



Ministry of Health

THE KENYA HIV TESTING SERVICES GUIDELINES



National AIDS and STI Control Programme
(NASCOP) 2015



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National AIDS and STI Control Programme (NASCOP)
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Foreword

Three decades ago, the first HIV diagnosis was made in Kenya. Since then the HIV Testing programme has evolved over time alongside the HIV epidemic. From a time when information about HIV was low, stigma was high and HIV testing could only be carried out for diagnostic purposes using complicated expensive laboratory procedures to what we currently have whereby stigma is not as much and HIV testing is acknowledged as a critical entry point to HIV prevention, care and treatment services. In addition, the use of simple point of care testing kits has resulted in many more Kenyans being aware of their HIV status as compared to the initial days of the epidemic.



The Ministry of Health through the National AIDS & STI Control Programme (NAS COP) continually works towards ensuring quality services are provided to all clients accessing health facilities for HIV related services. One of the key ways to doing this is through periodically revising guidelines so as to ensure that they are in line with the most current available body of knowledge. The publication of these guidelines is very timely, and it coincides 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. In the 90-90-90 strategy as outlined in the Kenya AIDS Strategic Framework 2014/15 – 2018/19, the first 90 relates to identification of all people living with HIV so that they can be put on life-saving antiretroviral therapy.

This document brings together updated guidance as regards to HIV testing and addresses issues that one should bear for the effective delivery of HIV Testing Services. In addition the document seeks to give clarity to the various issues that should be considered when offering HIV Testing Services to the various sub-populations. The guideline recognizes the potential of self-testing to act as catalyst in towards increasing access to and coverage of HIV testing. The pillars of effective HTS: Consent, Confidentiality, Counseling, Correct results and Connection best known as “the 5Cs of HTS” are emphasized throughout the guidelines.

It is envisioned that when implemented at all levels and emphasis is laid on targeted testing as per sub-population and provision of quality services these guidelines will provide a platform towards achieving the ambitious set targets in the KASF as regards prevention, care and treatment.

Finally, I encourage all HIV testing service providers and all managers involved in HIV programming – both at national and county levels throughout Kenya to familiarize themselves with the contents of this document and implement as per the guidance provided.

A handwritten signature in black ink, appearing to read 'Muraguri'.

Dr. Nicholas Muraguri
Director of Medical services
Ministry of Health

ACKNOWLEDGEMENT

The revision of the National Guidelines for HIV Testing Services in Kenya is the result of determined collaborative efforts from many individuals and organizations. The revision process was carried out through several phases which included extensive review of the latest literature on HIV Testing to inform the process, consensus building amongst all key stakeholders and internal and external review.



Special thanks go to Dr Nicholas Muraguri, the Director of Medical Services and Dr. Martin Sirengo, Head NASCOP who provided strategic guidance throughout the whole process. Our sincere gratitude to Dr Jackson Kioko, Head Department Preventive & Promotive Health for keeping the team on track towards completion of this very noble task. A special thank you goes to the NASCOP HTS Team: to Dr Anne Ng'ang'a (formerly at NASCOP) who led the team that initiated the revision process; and to the HIV Testing Services Manager Dr. Joyce Wamicwe who, together with Pauline Mwololo provided leadership and support towards the eventual finalization of the guidelines revision process. Much appreciation to all members of the HIV testing and counselling (HTC) technical working group who contributed significant time and efforts to editing and reviewing the guidance outlined in this document.

The efforts put in by the LVCT Health consultants led by Annrita Ikahu and Dr Michael Kiragu for their technical support during the development of this document is appreciated. We appreciate the technical input contribution provided by the external peer reviewers from CDC- HTC team, WHO team, Dr. Miriam Taegtmeier of Liverpool School of Tropical Medicine, Prince Bahati of IAVI and Dr. Nelly Mugo of KEMRI.

A special appreciation goes to the editorial team with representation from NASCOP(Dr Martin Sirengo, Dr Joyce Wamicwe, Pauline Mwololo, Dr Shobha Vakil, Betty Chepkwony) , CDC- Kenya(Patricia Oluoch), WHO-Kenya (Dr Brian Pazvakavambwa and Dr Christine Kisia), KNH(Dr David Bukusi), LVCT Health(Dr Michael Kiragu, Annrita Ikahu and Daniel Koma), and MSH/HCSM(Cecilia Muiva) for compiling all the review inputs and keeping up the momentum upto the very end.

Specific acknowledgements go to the U.S. Centers for Disease Control and Prevention (CDC), Liverpool VCT, Care and Treatment (LVCT Health) and World Health Organization (WHO) for technical and financial support during the guidelines revision process.

Finally, a full list of contributors towards this document is provided in the annex section of these guidelines. To everyone, we say a big 'Thank You!'

A handwritten signature in black ink, appearing to read 'Sirengo'.

Dr. Martin Sirengo
Head NASCOP
Ministry of Health

EXECUTIVE SUMMARY

The Kenya HIV Testing Services (HTS) guidelines, 2015 departs from the previous National guidelines for HIV Testing and Counseling (HTC) in Kenya (2008) in the following ways:

1. Inclusion of roles of the national and county governments relating to HTS policy and coordination are stipulated in line with devolved system of governance under the Constitution of Kenya, 2010.
2. Shift from HTC to HIV Testing Services (HTS) which emphasizes on 5Cs of Consent, Confidentiality, Counseling, Correct results and Connection – linkage to care.
3. Lowering of consent for HTS: Provision for HTS to be offered to all the adolescents and youth from the age of 15 years requesting for HIV testing on their own, even where there are no signs of such children being emancipated minors. This is in response to the early sexual debut among children and the growing number of youths who were born with HIV or acquired HIV during their infancy.
4. Guidance on use of self-testing to increase access to knowledge of HIV status in Kenya.
5. The use of a tie-breaker in the national HIV algorithm sequence is no longer recommended.
6. Guidance on re-testing recommendations for various sub-populations is clearly outlined. This includes retesting of all newly diagnosed PLHIV before enrolment into care and treatment.
7. Proposals for programme integration relating to tuberculosis (TB), prevention of mother to child transmission (PMTCT), sexual and reproductive health services (SRH), voluntary medical male circumcision (VMMC) and other HIV prevention services including evidence informed behavioral interventions (EBIs). This will ensure HTS clients receive other related health information and services at the HTC centers.
8. Recognizes that gender based violence (GBV) is an important driver of the HIV epidemic and recommends that HTS providers offer information on GBV and ensure linkage of survivors to appropriate services.
9. Provides a clearer definition of pathways of referral (connection) from testing to treatment for those who test HIV positive and to other post-test services for those with such needs, e.g. eMTCT, VMMC, FP, TB and other prevention interventions.
10. Considers the provisions of other related guidelines and key policy documents

DEFINITION OF TERMS

Emancipated minor

A person, who is not legally an adult but who, because he or she is married, is the mother/father of a child, or otherwise no longer dependent on the parents. S/he may not require parental permission for medical or surgical care.

HIV self Testing (HIVST)

This is a process in which an individual collects his or her specimen, performs a test and interprets the test result in private. Reactive test results must be followed by additional HIV testing services.

HIV testing services

The term HIV Testing Services (HTS) is used to indicate the full range of services that a client is offered together with HIV testing. This includes counselling (pre and post testing); linkage to appropriate HIV prevention, care and treatment services and other clinical support services; and coordination with laboratory services to support quality assurance and delivery of correct results.

Key Populations

Groups who, due to specific higher-risk behavior, are at increased risk of contracting HIV, irrespective of the epidemic type or local context. Legal, cultural and social barriers related to their behaviour increase their vulnerability to HIV. In Kenya these populations include: men who have sex with men (MSM); people who inject drugs (PWID) and sex workers (SW).

Priority Populations

Individuals who because of their circumstances are at an increased risk of HIV transmission. These include but are not limited to Fisherfolk, Truckers, Persons in confinement and Adolescent girls and young women

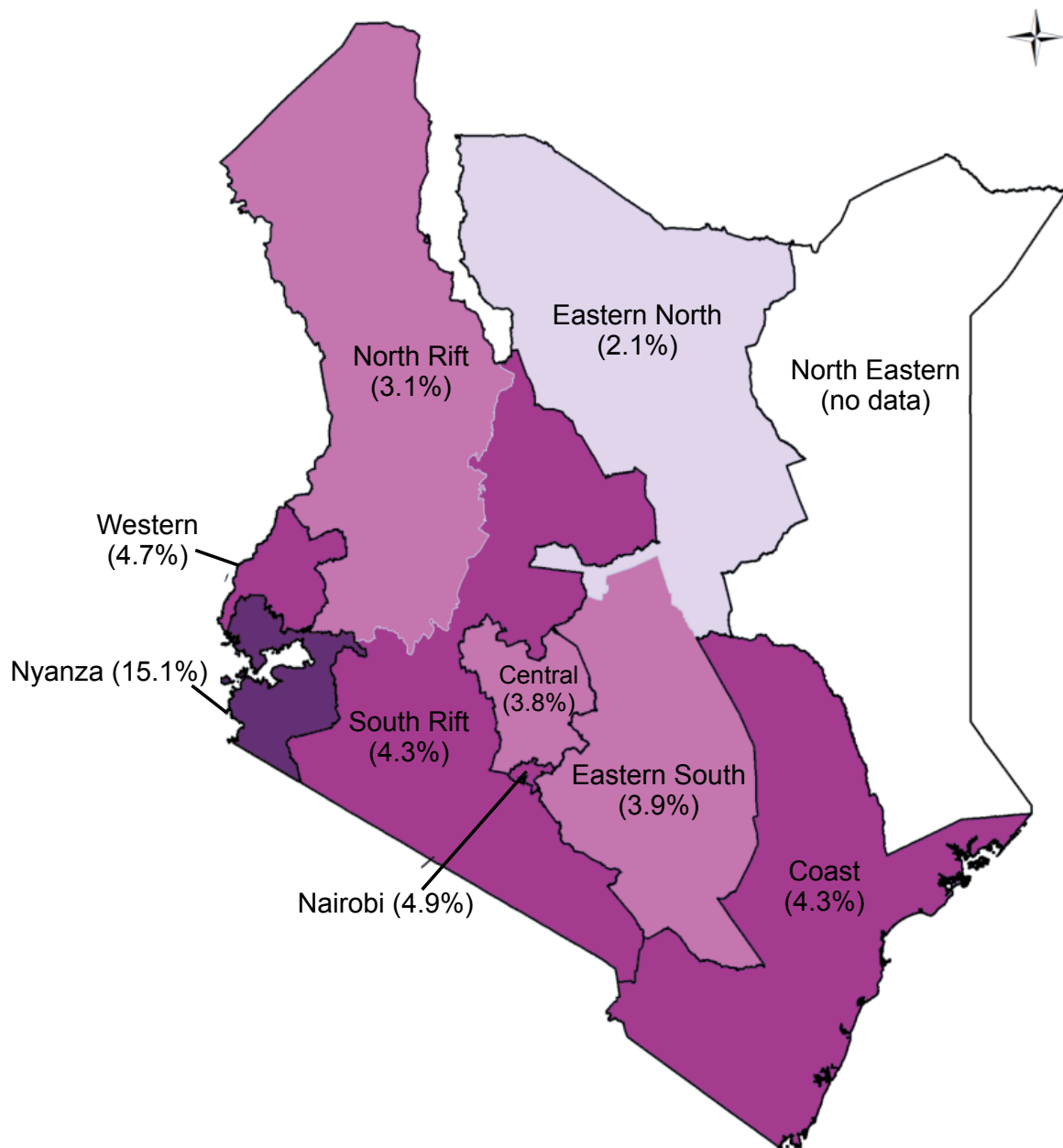
ABBREVIATIONS & ACRONYMS

ANC	Antenatal Clinic
ART	Antiretroviral therapy
DBS	Dry Blood Samples
CDC	Center of Disease Control and Prevention
CHMT	County Health Management Team
CITC	Client Initiated Testing and Counseling
CLC	County Laboratory Coordinator
CMLT	County Medical Laboratory Technologist
CPD	Continuous Professional Development
DHIS	District Health Information System
DQA	Data Quality Audit
EBIs	Evidence informed Behavioral Interventions
EID	Early Infant Diagnosis
ELISA	Enzyme Linked Immuno Sorbent Assay
eMTCT	Elimination of HIV transmission from mother to child
EQA	External Quality Assurance
F-CDRR	Facility Consumption Data Report and Request
FP	Family Planning
GBV	Gender-Based Violence
GOK	Government of Kenya
HBTC	Home Based Testing & Counseling
HBV	Hepatitis B Virus Vaccine
HIVST	HIV Self-Testing
HRIO	Health Records and Information Officer
HTC	HIV Testing and Counseling
HTS	HIV Testing Services
IEC	Information Education and Communication
IPV	Intimate Partner Violence
KAIS	Kenya AIDS Indicator Survey
KASF	Kenya AIDS Strategic Framework
KDHS	Kenya Demographic Health Survey
KEMSA	Kenya Medical Supplies Authority
KNASP	Kenya National AIDS Strategic Plan
KP	Key populations
KQMH	Kenya Quality Model of Health
LGBT	Lesbian, Gay, Bisexual and Transgender

M&E	Monitoring and Evaluation
MOH	Ministry of Health
MSM	Men who have Sex with Men
NASCOP	National AIDS and STIs Control Programme
NCHADS	The National Centre for HIV/AIDS Dermatology and STD Control
NHRL	National HIV Reference Laboratory
NPHLS	National Public Health Laboratory Service
NQIT	National Quality Improvement Teams
OJT	On-Job Training
OVC	Orphans and Vulnerable Children
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PITC	Provider Initiated Testing and Counseling
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Children Transmission
PRC	Post Rape Care
PT	Proficiency Testing
PWDs	Persons with Disability
PWID	People Who Inject Drug
QA	Quality Assurance
QC	Quality Control
QIT	Quality Improvement Teams
RRI	Rapid Results Initiative
RTKs	Rapid Test Kits
SCMLT	Sub-County Medical Laboratory Technologist
SDPs	Service Delivery Points
SOPs	Standard Operating Procedures
SRH	Sexual Reproductive Health
STI	Sexually Transmitted Infection
STPs	Standardized Testing Procedures
SW	Sex Worker
TB	Tuberculosis
UNAIDS	The Joint United Nations Programme on HIV and AIDS
UNICEF	The United Nations Children Fund
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization
YFS	Youth Friendly Services

CHAPTER 01

BACKGROUND



Kenya's HIV epidemic is described as generalized with an average HIV prevalence of 5.6% among the general population of ages 15-64 years, and an even higher prevalence among some populations and geographical regions. KAIS 2012 reported HIV prevalence of as low as 2.1% in the northern part of the former Eastern province to as high as 15.1% in Nyanza. The Kenya Modes of Transmission study (2008) demonstrated high incidence rates among stable heterosexual couples and among key populations (PWID, MSM and SW). The burden of HIV has also been shown to be higher among other populations such as truck drivers, male prisoners and fisher folks.

HTC is the gateway to HIV prevention, care and treatment. A lot has been done towards achieving universal knowledge of HIV status. Kenya Health Demographic Survey (KDHS 2014) 83 % of women and 71% of men aged 15-49 years have ever been tested for HIV; however only 53% of HIV infected individuals have correct knowledge of their HIV status (KAIS 2012). Through HTC, individuals who are HIV positive are linked to care, treatment and support services. Those who are high risk HIV-negative persons are linked to prevention services.

Genesis and milestones of HTC

The realization that HIV testing and counselling (HTC) is the only entry to care and treatment services within the HIV response has led to several measures being adopted to scale up the knowledge of HIV status, including formulation of guidelines and quality assurance mechanisms. HIV testing centers (then popularly known as VCT sites) increased from three in 1998 to nationwide coverage of about 3,000 by 2013. Currently there are 5,980 testing sites in the country (NASCO, 2014). As part of the strategies to expand access to and uptake of HTC, Kenya adopted provider initiated HIV testing and counseling (PITC) approach to augment the existing client-initiated approach (NASCO, 2008).

For ease of access by different populations, PITC approach encompasses different strategies delivered in two main settings i.e. community-based (stand-alone HTC centers, outreach services, and home-based testing and counseling (HBTC)) and facility-based (static sites integrated within hospitals and clinics) (WHO, 2012).

Progressively, other innovative models of HTC have been introduced into the two broad HTC approaches in recent years to expand access of services by couples and key populations (sex workers (SW), People who Inject Drugs (PWID), men who have sex with men (MSM)), transgender people, and other target populations e.g. fisher folks, people in prisons and long distance truck drivers (WHO, 2013).

The HTC programme implementation in Kenya has been rolled out in accordance with the provisions of the national HTC guidelines and other policy documents like the Kenya National AIDS Strategic Plans (KNASP) I – III, Kenya AIDS Strategic Framework (KASF) and HIV and AIDS prevention Act of 2006. In 2008/9 the HTC roadmap was developed to address emerging challenges in scaling-up HTC services which was based on new evidence from population-based surveys and other studies. The roadmap also addresses KNASP III implementation gaps including lack of testing by certain populations such as men and youth. In addition, a quality regulatory framework was developed to guide assessment, monitoring and continuous improvement of the quality of HTC services.

This guideline is aligned to the existing policies that define Kenya's progress towards responding to the HIV challenges and summarizes current existing legal and ethical considerations for implementing HTS programmes in the country. It is aligned with the goal and objectives of the Kenya AIDS Strategic Framework 2014/15 – 2018/19.

Objectives of the HTS Guidelines

The guideline aim to:

- ◆ Provide comprehensive policy guidance for the delivery of quality HIV Testing Services (HTS) in all approaches and settings in Kenya
- ◆ Offer guidance to HTS operational manuals
- ◆ Provide guidance for strengthening linkage to care and treatment and other post-test services
- ◆ Define various HTS strategies for different settings and types of populations.
- ◆ Define key and target populations who may particularly benefit from HIV testing services
- ◆ Outline the data collection, reporting mechanisms and utilization
- ◆ Describe responsibilities of various players in HTS policy formulation/review and implementation

Target Audience

The guideline is targeted at a range of users including health workers in facility and community -based settings, lay HTS counselors, programme managers and policy-makers in national and county governments and non-governmental institutions. This document was developed in consultation with a wide range of stakeholders including relevant government bodies, development partners, implementation partners, civil society organizations and persons living with HIV.

What informs this guideline?

Relevant international and national policy documents were reviewed during the preparation of the guideline including guidance from WHO, CDC, UNAIDS. The Kenya AIDS Strategic Framework and the Kenya National Prevention Revolution Road were among key national documents that guided this process. The HIV Prevention Revolution Road Map informed the population driven interventions, combination and multi-sectorial approaches in this document.

Additionally, other Ministry of Health (MoH) documents related to HIV Care and Treatment, Prevention of Mother to Child Transmission (PMTCT), Tuberculosis (TB) and Leprosy, Sexually Transmitted Infections (STI), Family Planning (FP) programs also informed the review process.

This document considers the basic rights of individuals and families; the legal and ethical considerations were informed by the following legislative documents:

- ◆ The Constitution of Kenya, 2010
- ◆ The HIV and AIDS Prevention and Control Act, 2006
- ◆ The Sexual Offences Act, 2006
- ◆ The Children's Act, 2001
- ◆ The GoK Public Health Act (Cap 242)
- ◆ The Medical Laboratory Act, 1999
- ◆ The Science and Technology Act, 1980
- ◆ International Labour Law

CHAPTER 02

APPROACHES AND SETTINGS OF HIV TESTING SERVICES



HTC services have evolved over the years in response to the dynamics of the HIV epidemic in Kenya. As a result, different approaches have been developed to address the needs of diverse populations. The categorization of the approaches is broadly based on who initiates the HTC service. This chapter describes the approaches and settings for HTC services in Kenya.

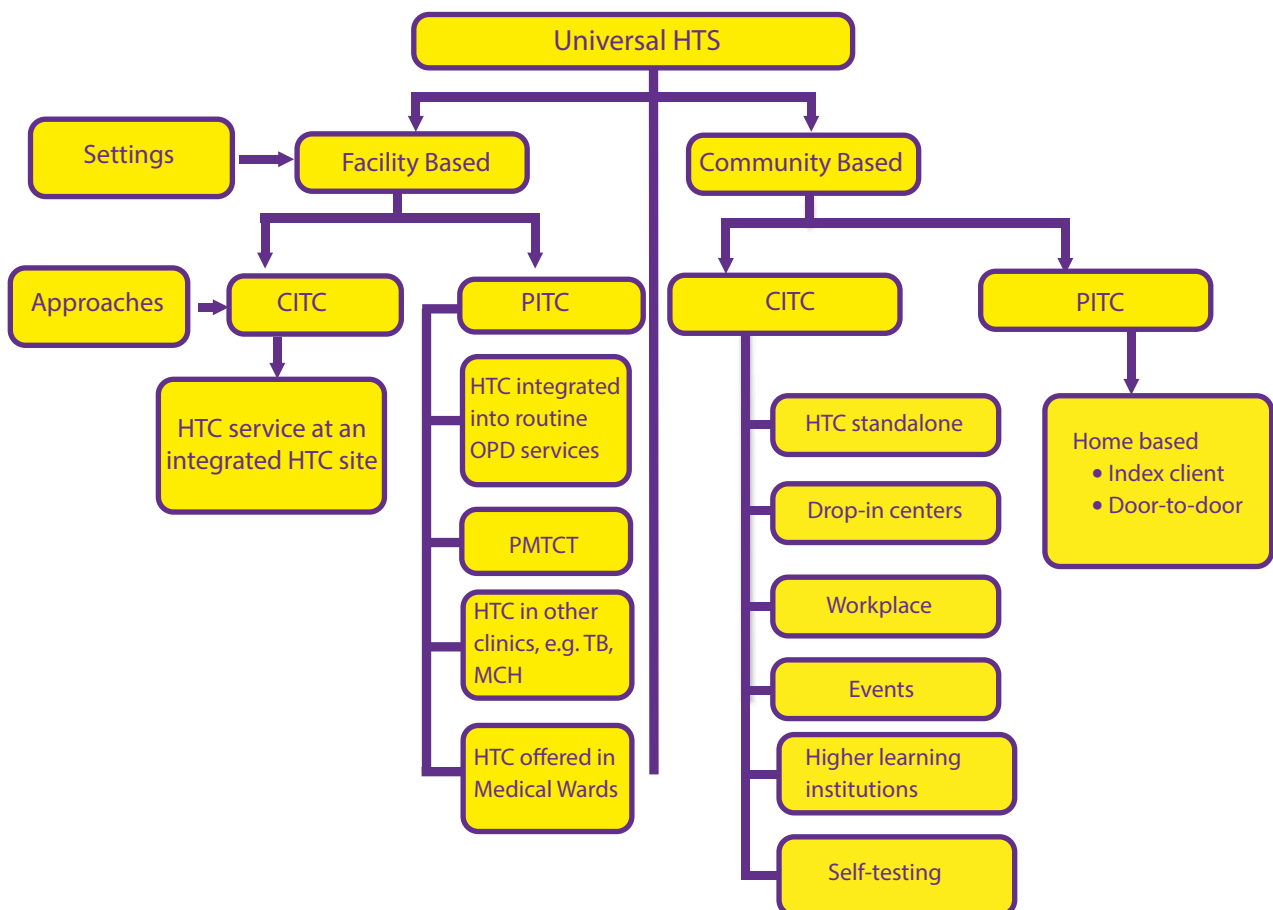
2.1 Approaches and settings

The two approaches for HTS in Kenya are Client Initiated Testing and Counseling (CITC) and Provider Initiated Testing and Counseling (PITC). Both approaches are premised on the need to expand options available to clients while seizing presenting opportunities to accelerate HIV testing coverage.

Client initiated testing and counseling (CITC) entail the client seeking and initiating the HTC service either in the community or health facility settings based on own volition. Provider initiated testing and counseling (PITC) entails when a service provider offers HIV testing to clients within a facility, regardless of the reason for the visit. PITC places the onus of initiating HTC on the health provider, rather than the client. PITC service is offered with an “opt-out” option based on informed choice.

The HTC services are delivered in two broad settings, namely community and facility based settings. It is acknowledged that different populations may access HTC services in different settings. Therefore, it is recommended that counties offer a mix of HTC service delivery models, and that organizations providing HTC services select the right setting and approaches suitable for the target populations.

Figure 2.1: HTS approaches and settings



a. Facility based HTS strategies

Kenya has a mixed generalized and concentrated epidemic. According to WHO in generalized HIV epidemics, HIV testing and counselling should be offered to all patients attending all health facilities, whether or not the patient has symptoms of HIV and regardless of the reason for attending the health facility. Routine opt out PITC should therefore be offered in all facilities and prioritized in all the service delivery points, including those listed below;

- ◆ Inpatient including adult and pediatric facilities,
- ◆ Outpatient facilities or departments, including TB, STI, VMMC, Post Rape Care (PRC), SRH/ Family Planning (FP) clinics,
- ◆ Maternal and child health clinics, including antenatal care clinics where PMTCT services are offered,
- ◆ Integrated HTS sites

There are various strategies under which PITC services are offered in health facility settings. These are:

1. ANC, PNC and maternity wards for eMTCT

HTC services are routinely offered to pregnant women attending ante-natal services and the post-natal mothers within a health facility with the aim of interrupting HIV transmission to the unborn/newborn child while facilitating early entry into eMTCT programme for care and treatment for the infected mother.

2. Integrated HTS

The integrated HTC sites may be a separate building within the grounds of a functioning health facility, or designated room/s within the main facility. The primary function of an integrated HTS site is the provision of HIV testing services. However it is recommended that other related services such as family planning (FP), TB screening, and referrals for other services be integrated into HTS to minimize on missed opportunities. This is referred to as HTS since the services go beyond counselling.

b. Community based HTS strategies

The provision of HTC services in the community based settings is in line with the Ministry of Health (MoH) Community Strategy (Kenya MoH, Health Sector Reform Secretariat) and the National Health Sector Strategic Plan-III (3) that has been classified as level one of the health care system in Kenya. It is also in line with the KASF 2014/15 -2018/19 Strategic Objective of strengthening integration of community and health systems. The HTC strategies under community-based settings include;

1. Stand-alone HIV testing and counseling centers

These are static VCT centers that are located in the community. VCT static sites, aim at increasing knowledge of HIV status among individuals in the community who are well and may not need to go to a health facility. This strategy is more aligned with the client-initiated approach and offers comprehensive counseling, same day results appropriate linkages to care and treatment. These sites are commonly operated by non-governmental organizations (NGOs), faith and community-based organizations (FBOs/CBOs). The above mentioned centers target high risk individuals within the general population, including key populations; sex workers (SW), transgender people (TG), People who inject drugs (PWID) and men who have sex with men (MSM), and other targeted populations such as adolescents/youth. Other populations that are served through standalone sites include those with special needs such as persons with disability (PWD).

Expanded roles of the stand-alone HTC centres

While stand-alone centers have exclusively offered HTC services, they can be utilized to address broader health needs within the community in line with the community strategy. Some of the services that can be offered at the stand alone HTC centres are;

- ◆ **Sexual reproductive health:** With additional capacity, these facilities can conduct assessments on clients to identify unmet family planning needs, likelihood of STI and other SRH related needs. With the availability of a nurse or clinician the centers can offer family planning services as well as screen for STI and provide treatment. Post exposure prophylaxis (PEP) can be provided to survivors of sexual violence, and to clients who report exposure following occupational accidents and condom bursts with a person of unknown or known HIV positive status. .
- ◆ **TB:** With the right tools and skills, HTS service providers should be able to conduct an assessment to identify the possibility of TB infection and refer for diagnosis and treatment.
- ◆ **Drugs and Substance abuse:** The providers should also be able to assess clients for drug and substance abuse and offer brief addiction counseling HTS and refer for further support where necessary.
- ◆ **HIV prevention:** HTS providers in the stand-alone sites should identify clients at high risk of HIV and provide appropriate risk reduction counseling. In addition to demonstration and distribution of condoms and lubricants the service providers in these centers should also offer post-test behavior change interventions, such as evidence informed behavioral interventions (EBIs) and psychosocial support.
- ◆ **Voluntary male medical circumcision (VMMC):** HTC providers should screen male clients to identify those not circumcised and provide the relevant information on advantages of VMMC. They should also refer the clients appropriately to the sites offering VMMC.
- ◆ **General HIV Information:** HIV continues to be stigmatized in many communities and going to a VCT centre still provokes feelings of questionable conduct for many. It is recommended that stand alone HIV testing and counseling centres provide information about HIV prevention to individuals and groups to de-stigmatize HIV services and also serve as a source of correct information on HIV.

2. Home based HTS (HBTC)

This is a provider-initiated strategy that seeks to make access to HTS more convenient and to remove structural and logistical barriers (Bateganya et al., 2010; Negin et al., 2009; USAID/AIDSTAR-One, 2009). Under this strategy the HTC service provider goes to the home of a potential client and initiates HTC. The HBTC strategy has shown potential for attracting first time testers and has reduced stigma associated with HIV testing. It also promotes partner and family testing, besides the potential of reaching children whose mothers are infected for testing.

In order to achieve maximum benefits from the implementation of this strategy the following considerations should be made:

- ◆ Consideration should be given to high prevalence and incidence areas with low testing coverage
- ◆ Focus should be on high density population and low income areas e.g. informal settlements.
- ◆ Due consideration should be made to ensure referral & linkage to comprehensive post-test support services within the area of coverage, including care clinics.

The HBTC services focus on the general population (in a specified geographical area) and index clients' follow-up in households with known HIV-positive clients. For general population HBTC is offered as door-to-door service within the identified area while index client follow-up involves providers visiting the homes of Person Living with HIV (PLHIV) to test their partners and family members. Index client follow up strategy has been shown to be cost-effective and is associated with uptake rates above 95%. Using this strategy, more people living with HIV are likely to be identified.

3. Drop-in Centers

Drop-in service centers that are located in strategic locations to provide comprehensive HIV prevention services specific to key populations in an environment that is friendly to them. The services provided include, but not limited to, HIV Testing and Counseling, STI screening and treatment, FP services, cervical cancer screening for female sex workers, education by peers, condom and lubricant promotion and distribution. It is recommended that peers among the key populations are identified and trained to offer these services in order to make the drop-in centers truly peer led and attract the target clients.

4. Outreach HIV testing and counseling

Outreach HTC refers to services offered outside of a static site, such as mobile, moonlight, higher learning institutions-based or workplace programmes. This strategy aims at enhancing access among hard to reach populations, including key populations that have limited access to health care systems due to structural, policy and legal barriers as well as stigma and any other constraints such as distance from stand-alone sites and health facilities. Some of the means used for providing outreach HIV testing services in Kenya include:

- ◆ Mobile trucks with counseling rooms
- ◆ Using tents as counseling rooms
- ◆ Moonlight services to reach special populations such as sex workers, fisher folks, truck drivers, people who inject drugs and men who have sex with men (MSM)
- ◆ Utilizing pre-existing community facilities such as community halls, churches, schools and other institutions or hired rooms at market centres
- ◆ Innovative strategies such use of a camel, donkey or bicycle to access hard to reach areas and populations such as pastoralist communities

All outreach HTS should be offered in strict adherence to community based HIV testing services policy guidelines in addition to ensuring that the rights of key populations are protected. For key populations outreach, appropriate linkage to treatment and prevention services should be given high priority. They should also be linked to drop-in centers for access to information and other necessary services (such as access to condoms and lubricants) (MOH/NCHADS/UNICEF, 2007).

5. Workplace HIV testing and counseling

This is a strategy in which HTS is offered in formal or informal workplaces and may be organized through employer or organizations who wish to ensure their employees have access to quality HTC services. Where possible workplace HTS should also extend to the surrounding community to allow the workers' spouses and families access to the services (Corbett et al., 2006). It is important to note that workplace programmes are not compulsory or mandatory. Reports to the employer with regard the services offered should not include clients' identification but can highlight the number of staff and community members tested and the positivity rate. Employees are encouraged to disclose their status to their employers on their own volition in order to receive support, including care and treatment.

6. Self-testing for HIV

HIV Self-Testing (HIVST) is relatively new in Kenya; hence data is required to inform scale-up and the HTS program in general. HIVST is a process in which an individual collects his or her specimen, performs a test and interprets the test result in private. HIV self-testing transcends barriers such as stigma, lack of time and distance to health facilities or HTC centers. HIVST aims to make HIV testing more and easily accessible to populations such as men, key populations such as MSM and sex workers and hence facilitate knowledge of HIV status. Some research studies have found HIVST to be highly acceptable across diverse populations and settings, including general population, men who have sex with men (MSM) and sex workers. In particular, in Kenya, HIVST is highly acceptable, among health workers who have reported self-testing "informally" at least since 2005 (Kalibala, S. Waimar T et al., 2014; NASCOP, 2006). Additionally, although evidence is limited, research suggests HIVST is empowering to users, can be cost-effective, and has potential to increase access to and uptake of HIV testing, particularly among individuals who may not otherwise test.

There are many possible models in which HIV rapid tests could be made available for the purpose of self-testing which vary in the amount of support that is provided (supervised or unsupervised), level of access (clinically restricted, semi-restricted, or open access) and how and where HIV rapid tests are distributed or performed (facility-based, community-based, or other settings-figure 1 above - HTC approaches and setting).

HIVST should be performed using approved HIV rapid diagnostic tests that use either finger stick whole-blood or oral fluid (mouth swab). HIVST does not provide a diagnosis. All reactive (positive) self-test results should be confirmed in a health facility according to nationally set standards (*An operational manual for delivery of HIVST detailing approved HIVST Kits will be developed to provide clear guidance*).

Other purposes of HIV testing

a. Required HIV testing

Kenyan law prohibits compulsory HIV testing (HIV and AIDS Prevention and Control Act [2006]). However, HIV testing may be performed without consent in certain specific circumstances when ordered by a court of law, for example, a person charged with an offence of a sexual nature under the Sexual Offences Act, 2006, may be compelled to undergo a HIV test. However, the person being tested should receive their test results and adequate counseling done in an appropriate setting. The clients should also be provided with the necessary referrals.

b. HIV testing of blood and tissue donations

According to the Policy Guidelines on Blood Transfusion in Kenya (2001), 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 blood or tissue transmissible infections.

All blood and tissue donors should be given general information about HIV testing, and should have access to their HIV test results. Blood donor services may also integrate other HIV/AIDS services to provide those blood donors who need more information and further support with appropriate services. It is recommended that HTC services be offered along blood donation services and results given on the same day to minimize any lost opportunity and to ensure appropriate referral and linkage. The blood donor service providers should ensure that arrangements are in place to provide counseling to the donors in relation to their HIV infection risks and prevention interventions.

c. HIV testing for research and surveillance

All HIV testing conducted as part of research or survey must be delivered in line with this guideline and other relevant policy guidelines. Particular care should be taken to ensure that rights of the study participants are protected under existing laws and ethical considerations. Measures should be taken to ensure that study participants who test for HIV for research purposes receive their HIV test results (MoH, 2005). Measures should also be put in place to ensure that participants receive appropriate post-test referral & linkage, including care for HIV positive and other services as need be.

CHAPTER 03

POPULATIONS TARGETED FOR HTS



In order to achieve the KASF (2014/15 - 2018/19) goal of contributing to the achievement of Vision 2030 through universal access to comprehensive HIV prevention, care and treatment, HTS should be offered to persons of all age groups. However, special attention should be placed upon populations where the HIV epidemic is concentrated. The categories of the populations targeted with HTS are as follows;

3.1 General Population

Adults

All adults should be offered HTS in order to know their HIV status, to prevent HIV transmission and acquisition as well as facilitate uptake of HIV care and treatment services, adherence and retention into HIV care programs, which has been demonstrated to be effective in reducing HIV transmission.

Youth and adolescents

Data show that adolescents (defined as those ages 10 to 19 years of age) and youth are at significant risk of acquiring HIV. KAIS 2012 reported that up to 7% of children had sex by the age of 10 years. 21% of new HIV infections occur among young women aged 15-24 every year. Condom use among the same age group was significantly lower for women and men who had their sexual debut before age 15 years (52.9% and 33.7% respectively). KAIS 2012 report also shows that the increase in the HIV prevalence starts at the age of 17 years reaching the peak at 22 years within the age group of 15-24 years, with the highest increase in women. It is therefore important to put interventions in place for those below the age of 17 years to curb the new infections as the adolescents become actively engaged in sexual activities. For this reason age for HTS without the guardian/parent consent, has been reduced to 15 years including all emancipated minors who may be below 15 years of age.

HIV testing services for adolescents are highly beneficial; noting that the main mode of HIV transmission is unprotected heterosexual intercourse. Adolescents are also easily exposed through injecting drug use, sex work and anal sex particularly by LGBTs (UNICEF, 2010). In generalized epidemics, adolescent women are particularly vulnerable to HIV infection. Early sexual debut, often with older partners, coerced sex and low rates of condom use, combined with their biological vulnerability at that age, increase the risk of HIV infection. Further, adolescents are also exploring sex on their own in forms of social settings, spurred by changes in their sociological environments including media promotion of sex among others

Youth who are HIV positive should be encouraged to disclose their status to their parents/guardians and if they have challenges in disclosure they should be supported by the health provider to disclose, to facilitate access to care and treatment and other services. HIV negative youths should be linked to other supportive HIV prevention services as appropriate, including nationally approved evidence informed behavioral interventions (EBIs) for this population. Programmes are also encouraged to establish Youth Friendly Services (YFS) with integrated HIV Testing services.

Infants and children

KAIS 2012 established a HIV prevalence of about 1% among children aged 18 months to 14 years which translates to about 104,000 children while the ARV coverage for children as at 40% 2014. Thus there is need to scale up provision of HTC for children in order to identify all those infected or exposed to HIV for prevention purposes. Infants and children get exposed to HIV mainly from their infected mothers. This makes it imperative for children and infants to be tested to determine their HIV status and link them appropriately to care and treatment.

The following considerations should be made to ensure infants and children are tested for HIV:

- ◆ Strengthening early infant diagnosis (EID) for HIV-exposed infants (find, treat and retain them)
- ◆ Test all children of adults receiving any HIV service (PMTCT, Care, ART) or those born of known HIV positive mothers through facility or home-based index case testing
- ◆ Test all children and adolescents attending TB clinics, malnutrition services, and/or admitted to the pediatric ward
- ◆ Test all orphans and vulnerable children (OVC)
- ◆ In high prevalence settings (>5%), ascertain HIV exposure status of all infants attending immunization or under-5 clinics to identify HIV-exposed infants (see latest HIV County Profiles)
- ◆ Test all sick children with unknown HIV status presenting at health facilities
- ◆ Test all children whose mothers died of unknown conditions
- ◆ Test all children with a history of exposure to exceptional circumstances including, sexual abuse and wet nurse babies

HIV testing and counseling should be offered to guardians and parents, who should also give consent for themselves and their children to be tested. Parents should also be supported to disclose the HIV positive status of their children to facilitate their children's involvement in treatment and adherence. Children should also be offered counseling and other psychosocial support.

Early infant diagnosis (EID)

PCR or any other appropriate and other approved technology should be used for diagnosis of all children aged below 18 months who are exposed to HIV. Where a child tests positive, immediate initiation of ART is recommended and attempts should be made to reach other children in the family. Child immunization campaigns may also be used as an opportunity to disseminate information about HTS, and can be an opportunity to test children (and adults) of unknown HIV status.

DNA PCR should be conducted at 6 weeks or at first contact after 6 weeks. Infants aged 9- 18 months can be tested using the Rapid HIV testing to establish possible exposure status. (Refer to algorithm on EID).

Couples

Prevalence of HIV discordance among couples in Kenya is high; 45% of married or cohabitating HIV infected persons have an HIV-negative sexual partner (KAIS, 2012). HIV transmission among discordant couples could be as high as 10%-12% each year (Quinn et. al. 2000, NEJM). Couples HTS has been associated with large reductions in HIV transmission risk within discordant couples (Allen et al., 2003; Sweat. et al., 2007)

It is recommended that HTS service providers encourage individual testers to test together with their sexual partners as couples, whether heterosexual or same sex. Couple/partner counseling should facilitate disclosure and adequate referrals to prevent HIV transmission within the discordant couples as well as facilitate linkage to care and treatment and access to psycho-social support. During couples HTC, each partner should be given an equal opportunity to talk and ask questions. Couples should be supported to disclose their results to other family members. The HTS service provider should screen for potential domestic violence risk and make appropriate referrals. Information about prevention of mother-to-child transmission (PMTCT) and family planning (FP) services should be provided to couples where appropriate.

It is recommended that the families of patients receiving care for HIV/AIDS related illnesses should also be offered HIV testing services, either through index client follow-up strategy or being encouraged to bring their family members to the facility for HTS. Couples in an HIV discordant relationship should both be effectively linked and followed-up to ensure entry and retention in care and treatment programs as well as appropriate EBIs such as Eban-K and Positive health dignity and prevention (PHDP).

Evidence-informed behavioral interventions (EBIs) are interventions that have been rigorously evaluated and have been shown to have significant and positive evidence of efficacy in behavior change and are considered to be scientifically sound. Some of the EBIs that have been adapted and approved for implementation in Kenya include; Healthy Choices for a Better Future (HCBF) , My health; My Choice, Shuga, Families Matter! Program (FMP), Eban-K, RESPECT-K, OCaT and Positive Health, Dignity, and Prevention (PHDP).

Discordant couples

Discordant couple refers to a situation where one of the sex partner's HIV status is positive while the other partner is HIV negative. In 2009, MoH data indicated there were approximately 400,000 discordant couples in Kenya (MoH, 2009). The Kenya AIDS Indicator Surveys 2007 & 2012 indicate that, of all the individuals living with HIV and with a steady sex partner, 45% of them have a sex partner who is HIV negative. The HIV negative partner is at high risk for HIV acquisition and requires a couple specific HIV prevention package. In line with the WHO guidelines, the HIV negative client should be re-tested 4 weeks after initial testing and thereafter annually.

This guideline recommends delivery of the prevention package for the negative partner to be done at the comprehensive care clinic (CCC) and other settings whenever possible. The prevention package should include HIV re-testing, evidence informed behavioral interventions such as EBAN-K (an intervention for discordant couples), VMMC and support groups.

Benefits of re-testing the HIV negative partner

- ◆ Motivates the negative partner to take-up prevention measures to maintain the negative HIV status
- ◆ In case of sero-conversion, early diagnosis of HIV infection enables linkage to care and treatment and other support services such as eMTCT to prevent further HIV transmission
- ◆ Re-testing may be offered as a prevention package for the negative partner and thus will facilitate better support to the partner living with HIV

3.2 Other Special Category Populations

Persons with disabilities (PWDs)

This category includes persons with physical, visual, hearing, sensory, and mental impairment. PWDs should be targeted with HTS because of their limited access to information, education, and facilities. Provisions should be made for (PWDs) to access HTS in a manner that meets their specific needs. Some of these provisions include: incorporating Kenya sign language, braille, ramps for those using wheelchairs and crutches. Where possible there should be HTC providers with capacity to handle issues of PWDs within the service delivery settings. Efforts should also be made to reach the PWDs where they can conveniently access the services, e.g. institutions for special needs. Clients who are mentally impaired should be accompanied by a caregiver who should consent and offer the support needed. The following measures should be taken to promote services to PWDs:

- ◆ All service providers should be sensitized on the unique needs of PWDs
- ◆ Implementers should determine their human resource capacity for dealing with PWDs especially sign language interpreters and plan appropriately for service provision
- ◆ Mainstream HTS in institutions and organizations dealing with PWDs

Considerations should be made to mainstream the special needs of the PWDs into all HTC activities.

Key populations

The Kenya AIDS Strategic Framework defines the key populations as the groups who, due to specific higher-risk behavior, are at increased risk of HIV, irrespective of the epidemic type or local context. Legal, cultural and social barriers related to their behaviour increase their vulnerability to HIV. In Kenya these populations include: men who have sex with men (MSM); people who inject drugs (PWID) and sex workers (SW). Despite their small number, these populations contribute an estimated 30% of new infections annually. Key populations should be re-tested in line with the national Key Populations Guidelines.

Survivors of sexual and gender based violence

Sexual and Gender Based Violence (SGBV) is one of the most serious, and life-threatening forms of violence. The Kenya Demographic and Health Survey (2014), showed that 49% of women aged 15-49 years have experienced either physical or sexual violence, while 38% of those ever married experienced emotional, physical or sexual violence.

There is a strong link between sexual violence and the risk of HIV infection. Evidence has shown that women and men who report a history of intimate partner violence (IPV) victimization are more likely to report factors known to increase the risk for HIV, including injection drug use, sexually transmitted infection (STI), giving or receiving money or drugs for sex, and anal sex without a condom (CDC, 2014).

Clients who report sexual violence should receive HTS at the first contact. They should immediately be referred for clinical evaluation, documentation and treatment, trauma counseling and initiation of post-exposure prophylaxis (PEP). Health facilities should fast-track services and ensure survivors are initiated on PEP within the shortest time possible but not later than 72 hours from the time of sexual assault. If HTS is not immediately possible clients should be initiated on PEP, provided with clinical evaluation and issued with an appointment to come for HTS within the next 3 days. The survivors who test HIV negative should be re-tested after 4 weeks and if still negative or in a discordant relationship re-test at 12 weeks in line with the WHO guidelines.

In cognizance of incidences of sexual violence against children where the perpetrator is the parent or guardian, these guidelines recommend that children survivors of sexual violence can be tested without the consent of their parents/guardians but they should be given age appropriate counseling.

Vulnerable populations

People who because of their circumstances are at an increased risk of contracting HIV.

Vulnerable populations include;

- ◆ Widows and widowers
- ◆ Orphans and vulnerable Children (OVCs)
- ◆ Families and children living in the streets
- ◆ Young women aged 15-24 years
- ◆ Service men and women, and their families
- ◆ Refugees, displaced persons and migrants
- ◆ People who abuse alcohol
- ◆ Fisherfolk
- ◆ Truckers

Efforts should be made to ensure that the populations listed above have equitable access to HIV testing and counseling. This is because these populations are exposed to circumstances that put them at an increased vulnerability to HIV infection. Where applicable these persons should also be encouraged to be tested with their sex partners.

CHAPTER 04

HTS PACKAGE



4.1 Core principles of HIV testing and counseling

In consistent with international policy and technical standards, the ministry of health (MOH) emphasizes that all HIV Testing Services in Kenya should be conducted in accordance with the best interests of the client. HIV testing should never be coercive or mandatory except in unique situations such as court orders. HTC services are guided by 5 core principles (5Cs); consent, confidentiality, counseling, correct results and connection-linkage to care and other appropriate post-test services. These fundamental principles are described in detail below.

Informed consent

Informed consent in the context of HTC is a process of giving adequate information to clients to facilitate proper decision making prior to obtaining permission for conducting HTC. Consent can either be written or verbal and should be voluntary as informed in the HIV and AIDS Prevention and Control Act (2006), “no person shall be tested without their consent”.

Children and youth up to the age of 14 years should be tested with the consent of a parent or guardian. However those from 7 years and above need to give assent after the parents give consent. Other clients from 15+ years and emancipated minors irrespective of age can give their own consent. A person with a disability that prevents them from giving consent may be tested with the consent of their caregiver. 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.
- 2) When a person is unconscious and unable to give consent and the test is medically necessary for a clinical diagnosis for the benefit of the client.

Under no circumstances should a person be required to have a HIV test for purposes of employment, marriage, education, travel, or for provision of health care insurance cover, or any other service.

Consent for HIV testing for adolescents

The Kenya AIDS Indicator Survey, 2012, showed that by 15 years of age, 11.6% of adolescent girls and 20.2% of adolescent boys already had sex at least once in their life time. It is therefore recommended that adolescents and youth of 15 years and above can give their own consent for testing without the parent/guardian consent. Kenya is noted as one of the countries in the world that is experiencing a mature HIV epidemic, as evidenced by the stabilizing HIV prevalence and declining HIV related morbidity and mortality. There are individuals in the country who were born with HIV and have grown to adolescence or adulthood. All efforts, including counselor or health provider supported disclosure should be made to ensure the support of children and parents /guardians is provided to facilitate uptake of post-test services, and care and treatment for those diagnosed HIV positive.

Confidentiality

Confidentiality in the context of HTC refers to privacy of interaction between the client and the service provider and obligation to hold in confidence medical or personal information regarding their clients. Confidentiality shall be maintained even after the patient's death. Confidentiality is not secrecy. Client's names will be used in order to facilitate referral to other services and test results may be shared with other health care workers providing services to the client; referred to as shared confidentiality. Confidentiality shall be upheld except where consent has been expressly given or disclosure is allowed by law in the interest of public health.

Confidentiality must be maintained when conducting all types of HIV testing and in all settings. All HTC service delivery points should ensure that the policies, training and infrastructure needed to uphold client confidentiality and privacy are in place and adhered to. HTC records and information, just like any other health records, should be kept confidential in all circumstances and stored in lockable cabinets accessible only by authorized personnel. A person who contravenes confidentiality provisions commits an offence under the HIV and AIDS Prevention and Control Act (2006).

Counseling

HTC counseling is a confidential interaction between the HTC service provider and the client aimed at allowing for informed decisions and benefit from the HIV service package by the clients. Counseling includes pre-test counseling/information, HIV test, post-test counseling and referral and linkage. Everyone who receives an HIV test is entitled to adequate information and counseling before and after the test to allow making of informed decisions. The length and scope of the counseling session will depend on the specific settings and needs of the client. It is recommended that pre-test counseling focus on providing information to facilitate informed consent while the post-test counseling should be tailored on the outcome of the test and the individual client needs, including referrals and partner/family testing. High risk HIV negative individuals should receive counseling tailored on the on-going risks and linkage to the specific behavioral interventions.

Correct test results

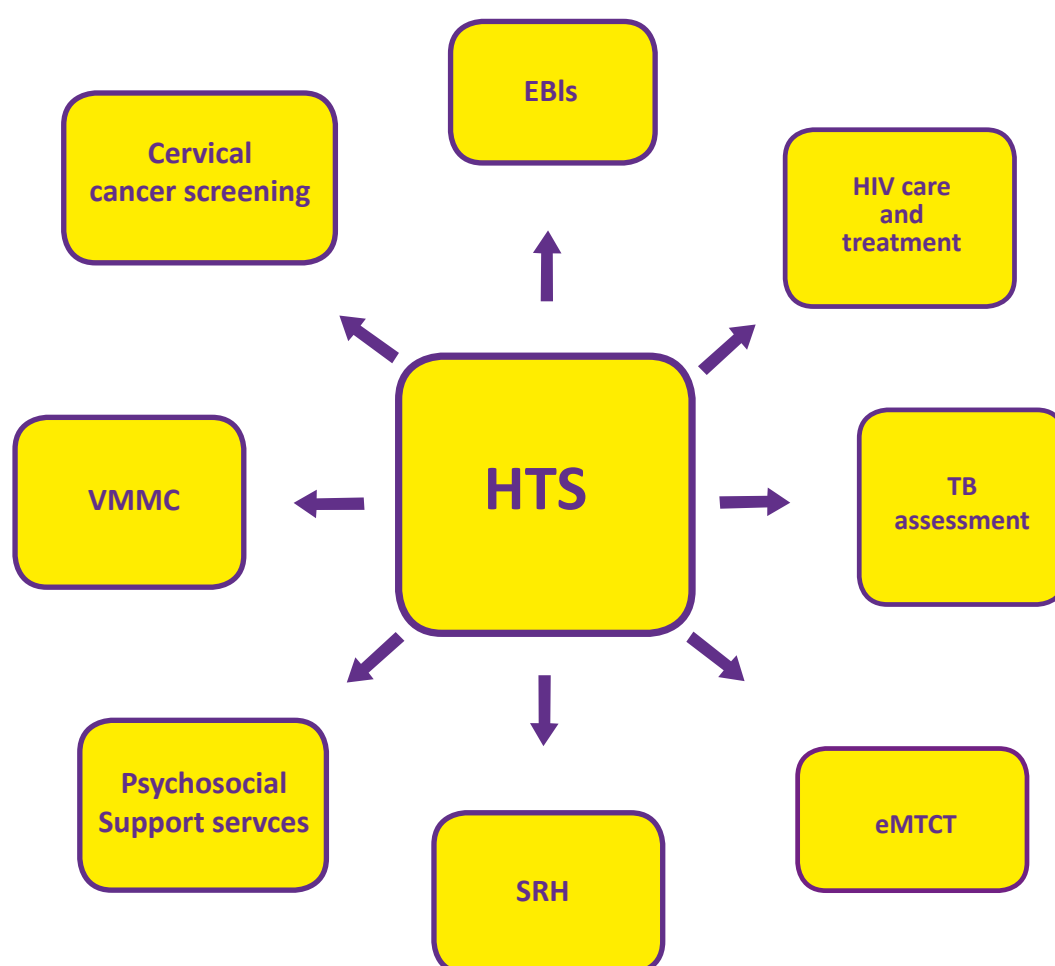
There have been reports of HIV status misclassification, with both false positive and false negative results thus raising concerns on the quality of the HIV test results issued (WHO, 2014). HTS providers should strive to provide quality testing services and quality assurance mechanisms should be in place to ensure the provision of correct test results to clients.

Quality assurance and control to ensure quality testing and issuance of correct results should include both internal and external measures. Providers should adhere to the national HIV testing algorithm as part of the effort to achieve acceptable standards in test results given to clients. In circumstances where, the testing algorithm is not complete due to shortage or damage/expiry of one/more of the test kit, **HTC SERVICES SHOULD NOT BE OFFERED** (See Chapter 8 : Quality Assurance).

Connection - Referral and linkage to care

HTS services should be accompanied by appropriate, comprehensive and effective referral and linkage to post-test services. Clients who test HIV positive should be linked to care, treatment and support services. Those who test HIV negative and are at the risk of HIV infection should be linked to effective prevention interventions. Clients in need of other post-test services such as SRH or TB services should be linked appropriately. Clients who need post-test services, including HIV care and treatment will be issued with a standard referral form which should be filled in triplicate, (Appendix one). The client should receive the original of the referral form. The duplicate copy should be left at the point of receiving referral services and the triplicate copy left at the HTC center/health facility/point of testing for reference. Efforts should be made to ensure follow up of the clients to determine if they accessed the services referred for. Client linkage should be documented in the HTS lab register.

Figure 4.1: Examples of the referral options



4.2 HIV TESTING AND COUNSELLING PROTOCOL

The primary components of HTS service package include:

- i. Pre-test session
- ii. HIV test
- iii. Post-test session
- iv. Referral and linkage to other appropriate health services
- v. Assessment of other health related conditions such as Tuberculosis

These four elements make up the minimum service package of HTC. The package is aimed at enabling the clients to understand their HIV risk, take the HIV test, come up with a risk reduction plan, and take up appropriate referrals. This package will be delivered by utilizing the approved HTC protocol as summarized below.

Table 4.1: Summary of HTS service package

<p>Pre-test counselling/ Pre-test information</p> <p>Client initiated HT (CITC)</p> <ul style="list-style-type: none"> ◆ Introduction and orientation to session ◆ Risk assessment ◆ Consent for the test <p>Provider initiated HTS (PITC) in health facility settings</p> <ul style="list-style-type: none"> ◆ Introduction and information on importance of testing for HIV ◆ Consent for the test ◆ Test preparation 	
<p>Perform test</p>	
<p>Post-test counselling for negative results</p> <ul style="list-style-type: none"> ◆ Risk reduction plan ◆ Linkage to other HIV prevention initiatives ◆ Re-testing where applicable 	<p>Post-test counselling for positive results</p> <ul style="list-style-type: none"> ◆ Enrolment to care and treatment ◆ Risk reduction and positive living counselling ◆ Partner/ family testing
<p>Referral and linkage</p> <ul style="list-style-type: none"> ◆ Document the referrals; HIV positive and HIV negative clients in need of further health services will be issued with a copy of the referral form. ◆ Where possible, escort the HIV positive clients to care for enrolment 	

Step 1: Pre-Test Session

The pre-test session introduces basic HIV information to the client wishing to receive a HIV test, and may be provided to an individual or a couple. Group information is not part of the pre-test session. Clients should be given opportunity to give consent to be tested. Confidentiality and its exception should be explained to the client.

(a) CITC

The objectives of the pre-test session are to:

- ◆ Obtain informed consent for HIV test
- ◆ Give information on the benefits of knowing one's HIV status
- ◆ Explain the benefits of couple testing
- ◆ Prepare the client for the HIV test and provide an explanation for the HIV testing process
- ◆ Explore/discuss the client's risk of HIV infection
- ◆ Discuss the importance of disclosure to partners and other family members, and available post-test services, including referrals.

(a) PITC

The objectives of the pre-test session are to:

- ◆ Give information on the benefits of testing for HIV
- ◆ Explanation for the HIV testing process and obtaining informed consent for HIV test
- ◆ Discuss the importance of disclosure to the health providers
- ◆ Information on available post-test services

Step 2: HIV Test

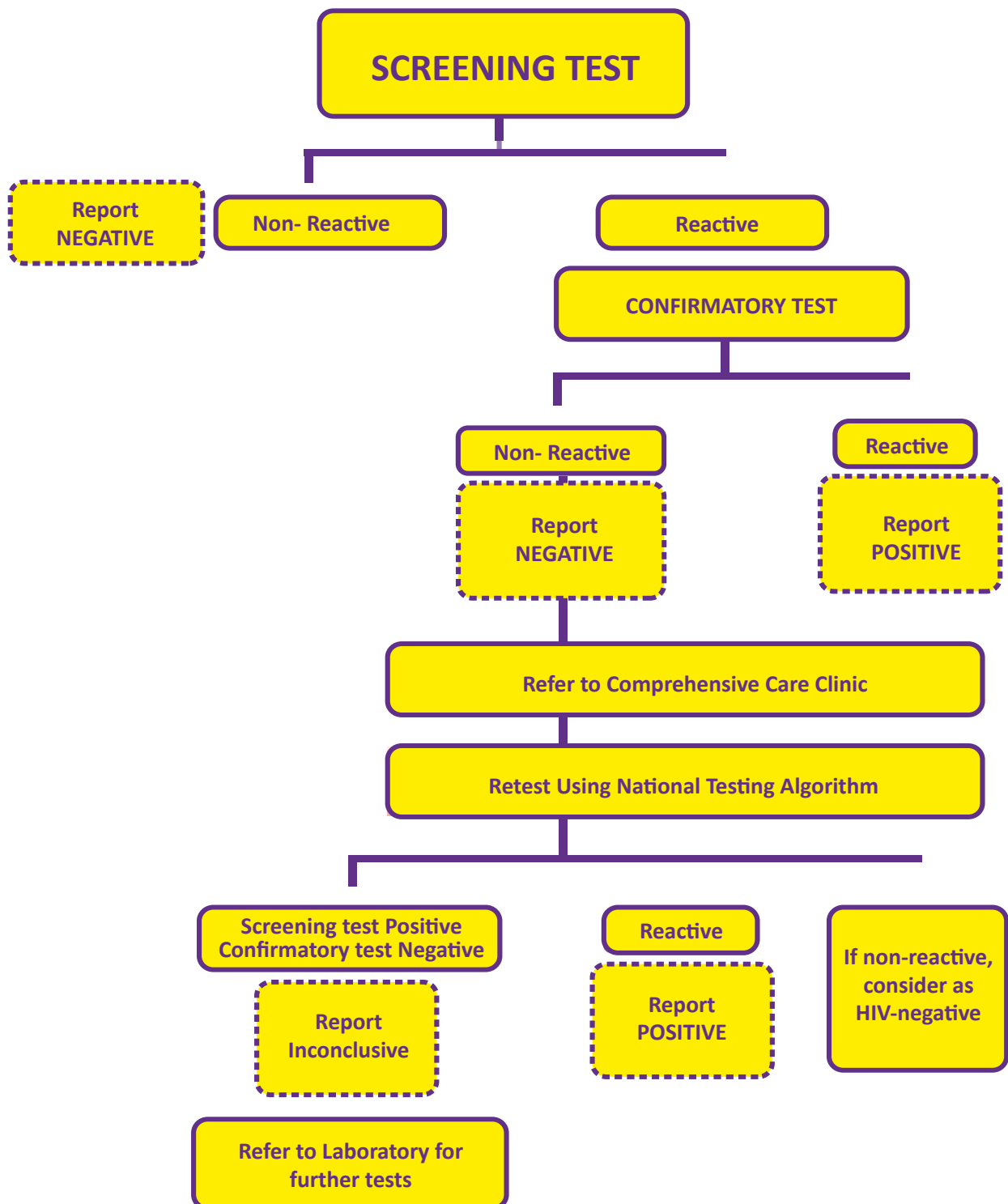
The goal of HIV testing is to:

- ◆ Conduct an HIV test as per the nationally approved testing algorithm (Figure 4.2)
- ◆ Provide correct same day session HIV test results

The HIV test should be performed according to approved national testing algorithm and strategy and in accordance with the current HIV test standard operating procedures (SOPs). The diagram below illustrates the serial testing algorithm. Anyone receiving an HIV test should be encouraged to receive their HIV test results in the same session. In some instances at a health facility, clients may be referred to another on-site HTC service provider or laboratory for the test. Specimen may also be obtained and sent to the laboratory for the test. Whatever the case, it is important that clients should be given their HIV test results, regardless of where the HIV test is conducted. All clients with positive and discrepant results will be referred to a Comprehensive Care Clinic for retesting. In instances where the confirmatory results disagree with the screening results at the CCC, clients will be referred for a laboratory and tested where their samples will be tested using a using a separate and distinct assay from the screening and confirmatory tests.



Figure 4.2: HIV Testing Algorithm



NB: The use of TIE BREAKER is no longer recommended

Step 3: Post-test

The goal of the post-test counseling for both HIV positive and negative results is to achieve the following;

- ◆ Communicate the HIV test results
- ◆ Assess the client's understanding of the test results
- ◆ Discuss referral to care and treatment for HIV positive clients and benefits of early treatment and adherence."
- ◆ Development of client's risk reduction plan
- ◆ Review disclosure options and partner testing
- ◆ Referral to additional prevention services , especially for high risk HIV negative persons as needed
- ◆ Condoms and lubricant demonstration and issuance

The need for quality post-test counseling cannot be overemphasized. The client's uptake of post-test referral and adoption of safe sex behavior is dependent on the quality of the post-test session. The post-test counseling session should be tailored to the test results and the clients HIV risk assessment.

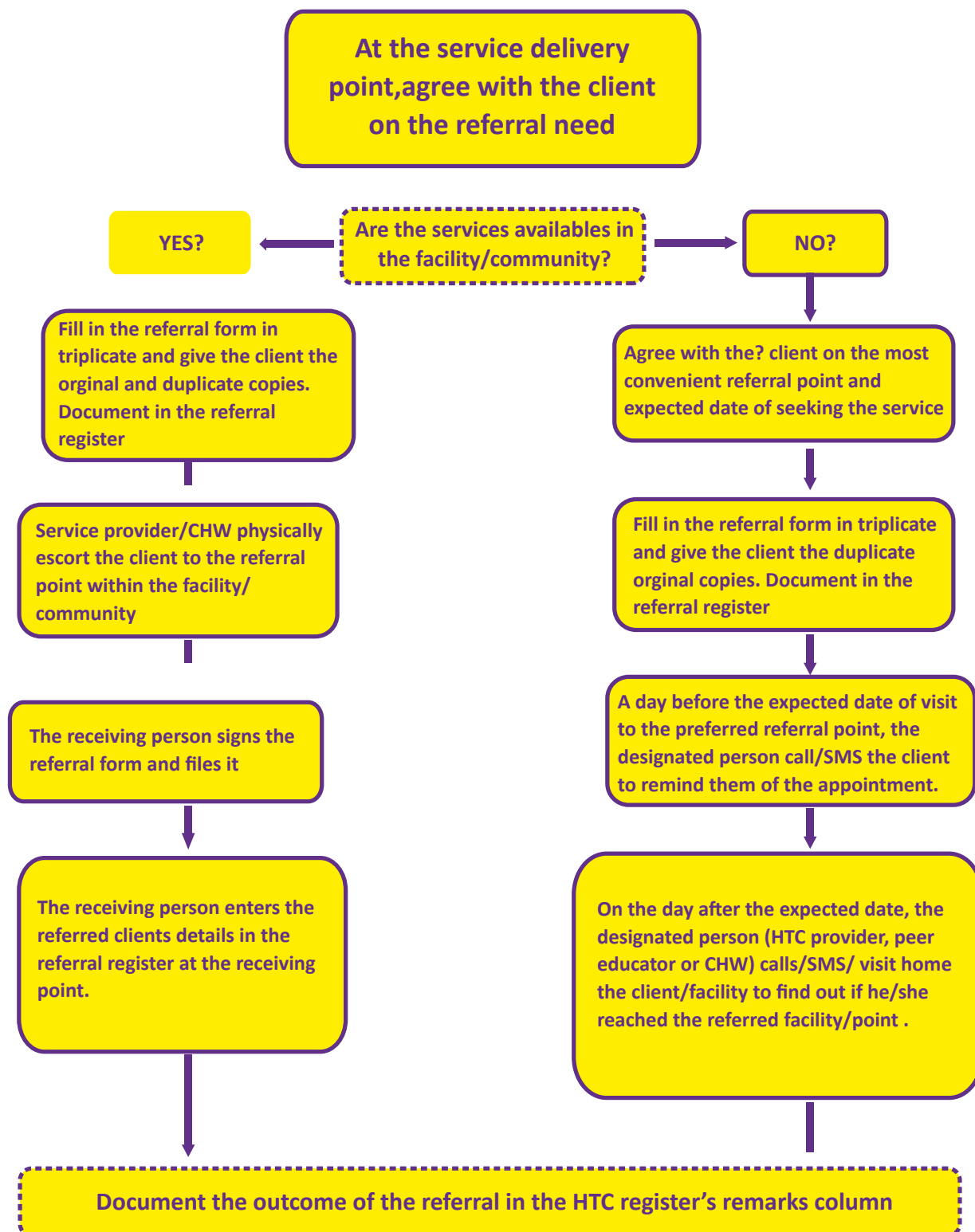
Step 4: Referral and linkages

HTC services should be accompanied by appropriate, comprehensive and effective referral and linkage to post-test services. Clients who test HIV positive should be linked to care, treatment and other support services. HIV negative clients at risk should be linked to effective prevention interventions. All clients in need of other post-test services such as SRH or TB services should be linked appropriately. Whenever possible the client should be escorted to the care clinic by the HTS provider, a peer educator or a community health worker (CHW).

Documentation for referral uptake should be done using nationally approved referral tools and tracking undertaken by the HTS providers, community health workers or peer educators to ascertain if the clients accessed the services referred for. Tracking should be done within a period of one to three months from the time of testing, either through physical visit or telephone call, to confirm with the point/facility of referral if the referred clients received the services. This should be documented in the HTS register in the remarks column. (Appendix 1: Client referral form).



Figure 4.3: Referral process



HIV Re-testing

Re-testing refers to additional testing performed to an individual after a defined period of time for explicit reasons, such as;

- ◆ A specific incidence of HIV exposure
- ◆ Ongoing risk of HIV infection
- ◆ Initiation of antiretroviral therapy

Re-testing recommendations

Re-testing refers to additional testing performed to an individual after a defined period of time for explicit reasons, using the same testing algorithm on a second specimen from the same individual.

The following are the recommendations for re-testing in generalized epidemics based on specific reasons:

I. Inconclusive results: Re-test after 2 weeks

An inconclusive HIV test result occurs when the screening (the first line assay) test is positive and the confirmatory (second line assay) test is negative. All inconclusive results should be referred to the CCC for retesting using a second specimen, preferably by a different service provider.

II. Population settings;

- a. General population: Re-test annually
- b. Key populations: Re-test quarterly (after every 3 months) in case of frequent specific incidences of exposure.
- c. Negative partner in discordant unions: Re-test at the initiation of ART for the HIV positive partner and then every 6 months once viral suppression has been achieved and other prevention services are well adhered to, including consistent and correct use of condoms.
- d. HIV negative pregnant women: Test in first trimester/first visit and re-test in the third trimester; re-test 3 months post-delivery
- e. Breast feeding mothers: Annual testing. For breast feeding mothers at high risk of infection e.g. those in discordant unions retest after every six months.
- f. Persons who had a most recent (e.g. less than a month) specific exposure incidence; Test at initial presentation and re-test at 4 weeks, after which annual re-testing applies.
- g. Symptomatic (STI,) patients: Re-test after 4 weeks after initial test
- h. All persons newly diagnosed as HIV positive: retest with a second specimen using the same testing algorithm at CCC, before enrollment into care initiation of ART (particularly pregnant or lactating women, children under 5, TB patients, KPs), to rule out potential misdiagnosis.

Invalid results

An invalid result is whereby:

- both lines at the control or the test site are not there OR
- the line appears at the test site and no line at the control site

In case of an invalid result, the HTS provider should repeat the HIV test at the same session using the national algorithm.

4.3 Disclosure of HIV status

Disclosure in HTS is the process through which a client shares information about their HIV test result with significant others or a third party. The goal of HIV disclosure is to share one's challenges and get support that enhances access to care. However this support may not always be forthcoming and clients

may face situations of stigma and discrimination. Therefore the health care provider should encourage and support the client to disclose and should not be treated as an event that must happen.

HTS service providers should encourage their clients to disclose their HIV test results to significant others. . In some situations, a health care provider may disclose patient HIV results to another provider for purposes of further care/management.

Disclosure to a child about their HIV status

HIV test results for children upto 14 years will be given to the parents / guardians whose consent is needed for testing them. Parents, guardians, and caretakers should be guided on disclosing to children their HIV status using age appropriate language. WHO recommends that the decision on who to disclose to the child be guided by the intent to improve/promote the child's welfare and minimize the risk to his or her well-being and to the quality of the relationship between child and parent/caregiver.

HTS 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. The aim of disclosure to children is to start to involve them in the management of their own health and reduce stigma associated with HIV. Thus there is need for 'graduated disclosure' depending on the child's level of understanding of concepts of ill health and subsequently specific HIV infection. HTS service providers should offer to assist with disclosure in case difficult questions arise. HTC service providers should also be available to provide ongoing support and counseling for the family as necessary.

Disclosure involving youth and adolescents

Adolescents below 15 years should be offered their HIV test results in consultation with their parents, guardians, or caretakers. Post-test counseling should be offered to the adolescent together with the parent. Youth of 15 years and above should receive their HIV test results if they request the HTC services, but where they wish to receive the results in the company of their parents/guardians they can choose to. Adolescents and youth should be counseled about the potential health benefits of disclosing their HIV status to Significant others, including their parents/guardians and supported to determine, when, how and to whom to disclose. Parents / guardians, who find it difficult to disclose the HIV status of their children, should be supported by the HTC providers to disclosure.

Disclosure to a third party

In line with the HIV Prevention and Control Act (2006), no person should disclose any information concerning the result of an HIV test or any related assessments to any other person except with the consent of that person. If that person has died it should be with the written consent of that person's partner. If that person has a disability which would make him/her incapable of giving consent for the results to be disclosed , consent can be given by a legal parent of that person, legal guardian, legal partner, an adult offspring or a health care worker who is directly involved in the treatment or counseling of that person. 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 well as the person or body legally entitled to receive the test results such as the court.

Disclosure to other health care workers

A health care worker who provides an HIV test or other related assessments for a client is permitted to disclose information concerning the results of those tests to other health care workers who are directly involved in the management of the client. Personal information 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 client's medical diagnosis, care, or treatment.

Disclosure to a sex partner or other person at risk

HTC service providers should make every effort to encourage and support clients and patients to disclose their HIV status to their sex partner(s). 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 (1986) and the HIV and AIDS Prevention and Control Act (2006). In this regard refusal to notify a sex partner(s) that one is HIV positive is an infringement of the right to health and wellbeing of the sex partner(s) at the risk of infection.

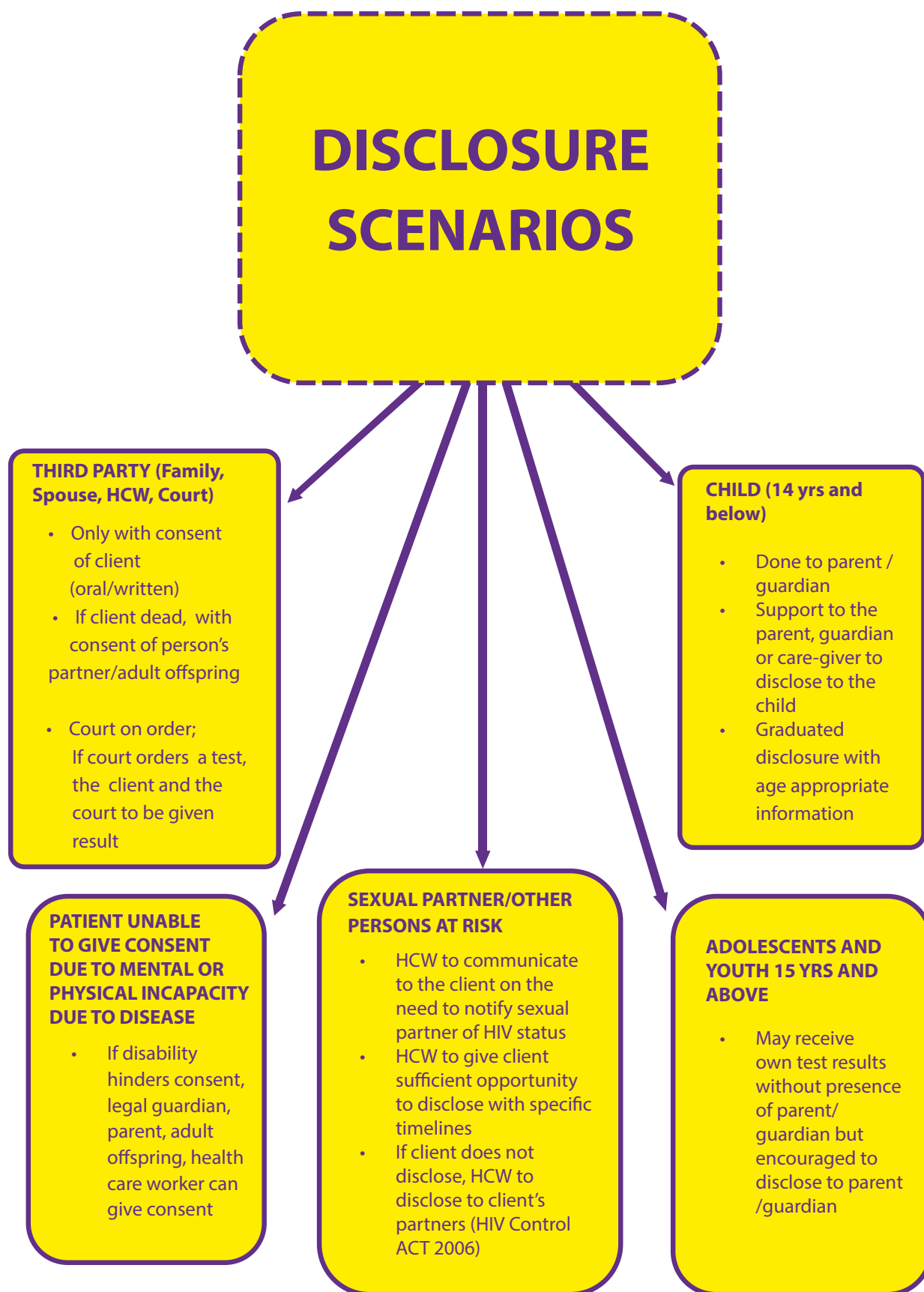
In line with the Kenya HIV Prevention and Control Act 14 of 2006, if efforts to encourage the client or patient to disclose their HIV status fail, and if the client or patient is placing a sex partner(s) or other persons at risk, a medical practitioner may disclose that person's HIV status to their sex partner(s) or other person at risk. However, persons must be given a reasonable opportunity to disclose their HIV status to the sex partner(s) on their own, before a medical practitioner intervenes. In order to respond to high risks of HIV acquisition and transmission among steady sex partners, contact tracing and partner notification is recommended.

It is clear that there is a high rate of HIV discordance among couples in Kenya (KAIS 2012), a situation that places the HIV negative partner at the highest risk of HIV acquisition. HIV post-test counseling should include efforts to support HIV positive persons to return with their sex partner(s) to be tested in order to facilitate the disclosure process. This may be done through couples HTS, where both partners learn their results together in the HTS 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. Counselors/HTS providers should be prepared to address the unique challenges that may arise during couples HTS.

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 in these statutory documents.

FIGURE 4.4: GUIDANCE FOR MAIN DISCLOSURE SCENARIOS



CHAPTER 05

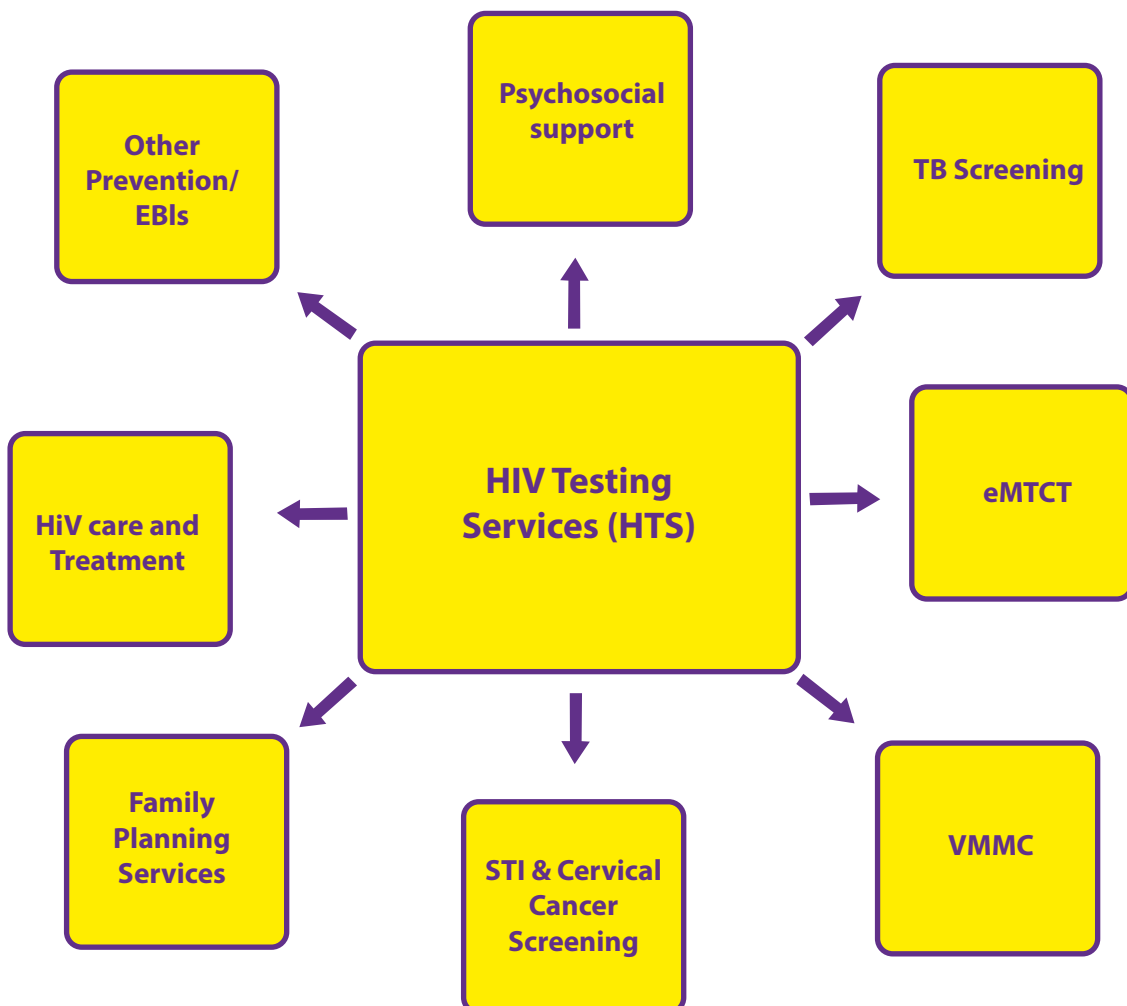
INTEGRATION OF SERVICE



Integrated service delivery is the management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system (WHO 2008). Integrated services can be offered by one service provider during the same consultation or by more than one provider within the facility during the same visit.

The aim of integrating services is to ensure that clients get the services they need, when they need them, in ways that are user friendly, achieve the desired results and provide value for money (Policy brief MOH 2012). Due to the potential benefits of integration, it is highly recommended that all health service delivery points integrate HTC. Additionally, in settings where HTC is the primary service, other health services as outlined below should be integrated. This relationship will lead to early detection of HIV/AIDS and better health care for people living with HIV/AIDS as well as reduce HIV acquisition while increasing access of other health services for HIV negative persons. This makes the health more cost effective as clients do not need to spend time and money moving unnecessarily to different service delivery points. All health care providers should be equipped with necessary skills to provide integrated services.

Figure 5.1: Service integration within HTS delivery settings



The following services are recommended to be provided as a minimum package at HTS service delivery points at the community and health facility level:

- ◆ Couple testing and Counseling
- ◆ Family planning
- ◆ Tuberculosis services
- ◆ Gender based violence risk assessment and appropriate referral
- ◆ STI screening and referral/treatment
- ◆ Condom demonstration and distribution
- ◆ Where feasible evidence informed behavioral interventions (EBIs) should be provided.

In health facilities, all service delivery points should integrate HTC into their services. These service delivery points include, but are not limited to the following: outpatient services, inpatient services, Maternal and child health services, Family planning clinics, STI clinics, TB clinics, Laboratory, Antiretroviral therapy clinic, VMMC clinics, Post rape care / sexual assault

Family Planning

Evidence shows that that 58% of married women and 65% of sexually active unmarried women use some method of contraceptive (KDHS 2014). This indicates the need to continue increasing the coverage of contraceptive use. It is recommended that contraceptive information and services should be offered to all clients including adolescents, within HTC, care and treatment settings (UNAIDS and WHO 2007, WHO 2014, the eMTCT strategy 2013). All HTS service delivery points are encouraged to identify clients with unmet family planning needs and refer or provide them with FP services where feasible. Clients visiting health facilities seeking for FP services should also be provided with HTS.

Condom use

Correct and consistent use of condoms has been shown to be effective in HIV prevention. Male and female condoms are recommended for use in Kenya. HTS service providers should therefore promote the use of condoms and ensure that they are available and accessible to the clients. The provider should demonstrate the proper use of both male and female condoms using correct dummies. The providers should confirm that clients understand the correct use of the condoms before issuing them. . Where necessary the provider should also demonstrate use of condom and the recommended lubricants.

Maternal and child health care (eMTCT)

Kenya has prioritized the prevention of HIV transmission in the context of maternal and child health. The National Guidelines for Prevention of Mother-to-Child HIV/ AIDS Transmission (PMCT), recommend that all pregnant women and their sexual partner(s) should be encouraged to know their HIV status and offered HIV testing services. HIV testing of pregnant women should occur during the first ANC visit and a repeat test done in the third trimester and three months after delivery. If HTC is not done before delivery it should be offered during delivery or as a routine standard of care immediately following delivery.

WHO recommends lifelong ART to all pregnant and breastfeeding women living with HIV, regardless of CD4 count or WHO clinical stage i.e. ART should be maintained after delivery and completion of breastfeeding for life.

Knowledge of HIV status is also necessary for the partners of women seeking maternal and child health services in order to make appropriate decisions about their families' health. Thus health providers should encourage the mothers to bring their partners for couple HTS. This should also be offered to HIV exposed children during immunization and other scheduled clinic visits. Community and facility-based HTS service providers should also identify pregnant women and refer them for early enrollment in antenatal services

Tuberculosis services

The correlation between TB and HIV has been demonstrated in terms of the co-morbidity. It is the goal of TB-HIV collaborative activities to integrate HIV activities into the core TB functions, and also to integrate TB activities into core HIV functions such as HTS. Current National Tuberculosis and Leprosy Guidelines recommend that all clients suspected or confirmed to have TB should receive an HIV test. All persons receiving HTS services should be screened for TB and those suspected to have TB referred for confirmatory diagnosis and treatment if confirmed to be infected. Screening for symptoms of TB should be done using the National TB Intensified Case Finding tool.

STI services

There is a strong correlation between HIV and sexually transmitted infections (STIs). It is recommended that STI services should integrate HTS while HTS service delivery points should provide STI screening. All persons who have STI should be offered an HIV test, and persons who receive HTC should be screened for symptoms of STI and given appropriate referrals for effective management.

Screening for cervical cancer

The number of women reported to have cervical cancer is on the increase in Kenya and is one of the leading killers of women of reproductive age. Research has shown a strong correlation between HIV and cervical cancer. It is therefore recommended that where possible HTS services should integrate cervical cancer screening especially among women who test HIV positive and those with multiple sexual partners. Health providers should encourage all women of reproductive age to seek cervical cancer screening from trained health providers.

Voluntary male medical circumcision (VMMC)

Research has shown that circumcised men have a lower risk of acquiring HIV (Rakai et al. , 2007) with the risk of female-to-male sexual transmission reduced by approximately 60% (WHO 2012). The Kenya Ministry of Health has published policy guidance on VMMC (2008) and (2015) that recommends that HTC be provided as part of the minimum package of VMMC services. HIV testing should however not be a precondition to access male circumcision services. Male clients receiving HTS services and who test HIV negative should have the benefits of male circumcision explained to them. The messaging should emphasize that "VMMC is not a guarantee for not acquiring HIV" and must be combined with other measures to be effective in preventing HIV, such as correct and consistent condom use.

Medical male circumcision is one-time intervention that provides men with life-long partial protection (60%) against HIV as well as other sexually transmitted infections. It should always be considered as part of a comprehensive HIV prevention package of services and be used in conjunction with other methods of prevention, such as female and male condoms- WHO 2012

Evidence informed behavioral interventions (EBIs)

Behavior change is essential in the HIV response. It is important that individuals who test HIV positive adopt and sustain behavior that improves their own health while preventing transmission of HIV to others. Those who test HIV negative also need to adopt behavior that prevents HIV acquisition. Nationally evaluated interventions to promote behavior change can be implemented in HTC settings at facility and community level.

Gender based violence

Evidence world-wide indicates a correlation between HIV and Gender Based Violence (GBV) which includes Intimate Partner Violence (IPV) (Dude, 2011; Makayoto LA, 2013; Abramsky T et al, 2011). Studies in Kenya have shown that it is feasible and acceptable to integrate screening of IPV in HTC services (Sakwa et al., 2014). IPV screening in HTC would reduce continued exposure to HIV through IPV and mitigate negative health outcomes of past and existing IPV experiences. It is important that the HTC service providers be aware of IPV as a one of the possible HIV risk factors and try to identify where such is the case to facilitate appropriate intervention or referral. Whereas feasibility and acceptability of IPV screening have been established, opportunities for appropriate interventions have not been stipulated in any policy guidance in Kenya. The National guidelines on management of sexual violence in Kenya (2009) provides a comprehensive guide on the services that survivors should receive, including clinical management, HIV prevention, psychosocial support and linkage to justice system.



CHAPTER 06

HUMAN RESOURCES



The critical role of human resources in the provision of high quality HIV services cannot be overemphasized. Kenya has a resource of well-trained health care workers but there is a huge disparity in distribution of the same across the country. Task-shifting which is a process of delegating of tasks to less specialized health workers has been recommended as a strategy to increase access to HIV services. This chapter describes the requirements of the personnel involved in the provision of quality HTC services.

It should be noted that delivery of HTS is only possible with concerted team effort. Besides HTC providers and health workers, other team members such as programme managers, administrative staff, data personnel, community mobilizers are required from time to time to support the HTC programme at different levels.

6.1 Who can provide HTC services?

- a) All qualified medical personnel from health care training institutions should be able to provide quality HIV testing and counseling, having undergone training based on any of the NASCOP approved curricular including those listed below;
 - ◆ HTC pre-service training from a recognized medical training institution
 - ◆ Health service workers who have undergone in-service training course in HTC and have been certified by NASCOP in PITC, PMTCT, HTC and / or PMTCT module in the harmonized HIV curriculum or structured OJT for HTC.
- b) Non-medical (Lay) HTS providers who have undergone the HTC training using approved curricular and certified by NASCOP. This category of providers should have completed at least a diploma level course in social or health sciences before training in HTC. They can be engaged to work in the community settings or in the health facility settings where task shifting is applied to supplement the health workers and undertake tasks such as HTC, linkage to care, adherence counseling and support group management.

It is recommended that all those trained in HTC, including those who undergo pre-service training should undertake practical sessions to master competency. They should also undergo refresher trainings or specialized trainings to update their skills to work with special populations such as couples, key populations, children, adolescents, girls and young women, persons with disability and to stay abreast with new developments in the HIV field.

6.2 Who can train HTC?

Trainers must have a minimum qualification of a diploma in social or health sciences, be a NASCOP certified Trainer of trainers and be proficient in HTC. All institutions conducting HTC trainings must have written approval by NASCOP based on assessment using the nationally approved tool. All HTC training must be conducted in accordance with the nationally approved curricular. It is recommended that training on testing/ laboratory component be handled by laboratory personnel who are TOTs.

Roles and responsibilities of staff within the facility

There are various personnel involved in ensuring provision of high quality HTC services including but not limited to facility managers and in-charges, HTC providers and coordinators, laboratory in-charges, health records and information officers (HRIOs), laboratory supervisors and counselor supervisors. It is recommended that all staff work as a team to ensure provision of quality HTC services at all times. It is also important that everyone clearly understand their roles in order for teams to deliver efficiently and effectively.

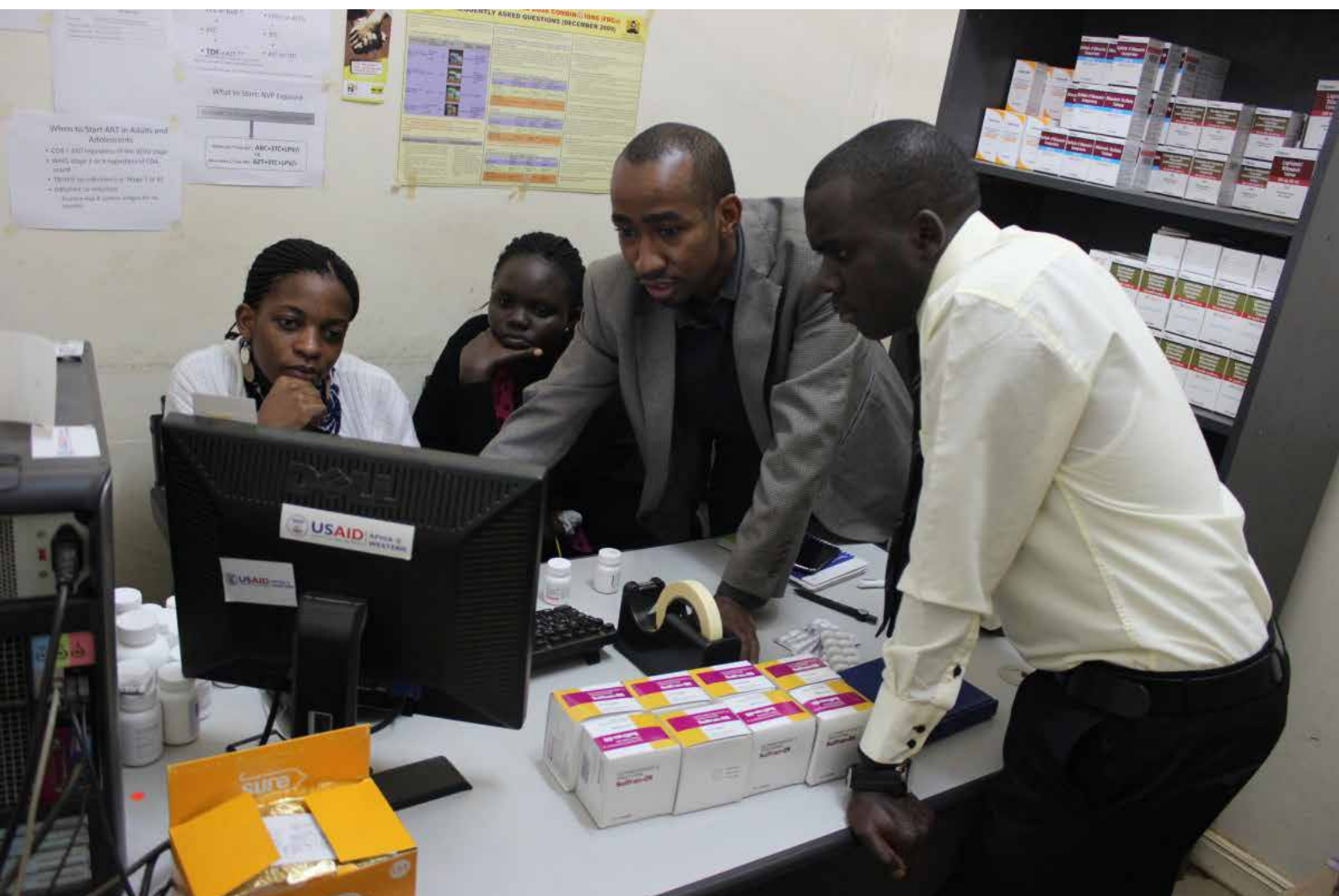
The table below summarizes the different roles and responsibilities of the personnel.

Staff/Cadre	Roles and responsibilities
HTC Providers	<ul style="list-style-type: none"> ◆ Create demand for HTS services through mobilization and health talks ◆ Provide high quality HTS services ◆ Conduct appropriate risk assessment and reduction counseling ◆ Conduct HIV test and give correct results ◆ Provide appropriate referrals and linkages through patient escort where possible and tracking of the referred clients ◆ Manage HTS commodities in accordance with the national guidelines ◆ Record the client and testing data using the nationally approved tools and report appropriately ◆ Within the community, coordinate post-test clubs and support groups ◆ Facilitate evidence informed behavioral interventions (EBIs) ◆ Participate in HTS refresher trainings at least annually
Facility in-charges	<ul style="list-style-type: none"> ◆ Oversee planning, staffing deployment, monitoring and evaluation of HTS services ◆ Ensure HTS services are promoted in the facility through support and administrative supervision. ◆ Ensure adequacy of commodities for HTS ◆ Communicate the HTS performance targets ◆ Ensure availability of conducive space for providing HTS services ◆ Facilitate timely reporting for HTS services and commodities to the relevant offices ◆ Provide regular administrative support supervision ◆ Receive and review facility reports for decision making

<p>HTC Coordinators</p>	<ul style="list-style-type: none"> ◆ Coordinate day-to-day HTS activities in a facility ◆ Assist HTC providers in creating demand for services ◆ Provide mentorship to the HTS service providers ◆ Facilitate and ensure adequacy of commodities for HTS, compilation of commodities reports in the facility from all the HTS service delivery points and timely reporting ◆ Work with the facility quality management team to ensure HTS services are of the highest quality ◆ Ensure effective referral and linkage mechanisms take place ◆ Provide feedback to the facility management on performance of HTS ◆ Facilitate client feedback on quality of services ◆ Ensure HTS providers are trained according to the approved requirements ◆ Ensure HTS providers are enrolled into a proficiency testing program and corrective measures undertaken where necessary
<p>Health records and information officers (HRIOs)</p>	<ul style="list-style-type: none"> ◆ Ensure adequate and necessary data tools for all HTS service delivery points are available in the facility ◆ Orientate all the HTS providers on the tools utilization ◆ Analyze HTS data for decision making and service improvement at facility level ◆ Collate data from the facility and report to the relevant sub-county offices. ◆ Conduct regular data quality audits and support supervision
<p>Laboratory in-charge</p>	<ul style="list-style-type: none"> ◆ Ensure quality assurance for HIV testing ◆ Ensure that all testing SOPs are in place and adhered to ◆ Facilitate observed proficiency testing to ensure adherence to SOPs. ◆ Conduct mentorship of HTS service providers on quality testing ◆ Perform QA audits and PT corrective actions ◆ Ensure accountability for HTS commodities (test kits, DBS commodities, PT panels etc.) management ◆ Ensure timely reporting for commodities consumption and accurate projection ◆ Ensure proper storage and management of testing commodities in accordance with the SOPs
<p>Counselor mentors</p>	<ul style="list-style-type: none"> ◆ Ensure that HTS providers receive regular debrief sessions to mitigate burn out in order to maintain provision of high quality HTS services ◆ Provide mentorship of HTS service providers through one to one or group sessions in the service delivery points ◆ Perform observed sit in sessions to ensure adherence to HTS SOPs ◆ Provide timely feedback to the HTS providers on their performance
<p>Health workers</p>	<ul style="list-style-type: none"> ◆ Inform the patients of the benefits of HTS ◆ Initiate/offer HTS to all the patients ◆ Provide HTS or refer to the HTS provider ◆ Document in the patient file/record the HIV status of the patient ◆ Provide appropriate referral and linkage for post-test services
<p>Community</p>	<ul style="list-style-type: none"> ◆ Participate in demand creation for HTS services ◆ Take up the HTS services ◆ Provide feedback on the quality of services

CHAPTER 07

COMMODITY MANAGEMENT FOR HTS



Uninterrupted supply of HTS commodities is critical for the success of HTS. An effective commodity management system must be put in place to ensure the accessibility of, and effective use, of HIV Rapid Test kits (RTKs) both at the service delivery level and the referral services. Commodity management for HTS should follow well established principles but must be flexible and responsive to varied settings and services offered.

7.1 Quantification

Quantification refers to the estimation of the quantity of commodities (and their costs) required for a specified period (forecasting), and planning when commodities should be delivered (supply planning) so as to ensure reliable supplies. Quantification is typically done at the national level (for the national country needs) and may be done at the county level (for county needs). National quantification for HTS commodities should be harmonized based on the national program needs, and aligned to the county HIV prevalence. At national level, the NASCOP Lab quantification team works with the HTS TWG to undertake quantification annually based on targets set by NASCOP and consumption data from the facilities. This will inform the quantities of commodities to be procured in line with consumption needs. NASCOP then shares the national quantification with the counties, among other stakeholders.

Beyond quantifying for commodities, the counties should quantify the commodity logistics tools required by their facilities, and budget for their printing and distribution. This will ensure that facilities are able to record and report on RTKs.

Commodity Reporting, Facility Ordering, Resupply and Distribution planning

At facility level, the facilities determine the quantities to order so that they are re-supplied as per their usage. All HTC testing points should compile and submit monthly summary of the consumption and stock balance of the Rapid test kits to the facility in-charge or laboratory in-charge to prepare the Facility Consumption Data Report and Request (F-CDRR) form (MoH 643). To record data for inventory management, facilities should keep updated stock cards, Lab Top-up forms and Daily activity registers for Lab commodities (MoH642) for all the Rapid Test Kits (RTKs). At the end of the month, these documents shall be used to generate data for F-CDRR compilation. The F-CDRR is compiled from the stock on hand (across the facility/lab store and all HIV testing points), the consumption and the number of tests done (across all testing points in the facility).

The F-CDRR should be submitted to the sub-county medical laboratory technologist (SCMLT) by every 5th date of the following month. SCMLTs will collate F-CDRR reports for all the facilities in the sub-county and forward to the county level, then to NASCOP. Reporting on consumption of commodities will be coordinated by responsible personnel at all levels, in collaboration with implementing partners.

At the national level, orders management for RTKs is done by the National Lab Allocation committee. The committee utilizes the FCDRRs and the central level stocks at KEMSA allocate RTKs based on facility consumption rates. The Allocation list is first shared with the County Medical Laboratory Technologists (CMLTs) so as to inform them on what NASCOP plans to issue to their facilities, and to obtain any comments.

Afterwards, the Allocation list is shared with the Kenya Medical Supplies Authority (KEMSA) who then pack and distribute the RTKs to the health facilities in the counties. KEMSA is required to share the RTK distribution list with NASCOP and the County Medical Laboratory Technologists (CMLTs) so as to inform them what KEMSA actually supplied their facilities per county and sub-county. The CMLTs should in turn share the same list with the Sub-County Medical Laboratory Technologists (SCMLTs) who will monitor the RTK consumption and reporting at Sub-county level. It is recommended that the distribution list be shared with the facility level so as to have relevant feedback on what the facility was issued by KEMSA and what the facility actually received.

Procurement

Standards defining the appropriate performance characteristics of HIV test kits shall be set by a committee of experts appointed by the MoH or a responsible ministry institution. All commodities procured for HTC in Kenya shall be approved and registered for use by the MoH.

KEMSA is the agency primarily responsible for procurement of HIV test kits in Kenya, based on funding provided through GoK, Global Fund, PEPFAR and other donors. Other institutions may also procure HIV test kits for their use as long as they are approved for use in the National Algorithm. For KEMSA, procurement will be done in accordance with existing GoK/MoH procurement regulations, and in consultation with NASCOP. NASCOP also provides the technical specifications used for procurement. The procured HIV testing kits should have a long shelf life of at least 6 months at the time of delivery to the facilities. All other HTC commodities (gloves, disinfectants, etc) should meet the set specifications before being procured and accepted.

NASCOP and KEMSA together will maintain a procurement plan showing the quantities under procurement from all funding sources and plans for additional stocks to ensure the country is adequately stocked.

Warehousing and Distribution management

KEMSA shall distribute test kits to the Counties or facilities, based on the allocation list provided by NASCOP, through an established distribution mechanism.

In addition, KEMSA will maintain adequate stock of rapid HIV test kits for back-up distribution when needed. KEMSA will also provide to NASCOP, on monthly basis, the stock balances in its warehouses, list of HTC commodities received, list of HTS commodities issued/distributed to facilities, and the status of any on-going or planned procurements. This is to assist NASCOP in planning and HTC program management.

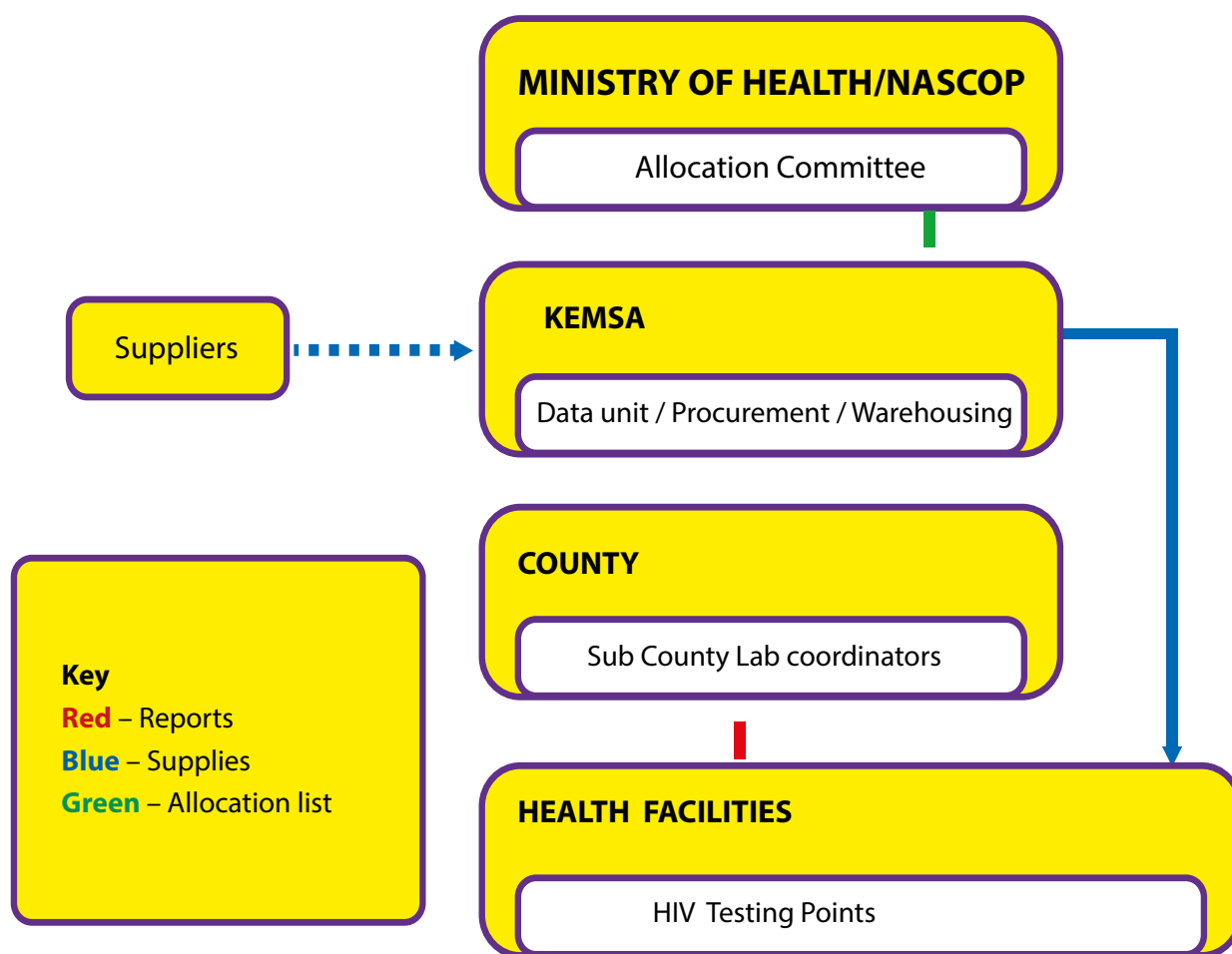
A regular audit of the supply chain management systems for HIV kits will be undertaken to prevent stock-outs, overstocking and pilferages as well to identify operational weaknesses that may require strengthening. The above system will also apply to other HTC related supplies including the commodity data tools, consumables, QA materials, etc.

Peripheral re-distribution: At the county level, the CMLT, CASCO and other health officials should assess the stock status of their facilities on at least quarterly basis. Re-distribution of RTKs for facilities with more than 6 months' of stock (based on their consumption) is advisable to minimize potential expiries. The stock should be taken to facilities with low stock levels or high usage. NB: To ensure accountability, any re-distribution must be recorded in the stock records of the issuing facility and the receiving facility; and must be only undertaken by an authorized official. Where redistribution of Rapid HIV test Kits is required; the laid down procedure and documentation should be utilized at all levels.

Storage

Test kits and other HTC commodities should be stored and managed as per the Laboratory commodity management guidelines which must at a minimum follow the manufacturer's instructions to ensure high quality of HIV testing. Storage conditions should be maintained and monitored at all health care levels, including during transportation. It is necessary to procure and utilize temperature and humidity regulated storage equipment such as refrigerators where applicable.

Figure 7.1: Commodity Consumption Report and Supply chain flow chart



7.2 Quality logistics management

Quality logistics management aims at ensuring commodity security; where commodities are in the right conditions and are available at the Testing points when needed. Cost efficiency is also achieved when expiry of commodities is minimized through quality logistics management. Measures to ensure quality logistics management include:-

- ◆ Utilization of a “pull” system where commodities are supplied based on the reports from the facilities who based their orders on their consumption and stocks
- ◆ Timely and accurate reporting at all levels: Consumption data from the various Testing points in the health facility will be analyzed by the laboratory or facility in-charge, and together with the stock at the facility, are used to form the basis for the facility’s order for more supplies. This report will be sent to the sub county level for onward transmission to the county level and then the national level, preferably by electronic reporting. All the counties will be expected to compile electronically the aggregated consumption, stock and orders from their various facilities and then rationalize the facility orders based on the provided data. These rationalized facility orders should be transmitted electronically to the national level where harmonized commodity allocation and distribution will be done.
- ◆ Commodity audits: regular comparison of service and commodity data should be done to evaluate the utilization and reporting for HTC commodities. These audits will also help to identify stock outs, expiries and pilferages; and provide corrective actions
- ◆ Use of standardized national inventory management and commodity reporting tools will ensure data is collected and reported routinely
- ◆ Counties should undertake regular supportive supervision exercises that check on commodity management. They should also conduct data review meetings involving the SCMLTs and facility data, so as to check on data quality and improve data use at county level
- ◆ Inventory management SOPs should be adhered to.



CHAPTER 08

QUALITY ASSURANCE



8.0 Introduction

Quality is a critical dimension of social justice and human rights principles and forms one of the pillars of a viable and sustainable healthcare system, Kenya Quality Model of Health 2011). The Constitution of Kenya in the chapter on Bill of Rights is clear on the need to address the expectations of citizens on the right to the highest attainable standards of health (Kenya Constitution, 2010). Therefore, it is imperative that the quality of HTS services is addressed through simple and practical approaches at all levels. QA should be an integral part of all the HTS and should be implemented during testing, counseling, commodity, human resource and data management. All stakeholders should have a systematic and planned approach to monitor QA on a continuous basis.

8.1 Benefits of Quality Assurance

- ◆ Ensures that the client gets a true test result
- ◆ Ensuring coherence and smooth functioning through various levels of service delivery
- ◆ Ensuring that the needs and expectations of clients and communities are being met
- ◆ Focusing on the processes and how service delivery can be improved
- ◆ Enabling standardization to ensure an acceptable level of quality services
- ◆ Encouraging a multidisciplinary team approach
- ◆ Lowering the operational cost for delivery of services

In order to ensure that maximum benefits of quality assurance for HTC are realized, the components of quality assurance listed below should be put in place.

8.2 Components of HTS Quality Assurance

i. Certification of HTS providers

Health service providers who receive HTS pre-service training will be certified by the health training institutions while those who undergo in-service HTC training will be certified by NASCOP. It is recommended that those health providers who undergo pre-service training undertake practical sessions (such as during internship) to acquire competency in HTC. Non-medical HTC providers who undergo HTC training must have NASCOP certification and should possess a minimum of Diploma qualification in health or social sciences.

ii. Continuous capacity development

After training, medical and non-medical HTC/S providers should receive continuous capacity development. Capacity development for health care workers can be monitored through a Continuous Professional Development (CPD) scheme in line with the relevant professional bodies.

It is recommended that all HTS providers should undergo continuous capacity development through annual refresher hands on training in order to ensure their competency is maintained. Annual hands on refresher trainings are also geared towards providing updates to HTS providers including on areas such as new policies, research, procedures and technologies. Mentorship of HTS providers should be done by

experienced HTC providers and technical persons using the nationally approved tools. Technical support for HTC services should also be provided regularly by the County and sub-county teams in consultation with NASCOP. Trained providers who have not practiced for more than a year should undergo refresher trainings before they resume HTC service delivery.

iii. **Quality assurance in HIV Testing**

Test kits that need to be considered for in country evaluation must have been approved by WHO and other internationally recognized bodies. In Kenya QA in testing begins at the national level with the evaluation, approval, and registration of HIV test kits. The coordination of test kits' evaluation will be done by the NHRL and the evaluation will be conducted in accredited laboratories. A national testing algorithms and strategy will be developed by the MoH from a list of

It is mandatory for all HTC service providers to undergo refresher training once a year and show evidence for it.

the approved kits which must be strictly adhered to. All testing sites should ensure that they have all the required test kits before they offer services.

Standardized testing procedures (STPs) are developed at national level and disseminated to ensure that testing procedures are performed similarly at all sites. These STPs should be available, understood and adhered to at all testing sites. All recommended quality control measures must be evaluated during the entire testing process. SOPs will be updated on a regular basis to reflect the most current testing procedures, and information inserts found inside HIV test kits should always be consulted for changes in test kit protocols. External quality control (using known HIV positive and negative samples) should be carried out at the county or facility level for all new kit lots, new kits consignments, and when storage facilities change.

◆ **Internal quality control at service delivery point**

Quality assurance in counseling

The counseling component of HTC provides the basis for HIV prevention, care and treatment. It prepares clients and patients to receive their HIV test results and to make necessary adjustments. It is therefore imperative that counseling services in HTC are comprehensive and effective. The prerequisites for comprehensive and effective counseling are quality training and supervision. Besides these the quality of counseling should be ensured through other mechanisms that include support supervision, peer supervision, client satisfaction surveys, and observed practice sessions. The length of counseling sessions may vary depending on the specific needs of the client (see the counseling protocols chapter). However, every HTC session should be client-centre, open, non-judgmental interaction between the HTC provider and the client seeking to provide emotional and social support for clients or patients.

◆ **Counseling support supervision**

Counseling support supervision/ debriefing is important for preventing 'burn out' of individual HTC service providers and maintaining high quality communication between providers and clients or patients.

Who is a HTC counselor supervisor? This is a qualified HTC provider who is experienced in HTC and has undergone a counselor supervision training a nationally approved counselor support supervision curriculum. It is recommended that each facility should have at least one HTC counselor mentor.

Supervision/debriefing is an opportunity for HTC service providers to discuss and process issues that arise during HTC with a qualified and experienced HTC supervisor either during group or one-on-one sessions. Supervision/ debriefing should be offered by a trained and qualified counselor supervisor to HTC service providers on a regular (at least quarterly) basis. It should be noted that counselor support supervision is different from administrative support supervision offered by the health management teams.

Counselor self-assessment

Counselors may also wish to employ the use of standardized NASCOP approved self-reflection forms to monitor the quality of their own service provision overtime. The counselors will be expected to fill self-assessment forms and analyze them by the end of the day. Improvements should be done on the weak areas identified for quality service provision.

Client satisfaction surveys

HTC sites and facilities should administer client satisfaction surveys quarterly 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, counselor attitude, and overall satisfaction with the service. Feedback from client satisfaction surveys should be shared with HTC service providers, and adjustments should be made to improve the quality of HTC service provision accordingly. Facilities should provide suggestion boxes for collection of anonymous client feedback. Face-to-face client feedback should also be encouraged.

Observed practice

A plan needs to be in place on the implementation of the observed practice (sit-inn) in all HTC settings by a trained and experienced counselor supervisor or more experienced service provider which is shared and agreed upon by other counselors. Observed practice is achieved when, with the consent of the client a HTC service provider is observed during the process of service provision. The observer may either do it in person or by video-taping the HTC session. 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. 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. Confidentiality should be observed by all parties.

◆ External quality assessment (EQA)

Measures will be implemented to allow for the assessment of the service delivery points quality of services. These measures will assist in identification of testing sites performing below standards so that measures can be instituted to improve their performance. EQA can be done in three complimentary ways;

Proficiency Testing (PT):

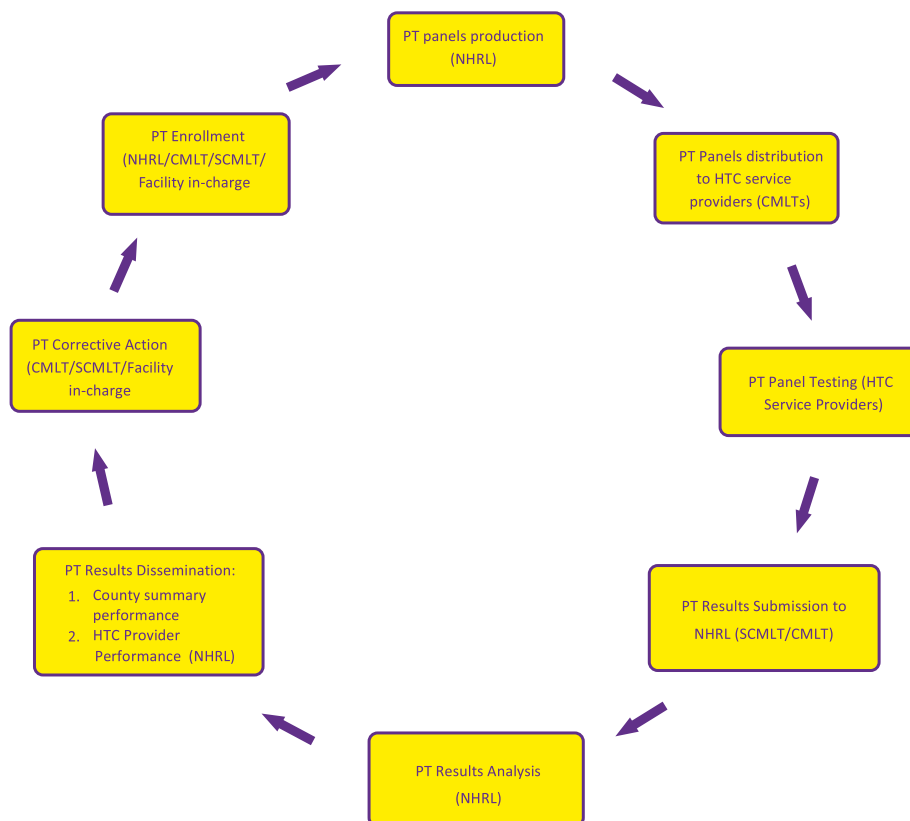
This is an evaluation to determine the competence of a service provider. PT involves the distribution of blinded panels of well characterized test samples which are sent to all enrolled individuals service providers periodically (two to three times a year) NHRL will coordinate the PT EQA scheme, produce the PT panels, enroll individual HTC providers and analyze PT performance. Testing should be done in accordance with the national HIV testing algorithm adhering to HIV the testing SOPs in adherence to the national testing algorithm. Results obtained should be submitted to the National HIV Reference Laboratory for performance evaluation using the channels determined by the NHRL. NHRL shall prepare a summary of PT participants' performance per county to enable the CMLTs execute appropriate corrective actions at facility level in liaison with HTC implementing partners. Feedback reports outlining the performance and suggested / trouble shooting procedures will then prepared and transmitted to the participants through the facility in-charges. Participants who post unsatisfactory performance should use the PT feedback as an opportunity to investigate the root causes and carry out appropriate QA interventions or corrective actions to ensure that the identified QA deficiencies do not recur. Providers with incorrect PT results should be provided with on the job training and mentorship. -

CHMTs should ensure that all providers who receive PT panels conduct the test and submit the results on time.

HTC providers whose performance is unsatisfactory for two consecutive PT cycles after institution of corrective action measures, will be required to undergo refresher training before they can resume HTC service delivery. PT panels addressed to participants who transferred or are on leave should be processed and tested by any other certified HTC service provider who is not enrolled on PT to avoid wastage. This will also present an opportunity for PT enrollment for the trained HTC service provider.



Fig 8.1: Proficiency Testing Cycle



Dry blood spot validation:

This involves a process in which samples from a proportion of clients tested at HIV service delivery point using HIV rapid method are collected and submitted for testing at the reference lab using the gold standard method e.g. ELISA for validation of results by comparing testing sites and reference lab results. DBS validation will be done only limited to;

- » Home-based testing providers
 - » Newly registered HTC sites
 - » Providers who obtain incorrect results in PT until they obtain satisfactory performance.
- ◆ On site quality management (QM) assessment: This involves periodic site visits to systematically assess the sites' HIV testing quality practices. The visits focus on how the sites monitor their operation and ensure testing quality and also provide information for internal process improvement. On site visits should be part of every site's quality system as they provide opportunity to learn "where we are", to identify gaps or deficiencies, and collect information for planning and implementation, monitoring and continuous improvement. They are necessary in order to confirm that all SOPs and other testing protocols are available and adhered to including QC, troubleshooting procedures, record keeping and observation of staff performance, test kit management, and kit performance data. If possible it should additionally provide opportunity to administer observed PT to each individual who performs testing. The use of a standardized checklist and evaluation methods is recommended in order to allow for collection and comparison of information from multiple sites consistently.

◆ Use of HTC Lab Register data for Quality monitoring and improvement

Data from the HTC standardized tool (the HTC Lab Register) should also be analyzed for use as an ongoing quality monitoring and improvement tool. It has the capabilities of monitoring:

- » Adherence to the national algorithm
- » Test performance (Agreement levels between test one and test two and test results invalidity levels)
- » Change in trends of HIV positivity rates
- » Test kits management

These data should be analysed on a periodic basis and corrective action done in a timely manner.

Other QA Approaches

Data quality management

Data is critical in informing and directing programme activities and hence provision of quality HTC services. Quality data should be accurate, complete and timely in order to make informed decisions. Standardized tools for HTC data collection and management shall be used in all service delivery points (approved by MOH). All service providers should read and understand instructions before filling the registers. Service providers should be well trained on data collection tools and sensitized on the reporting systems. Data quality audits (DQA) should be carried out at all levels of service provision regularly to assess the level of data quality, identify gaps and develop improvement measures. Data analysis should be done at the various levels and feedback provided to all stakeholders.

Quality Improvement Teams (QIT)

At the national level, the NQIT led by NASCOP is tasked with formulating and updating QA policies and frameworks in Kenya. At the county levels, QI teams will be responsible for overseeing the implementation of QA strategies. HTC facilities should have their own QA systems in place in accordance with national and county guidance. It is the role of the QIT to address clients' complaints within the facility.

QIT membership should take into consideration the representation of all stakeholders at various levels. Individual HTC service providers are also responsible for delivery of high quality HTC services to clients and communities, according to the defined standards. Whenever possible, QA for HTC services in health facilities should be integrated into other ongoing QA activities at the facility

Infection prevention and control

All biosafety and infection prevention control measures should be available and adhered to. Biosafety guideline and SOPs should be available in all service delivery points. Infection prevention control measures should be followed in all HTC settings. The testing facility shall ensure availability of personal protective equipment (such as gloves, lab coats), appropriate disinfectants, and running water to ensure optimal infection prevention to the service providers, clients and the community. Waste segregation and disposal should be practiced in accordance with the recommended biosafety guidelines. Infection prevention

control measures should be followed in all HTC settings. Sharps should be disposed of in designated sharps containers. HTC providers and support staff involved in handling and disposing hazardous waste should be adequately trained on infection prevention control and immunized against blood borne infections, at a minimum Hepatitis B Virus Vaccine (HBV). PEP protocols should be available in all the testing sites. The testing room should be well ventilated and illuminated. The above shall apply to both facility based HTC and community based HTC settings.

Additional Quality Assurance Processes

◆ Adoption of new technologies

The National Public Health Laboratory Service (NPHLS) 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 capacity-build the county trainers through refresher training. Some examples of new technologies in HIV testing include the use of oral fluid testing and urine testing.

◆ Evaluation of HIV test kits

NPHLS shall provide technical guidance in consultation with NASCOP on evaluation of individual test kits for approval and participate in the designing of the national testing algorithm. The approval will be done by a committee of national experts appointed by the MoH. Before approval, the test kits will be subjected to a rigorous process of evaluation in national level laboratories to ensure that they meet the expected performance standards. No test kit will be allowed for use in Kenya unless it has been approved and it is part of the national testing algorithm.

◆ New lot verification

This is to obtain evidence based appraisal of the incoming new kits against the ones in use to ascertain performance consistency between different lots from the same manufacturer and hence the reliability of test kits being received. The activity provides immediate means of collective actions in case of significant variations in performance. NHRL will be responsible for new lot verification prior to the release of kits from KEMSA into circulation.

◆ Post-market surveillance

The laboratory service will carry out a periodic random assessment of the HIV test kits that are used in the country. This will be done by carrying out a proactive collection of information on quality, safety and performance of test kits after they have been placed in the market to ensure that test kits being used in the field are of the highest quality. This function will be coordinated by NHRL, following approved protocols.

CHAPTER

09

HTS PROMOTION ACTIVITIES



Promotional activities are an essential component and are necessary for increasing awareness, acceptability, demand and utilization of HTC services. Additionally, they aim at advocating for increased resource allocation, formulation of policy and mainstreaming HTC in health service delivery. Promotional activities for HTC include communication, advocacy, capacity building and HTC campaigns.

9.1 Communication

Communication guidelines for the HTS program are drawn from the draft National HTC Communication Strategy 2015-2019 and the Health Promotion Strategy for Kenya 2013-2018. These guidelines provide a broad framework that will guide communication on HTS in Kenya. In line with the health promotion strategy for Kenya, these guidelines emphasize the strengthening of the stewardship role of the national government, working in synergy with county governments in implementation of health promotion approaches that address the risk factors and behavioral determinants associated with communicable and non-communicable diseases.

National level

The national level will be responsible for providing direction on communication nationally through identifying target audiences as well as national communication priorities, based on the latest available research data. At national level through the national technical working group and communication sub-committee, national communication campaigns will be developed to be distributed across various platforms (TV, radio, digital, newspapers and community based approaches). It will also develop guidelines on how the campaigns can be localized and adapted in order to be implemented at county and sub-county levels, using local mass media and interpersonal communication channels.

County level

Counties will be responsible for adapting already developed communication from the national level to ensure they are locally relevant. They will also be responsible for development of communication based on local needs. This will be executed through local media, including local / vernacular radio and TV stations, local newsletters, etc. The counties will also be responsible for ensuring that communication is cascaded through local channels such as the community strategy. Each county will be responsible for identification of their target population and their communication needs as well as designing appropriate messages for the respective target groups. The county governments should further coordinate the efforts by implementing partners to avoid duplication and wastage of resources in as far as communication initiatives are concerned.

Channels / modes of communication

Communication channels include but are not limited to the list below. Guidance on how to optimize the use of these channels is provided in detail in the HTC/S Communication Strategy 2015-2019.

- ◆ Print media: Newspapers, bill boards
- ◆ Electronic media: TV, radio, social media, text messaging
- ◆ IEC materials: Flyers, posters, pamphlets, booklets
- ◆ Community mobilization: meetings, barazas, community events

9.2 Advocacy

Advocacy should target everyone and especially the following leaders;

- ◆ Religious
- ◆ Administrative
- ◆ Political
- ◆ Business
- ◆ Other opinion leaders such as teachers, women and men group leaders

Advocacy efforts should also target the education sector to ensure integration of HIV education in the school health programmes. Workplace programmes across all sectors should include HTC. Leaders and partners at all levels should carry out advocacy for political and financial support and for promotion of HTC services. Advocacy will ride on national health days, civil servants week, local cultural events and agricultural shows to promote HTC.

Capacity building in HTS promotion

The national level which includes NASCOP and the Health Promotion Unit (HPU) will build the capacity of the counties while counties will be responsible for building the capacity of the lower levels to carry out promotion of HTC.

HIV Testing and Counseling campaigns (Rapid Results Initiative)

HTC RRI campaigns aim at promoting HTC uptake to a large number of people over a short duration. This is achieved by intensifying HTC activities using different approaches. Additionally, campaigns improve the visibility of the program, enhance knowledge and attitude about HTC and break down perceived barriers to HTC provision and uptake. During the campaigns, some of the principles and procedures of HTC may be modified with guidance from NASCOP so as to achieve the targets. Campaigns will be implemented at national and county levels and will be targeted to various populations based on identified priorities which vary with time and place. National campaigns will focus on identified national priorities. NASCOP will plan, guide and coordinate national campaigns which will be implemented in collaboration with counties. County campaigns will focus on issues specific to their counties in respect of gaps in service coverage and epidemiologic trends, among others. Quality assurance should be adhered to during these campaigns. Measures should be put in place to refer and link those who test HIV positive and high risk HIV negative persons to prevention, care and treatment services as appropriate. Clients in need of other services such as ANC, FP, TB testing and treatment, GBV and other services should also be referred as appropriate.

HTC promotion in health care settings

HTC promotion should be done in health facilities focusing on providers, health managers and clients. Among health care providers and managers promotion will aim at mainstreaming HTC within routine care, and increase ownership. Promotion will also target individuals accessing health services and their families to increase HTC acceptability and uptake.

These activities include:

- ◆ Inclusion of HTC in the facility service charter
- ◆ Setting of departmental targets
- ◆ Inclusion of HTC in HCWs Job descriptions
- ◆ Display of signage and IEC materials for HTC services
- ◆ Health education e.g. health talks and one-on-one sessions
- ◆ Continuous professional development sessions

CHAPTER 10

COORDINATION, MONITORING & EVALUATION



Successful implementation of HTC program requires effective coordination, coupled with robust monitoring and evaluation systems. This should happen at all levels of the health system.

10.1 Coordination

The coordination of HTC services is multi-faceted and multi-level, with responsibilities spanning national, county and lower level structures. At each level, various bodies are responsible for various functions as listed below.

Level	Body/ institution	Roles and responsibilities
National	NACC	<ul style="list-style-type: none"> ◆ Strategic guidance on the HIV response ◆ Multi-sectoral coordination ◆ Resource mobilization ◆ Advocacy ◆ HTS promotion
	NASCOP	<ul style="list-style-type: none"> ◆ Development and dissemination of policy documents ◆ Technical assistance and capacity building of counties ◆ Implementing Partner coordination ◆ Leadership of national technical working groups ◆ Monitoring trends of the HIV epidemic ◆ Performance monitoring and reporting (national and international) ◆ Development of M&E tools and indicators ◆ Development of training curricular ◆ Technical guidance on procurement and supply chain management ◆ Carrying out coordinating and disseminating research ◆ Resource mobilization ◆ Quality assurance ◆ HTS promotion activities
	NHRL	<ul style="list-style-type: none"> ◆ National quality assurance <ul style="list-style-type: none"> » EQA through PT and DBS validation » Test Kit validation » New lot verification » HIV test kit post market surveillance ◆ Supplemental and specialized testing including EID, P24 antigen, PCR, etc. ◆ Development of training material for HIV testing ◆ Technical assistance and capacity building of counties in HIV testing ◆ Performance monitoring and reporting on HIV testing quality indicators
	KEMSA	Procurement, warehousing and distribution of HTC commodities
	HIS	<ul style="list-style-type: none"> ◆ Development of data collection and reporting systems ◆ Data warehousing and management ◆ Registration of M&E tools ◆ Data quality audits

County	CHMT	<ul style="list-style-type: none"> ◆ Management of service delivery ◆ Human resource management ◆ Training of health care workers ◆ Monitoring of county HIV epidemic trends and program performance ◆ Forecasting, quantification and data management of HTC commodities ◆ Ware housing and distribution of HTC commodities ◆ Printing and distributions of M&E tools and the nationally recommended IEC materials ◆ Development and revision of indicators ◆ Infrastructure for HTC services ◆ Data quality audits ◆ Participate in EQA ◆ HTS promotion activities
	Sub-county HMT	<ul style="list-style-type: none"> ◆ Reporting through DHIS ◆ Supervision of service delivery ◆ Data quality audit ◆ Participate in EQA ◆ HTS promotion activities
	Health facility	<ul style="list-style-type: none"> ◆ Provision of quality HTC services ◆ Performance monitoring and reporting ◆ Commodity management and reporting ◆ Human resource management ◆ Data quality audit ◆ Participate in EQA ◆ HTS promotion activities
	Community level organizations	<ul style="list-style-type: none"> ◆ Community mobilization and advocacy ◆ Provision of quality HIV services ◆ Data collection and reporting ◆ HTS promotion activities

10.2 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.

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 trend, which can guide priority setting and resource allocation at the local, county and national level. M&E data can also be used to answer critical questions about Kenya's HIV epidemic at the service delivery, county, national, or international context. This data also forms a basis for research hence it is critical that the quality of data is assured at all levels.

Monitoring and evaluation involves

- ◆ Routine HTC data including linkage to care and treatment
- ◆ Periodic surveillance data tools
- ◆ National M&E tools should be used for HTC data collection and reporting at all levels; HTC Lab registers, client referral forms, reporting/summary forms, DHIS.

It is the responsibility of the county government to ensure continuous availability of the national M & E tools at all service delivery points.

Data demand and information use

It is the responsibility of HTC service providers to understand and use HTC data to improve the services. Further, it is the responsibility of managers at facility, sub-county, county and national structures to analyze and use this data to monitor quality of services, trends and allocate resources.

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

Counties have the responsibility to build capacity for data analysis and use for health service providers and managers in their counties. Data sharing forums are encouraged at all levels.

Service providers

All service providers should be trained / oriented on data collection, reporting and analysis. Service providers should be oriented on tools and indicators to enhance their understanding and correct use.

Data quality audit (DQA)

The importance of quality data cannot be overemphasized as it is critical for correct interpretation of data. It is the responsibility of all levels; service providers and managers at all levels to ensure accurate documentation and reporting as per data management guidelines.

DQA should be conducted at all levels with emphasis on completeness, accuracy, consistency and timeliness in reporting:

1. At service delivery level health care workers should use available instructions to complete tools daily
2. At sub-county level, DQA should be conducted on a monthly basis
3. County health managers should conduct quarterly DQA
4. National level DQA should be conducted quarterly

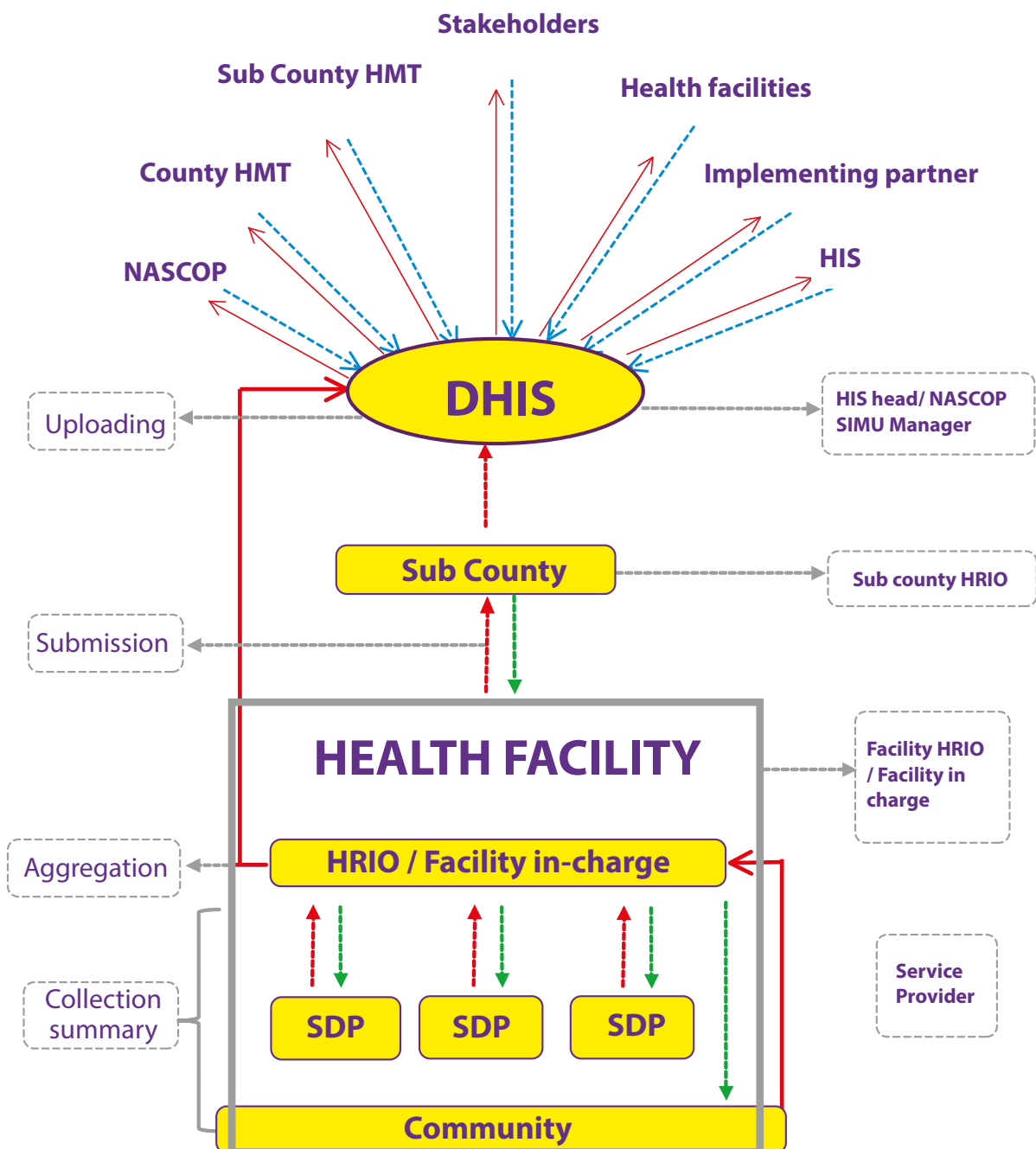
Confidentiality of medical records

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. Results of all HIV tests should be systematically recorded as well as the details of all the test kits used. Records must be kept confidential and in lockable storage location that is only accessible to authorized persons .

Data flow:

Data should flow from the service delivery points up to DHIS from where all stakeholders will access it as illustrated in the flow diagram below. Service providers will complete data collection tools, from which they will generate service delivery point monthly summaries. These summaries will be forwarded to the facility HTC coordinator or designated person to aggregate and forward to the HRIO or designated person. The HRIO or designee will enter the data into DHIS or forward to the sub-county HRIO for entry into DHIS within the stipulated time. The HRIO at the facility and sub-county should ensure the data is validated before entry into the DHIS.

Fig 10.1: Data Reporting Flow



KEY

- Red** solid arrow: Data flow from community, service delivery level to national (DHIS) and finally to stakeholders
- Green** dotted arrows: Feedback from records officer/ facility in-charge/ sub-county HRIO
- Blue** dotted arrows: Feedback from stakeholders to DHIS

Fig 10.1 Footnote

- ◆ Service delivery point(SDP) refers to a station within facility where HTC services are offered
- ◆ Community outreach service delivery points include HTS conducted in mobile, workplace, home based care and home based testing and counseling activities etc.
- ◆ HTS in Health facility also includes stand-alone HTC sites
- ◆ DHIS is a web-based data repository which contains facility level aggregate data and can be accessed by various stakeholders



REFERENCES

- ◆ Abramsky T, Watts CH, Garcia-Moreno C, Devries K, Kiss L, Ellsberg M, et al. What factors are associated with recent intimate partner violence? Findings from the WHO multi-country study on women's health and domestic violence. *BMC Public Health* 2011, 11:109.
- ◆ Dude AM. Spousal intimate partner violence is associated with HIV and Other STIs among married Rwandan women. *AIDS Behav* 2011; 15(1):142-152
- ◆ Government of Kenya (GOK), Ministry of Medical Services and Ministry of Public Health and Sanitation. Kenya quality model for Health 2011
- ◆ Government of Kenya (GOK), the constitution of Kenya, 2010. Nairobi Kenya, 2010
- ◆ Government of Kenya (GOK). Kenya HIV, Prevention and Control ACT, 2006
- ◆ Government of Kenya (GOK). Children's Act. Nairobi, 2001. Available online at www.kenyalaw.org. Accessed on: July 6, 2014
- ◆ Government of Kenya (GOK). Public Health Act. Nairobi. Available online at www.kenyalaw.org. Accessed on: June 22, 2014
- ◆ Government of Kenya, The Children Act, 2001
- ◆ Government of Kenya, The HIV and AIDS Prevention and Control Act, 2006
- ◆ Government of Kenya, The Sexual Offences Act, 2006
- ◆ Kalibala S, et al, Factors associated with the acceptability of HIV self-testing among health care workers in Kenya AIDS and behavior, Population council; 2014
- ◆ Kalibala S, Tun W, Muraah W, Cherutich P, Oweya E, Oluoch P. "Knowing myself first": feasibility of self-testing among health workers in Kenya. Nairobi, Kenya: Population Council; 2011.
- ◆ Kenya National Bureau of Statistics (KNBS) and ICF Macro. Kenya Demographic and Health Survey 2008-09. Calverton, Maryland: KNBS and ICF Macro, 2010.
- ◆ Ministry of Health (MOH), EMTCT national communication strategy 2012: available on [http://nascop.or.ke/library/pmtct/EMTCT on 20th July 2014](http://nascop.or.ke/library/pmtct/EMTCT%20on%2020th%20July%202014)
- ◆ Ministry of Health (MoH), Guidelines for Prevention of Mother to Child Transmission (PMTCT) of HIV in Kenya. 4th edition, 2012.
- ◆ Ministry of Health (MoH), The Medical Laboratory Act, 1999
- ◆ Ministry of Health (MoH); National AIDS and STI Control Programme (NASCOP). Guidelines on the use of Antiretroviral drugs for treating and preventing HIV infection: A Rapid advice; June 2014
- ◆ Ministry of Health. [Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines \(PDF as of 13 June 2006\)](#)
- ◆ Ministry of Public Health & Sanitation and Ministry of Medical Services, National Guidelines on management of sexual violence in Kenya. 2nd edition, 2009. Nairobi, Kenya

- ◆ MoH, National guidelines on management for survivors of sexual violence, 2009
Nairobi Kenya: NASCOP; 2008
- ◆ National AIDS and STD Control Programme. Preparedness for HIV/AIDS service delivery: the 2005 Kenya health workers survey. Nairobi, Kenya: Kenya Ministry of Health; 2006. Available at <http://popcouncil.org/pdfs/horizons/KenyaHealthWorkerSurvey.pdf>. Accessed 2011
- ◆ National AIDS and STI Control Programme, Ministry of Health, Kenya. July 2008. Kenya AIDS Indicator Survey 2007: Nairobi, Kenya
- ◆ National AIDS and STI Control Programme, Ministry of Public Health and Sanitation, Kenya. Guidelines for HIV Testing and Counseling in Kenya
- ◆ National AIDS and STI Control Programme, Ministry of Public Health and Sanitation, Kenya. Guidelines for HIV Testing and Counselling and Kenya. Nairobi: NASCOP; 2008
- ◆ National AIDS Control Council (NACC) Kenya National AIDS Strategic Plan 2009/10-2012/2013
- ◆ National AIDS Control Council (NACC) Kenya HIV Prevention Revolution Road Map, 2014
- ◆ National AIDS/STI Control Program (NASCOP). Guidelines for Antiretroviral Therapy in Kenya. 4th Edition. Nairobi, Kenya: 2011. Online available 20 July 2014 at <http://nascop.or.ke/library>
- ◆ National Blood Transfusion Service of Kenya (NBTS). Policy Guidelines on Blood Transfusion in Kenya. Ministry of Health, Republic of Kenya. Nairobi, 2006
- ◆ National Leprosy and Tuberculosis Programme of Kenya (NLTP). National Tuberculosis and Leprosy Guidelines. Ministry of Health, Republic of Kenya. Nairobi, 2006
- ◆ National STI and AIDS Control Programme (NASCOP) and National AIDS Control Council (NACC) Kenya national Prevention Revolution Roadmap, 2013
- ◆ National STI and AIDS Control Programme (NASCOP), Kenya AIDS Indicator Survey (KAIS), 2012 Nairobi Kenya, 2014
- ◆ National STI and AIDS Control Programme (NASCOP). Kenya AIDS Indicator Survey (KAIS) 2007 Nairobi Kenya: NASCOP 2009
- ◆ Sakwa. E, Kilonzo. N, Karuga, Gatuguta, A. Prevalence, Acceptability and feasibility of Intimate Partner Violence (IPV) screening and support in community Voluntary Counselling and Testing (VCT) settings HIV programs; LVCT Health study report, 2014
- ◆ United Nations (UN). Convention on the Rights of Persons with Disabilities, 2006. UN. Geneva 2006.
- ◆ WHO, Consolidated guidelines on the use of Antiretroviral drugs for treating and preventing HIV infection; 2013
- ◆ WHO, Service delivery approaches to HIV testing and counselling (HTC): a strategic HTC programme framework - available at http://www.who.int/hiv/pub/vct/htc_framework/en/ on September 4, 2014
- ◆ World Health Organization (WHO), Delivering HIV test results and messages for retesting and counseling in adults, 2010.

ANNEXES

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ANNEXES



Appendix One: Client Referral Form

Serial No: _____

Name _____ Client No. _____

DOB(dd/mm/yy) _____ Age _____ Sex: Male Female

Physical Address _____

Mobile No _____ Pregnant Yes No N/A

Marital Status Single Married Monogamous Married Polygamous Cohabiting Divorced/Separated Widow/Widower

Referred From (Facility / Organization & SDP)	Referred To (Facility / Organization & SDP)
MFL Code:	

Reason for Referral (Tick Appropriate service).

<input type="checkbox"/> HTC <input type="checkbox"/> VMMC <input type="checkbox"/> ANC / PMTCT <input type="checkbox"/> Early Infant Diagnosis (EID)/HEI follow up <input type="checkbox"/> Care and Treatment (ART, OI treatment, Prophylaxis, default on treatment, Adherence Counseling etc) <input type="checkbox"/> TB	<input type="checkbox"/> Family Planning <input type="checkbox"/> STI <input type="checkbox"/> Post Exposure prophylaxis (PEP) <input type="checkbox"/> Nutrition Services <input type="checkbox"/> Psycho-social Support (Including Support Groups) <input type="checkbox"/> Home-based Care <input type="checkbox"/> Drug and Substance Abuse Counseling Services	<input type="checkbox"/> Behavior Change Communication Program <input type="checkbox"/> Child Care Services (include OVCs) <input type="checkbox"/> Social Welfare Services <input type="checkbox"/> Legal Services <input type="checkbox"/> Others ()
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Clinical Information			
Date Last Tested		HIV Test Result	<input type="checkbox"/> N <input type="checkbox"/> P <input type="checkbox"/> Exposed <input type="checkbox"/> Unknown
WHO Stage	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> N/A <input type="checkbox"/> ND	CD4 Count/CD4 % <input type="checkbox"/> N/A <input type="checkbox"/> ND
Started on ART?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If on ART, Indicate Start Date:	
Current ART Regimen	<input type="checkbox"/> Treatment: _____ <input type="checkbox"/> ARV Prophylaxis: _____		
Other Diagnoses			
Other medication			

COMMENTS

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.....

Referred By		Received by	
Name	_____	Name	_____
Designation	_____	Designation	_____
Mobile No.	_____	Signature	_____
Signature	_____	Date	_____
		MFL code of receiving facility	_____



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