforce forms ad hoc committees as needed, providing technical support to NASCOP in key areas, including:

- Formulating HTC policy and establishing strategic plans
- Ensuring appropriate implementation of HTC policies
- Adequately managing HTC commodities, including test kits
- Monitoring HTC performance and assessing the quality of service delivery
- Building capacity of HTC service providers and systems
- Carrying out operations and health systems research

Provincial Level

The Provincial Medical officer (PMO) works through the Provincial Health Management Team (PHMT), with technical support from the Provincial AIDS/STI Coordinator (PASCO), to carry out the following activities at the provincial level:

- Interpreting, disseminating, and implementing HTC policy
- Coordinating and supervising HTC service performance
- Capacity building, including staff deployment, training, and certification
- Monitoring and evaluating HTC services
- Facilitating reporting from district to national level

District Level

The District Medical officer of Health (DMOH) works through the District Health Management Team (DHMT), with technical support from the District AIDS/STI Coordinator (DASCO) and in collaboration with the District Technical Committees and the Constituency AIDS Control Committees (CACC), to ensure appropriate implementation of HTC activities at the district level. The following activities are carried out at the district level:

- Managing HTC logistics and commodities
- Management and monitoring of HTC personnel
- Support supervision for HTC service providers
- Facilitating reporting from HTC sites to provincial level

This document supports the vision of the Ministry of Health Community Strategy (2006) within the National Health Sector Strategic Plan (2004). The strategy

emphasizes the importance of working within existing community structures for improving the health of these communities. As the regional coordinator of all HTC activities, the DASCO facilitates community level HTC with community health extension workers and relevant "level 2" and "level 3" facilities (Kenya MOH, Health Sector Reform Secretariat).

Both Provincial and District Medical officers (PMO and DMOH) are encouraged to hold multi-sectoral stakeholder meetings on a quarterly basis. These District Health Sector Forums (DHSFs) will provide opportunities for strategic planning, experience sharing, policy dissemination, and discussion of emerging issues in HTC. Organizations and agencies providing HTC services should be represented in these stakeholder forums.

Service Delivery Level

HIV testing and counselling services may be provided by the Government of Kenya (GOK), international and national non-governmental organizations (NGOs), community-based organizations (CBOs), and faith-based organizations (FBOs), among others. HTC may be provided in a wide range of settings as described in Chapter 3. The following activities are carried out by HTC service providers:

- Providing quality HTC services to clients and patients
- Managing site-level HTC logistics and commodities
- Monitoring HTC services
- Timely and accurate reporting to DASCO
- Mobilizing communities around HTC, raising awareness and providing HTC education
- Participating in relevant stakeholders' forums

All HTC facilities must have a clearly defined structure for site supervision, and the roles and responsibilities of HTC service providers and support staff should be clearly outlined and understood. This structure must include a facility supervisor who is responsible for the overall oversight and quality of HTC services. As part of general oversight and quality assurance, the responsibilities of the HTC facility supervisor should include strategic planning, logistics and commodities management, deployment, support supervision, data collection and monitoring, reporting, and other activities as needed.

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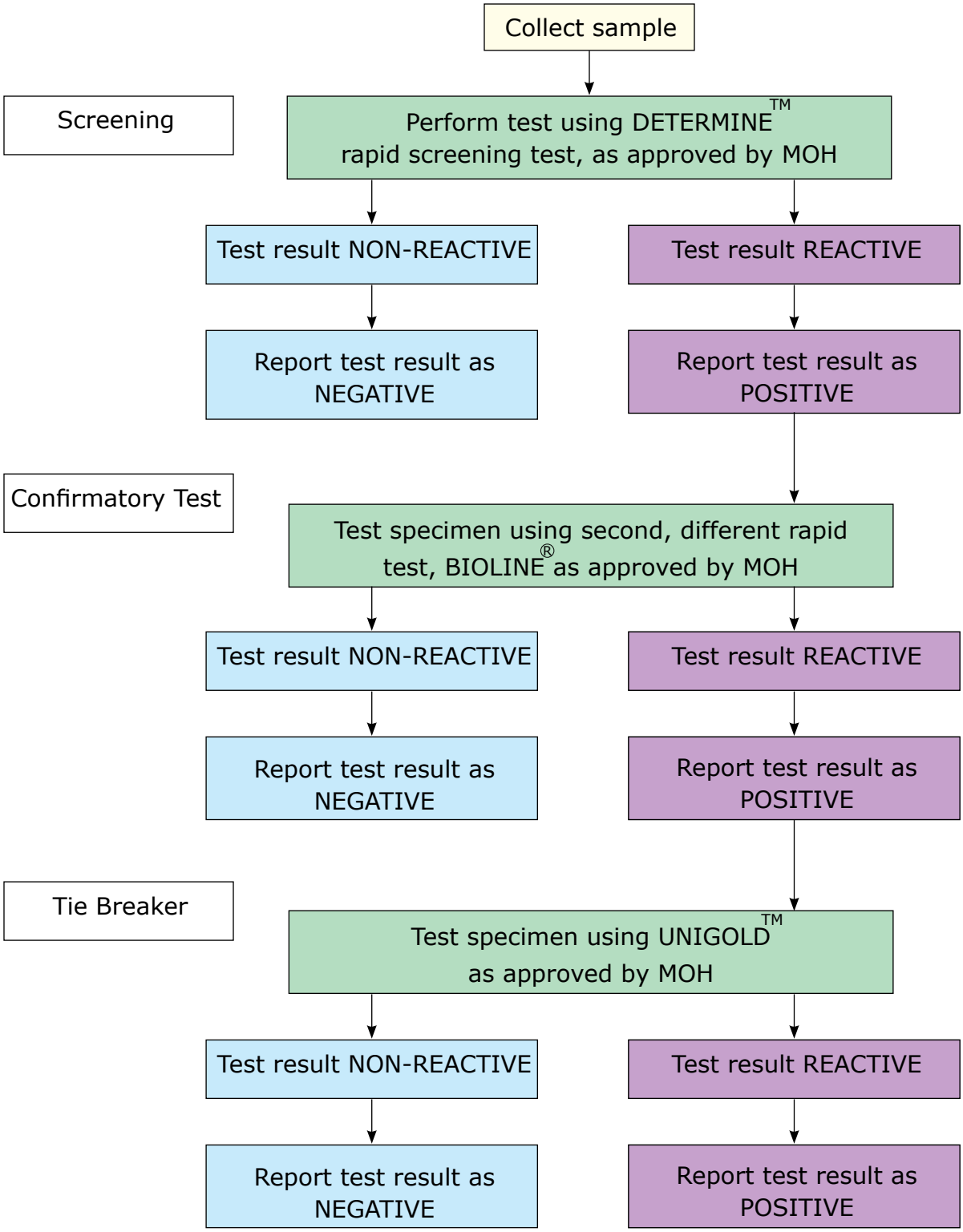
Annex

National Algorithm for HIV Testing in Kenya

23rd of September 2009
Approved Algorithm for Rapid HIV Testing
Serial Testing



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