MINISTRY OF HEALTH

THE KENYA HIV TESTING SERVICES OPERATIONAL MANUAL

2022 Edition

The Kenya HTS Operational Manual 2022 edition contain relevant information required by healthcare providers in the prevention of HIV transmission as of the date of issue. All reasonable precautions have been taken by NASCOP to verify the information contained in this operational manual.

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Foreword

The mandate of The Ministry of Health through the National AIDS & STI Control Programme (NASCOP) is to continually ensure quality HIV services are provided to all clients. To achieve this, it periodically revises the HTS operational manual to ensure that it is in line with the most current available body of knowledge. The document is anchored in the Kenya HIV Prevention and Treatment Guidelines, 2022.

The publication of this operational manual is timely, and coincides with a period of increased efforts by the Government of Kenya (GoK), with support from various partners, to increase knowledge of HIV status among all Kenyans.

The Kenya AIDS Strategic Framework II 2020/21 – 2024/25, outlines the first 95 key 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 to facilitate 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 operational manual recognizes the potential of self-testing to act as a catalyst towards increasing access to and coverage of HIV testing. The core principles of effective HTS: Consent, Confidentiality, Counselling, Correct results, Connection and creating an enabling environment best known as "the 6 Cs 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 this manual will provide a platform towards achieving the ambitious set targets in the KASF II as regards to 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.

Dr. Patrick Amoth, EBS
Ag. Director General, Ministry of Health

Acknowledgment

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

Special thanks go to Dr. Amoth, the Ag. Director General, MOH, who provided strategic guidance throughout the whole process. Our sincere gratitude goes to Dr. Andrew Mulwa, Ag. Head, Directorate Preventive, Promotive Health and Medical services for keeping the team on track towards completion of this very noble task.

I take this opportunity to appreciate the efforts of the Ministry of Health officers at NASCOP and other institutions who coordinated and provided leadership during the review process. Compliments to the HTS Technical working Group who worked tirelessly to ensure that the team produced a great quality document. Particular appreciation to the NASCOP team and numerous TA's who were instrumental in compiling the evidence review and developing the Operational manual. Special thanks to the consultant Prof. Carey Farquhar for her dedication to this process.

We also appreciate the technical input of the external peer reviewers from WHO, CDC, CHAI, JHPIEGO, KEMRI, KNH, NACC and County Government. A special appreciation goes to the editorial team with representation from NASCOP for compiling all the review inputs and keeping up the momentum up to the very end.

Special acknowledgements go to the CDC, CHAI, LVCT Health and WHO for technical and financial support during the revision process.

To everyone, we say a big 'Thank You!'

Dr. Rose Wafula,

Head, National AIDs and STI Control Programme

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List of abbreviation

AE	Accident and Emergency
AGYW	Adolescents Girls and Young Women
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
aPNS	Assisted Partners Notification Services
ART	Antiretroviral Therapy
ARVS	Antiretroviral Drug(s)
AYP	Adolescents and Young People
CASCO	County AIDS & STI Coordinator
CCC	Comprehensive Care Centre
CDC	Centre for Disease Prevention and Control
CDH	County Director of Health
CHAI	Clinton Health Access Initiative
CHVs	Community Health Volunteers
CITC	Client Initiated Testing and Counselling
CPD	Continuous Professional Development
CPT	Cotrimoxazole Prophylaxis Therapy
CQI	Continuous Quality Improvement
DBS	Dried blood spots
DICE	Drop-in Centre
DQA	Data Quality Assessment
DRT	Drug resistant test
EBI	Evidence Based Interventions
EID	Early Infant Diagnosis
eMTCT	Elimination of Mother to Child Transmission
EQA	External Quality Assessment
F-CDRR	Facility Consumption Data Report and Request
FP	Family Planning
FSW	Female Sex Workers
GBV	Gender-Based Violence

GoK	Government of Kenya
HAPCA	HIV and AIDS Prevention and Control Act
HBHTS	Home Based HTS
HBV	Hepatitis B Virus
HCMP	Health Commodities Management Platform
HCV	Hepatitis C Virus
HEI	HIV Exposed Infant
HIV	Human Immunodeficiency Virus
HIVST	HIV Self Testing
HPV	Human Papilloma Virus
HRIOs	Health Records and Information Officers
HTS	HIV Testing Services
IEC	Information, Education and Communication
IPV	Intimate Partner Violence
KASF	Kenya AIDS Strategic Framework
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KENPHIA	Kenya Population-Based HIV Impact Assessment
KHIS	Kenya Health Information System
KNEQAS	Kenya National External Quality Assessment Services
KP	Key Population
L&D	Labour and Delivery
M&E	Monitoring and Evaluation Supplies
MNCH	Maternal Neonatal and Child Health
MOH	Ministry of Health
MSM	Men Who Have Sex with Men
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Program
NAT	Nucleic Acid Testing
NCD	Non-Communicable Diseases
NHRL	National HIV Reference Laboratory
NPHL	National Public Health Laboratory

OJT	On Job Training
OPD	Out Patient Department
PAC	Post Abortion Care
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated Testing and Counselling
PLHIV	Persons Living with HIV
PMTCT	Prevention of Mother-To-Child Transmission
PNC	Postnatal Care
PPV	Positive Predictive Value
PRC	Post Rape Care
PrEP	Pre-Exposure Prophylaxis
PT	Proficiency Testing
PWD	Persons with Disabilities
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QIT	Quality Improvement Team
QIT	Quality Improvement Team
QM	Quality Management
RDT	Rapid Diagnostic Test
RHT	Rapid HIV Test
RITA	Recent Infection Testing Algorithm
RRI	Rapid Result Initiative
RTKs	Rapid Test Kits
RTRI	Rapid Test for Recent HIV Infection
SBC	Social Behavior Change
SCASCO	Sub-County AIDS & STI Coordinator
SCHRIO	Sub-County Health Records and Information Officer
SCMLC	Sub-County Medical Laboratory Coordinator
SDP	Service Delivery Points

SGBV	Sexual and Gender Based Violence
SMART	Specific, Measurable, Attainable, Realistic and Time bound
SNS	Social Network Strategy
SOP	Standard Operating Procedure
SPI - RT	Stepwise Process for Improving the Quality of HIV Rapid Testing
SQA	Service Quality Audit
SRH	Sexual Reproductive Health
STIs	Sexually Transmitted Infection
SW	Sex Worker
TB	Tuberculosis
TG	Transgender
TOT	Trainers of Trainees
TWG	Technical Working Group
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children Fund
VCT	Voluntary Counselling and Testing
VL	Viral load
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization
WIT	Work Improvement Team

Definition of Terms

Emancipated minor

A child who is pregnant, married, a parent or is engaged in behaviour which puts him or her at risk of contracting HIV may in writing directly consent to a HIV test (HIV & AIDS Prevention and Control Act (HAPCA) 2006).

HIV Case base surveillance

This involves the capture of individual-level information from persons diagnosed with HIV infection. It measures and characterize persons newly diagnosed with HIV, their immune status at diagnosis, number and characteristics of persons living with HIV. It also provides information on progression of PLHIV from diagnosis, entry into care and treatment, use of ART, retention, viral suppression and exit (death)

HIV self-testing (HIVST)

This is a process whereby an individual collects his or her specimen, performs a test and interprets the results, often in a private setting either alone or with someone he or she trusts. HIVST can either be directly assisted or un-assisted.

HIV testing services (HTS)

This is used to refer to the full range of services that a client is offered together with HIV testing. This includes counselling (pre- and post-testing); testing, linkage to appropriate HIV prevention, care and treatment services and other clinical support services. It also includes Collaboration with laboratory services to support quality assurance and delivery of correct results is necessary.

Key Populations

Groups who, due to specific higher-risk behaviour, 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), sex workers (SW) and transgender individuals.

Vulnerable Populations

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

Index client:

An individual newly diagnosed as HIV-positive and/or an HIV-positive individual who may or may not be enrolled in HIV treatment services including adolescents and young people. **Index testing:**

A voluntary process where a health care provider asks an index client to list all of their sexual and/or injecting drug partners within the past year, and/or biological children and offer them HTS.

Informed Consent:

As defined in section 2 of HIV/AIDs Prevention and Control Act, 2006 Informed consent in the context of HTS is the process of giving adequate information to clients to facilitate proper decision-making prior to obtaining permission for conducting HTS. Two key pieces of information that all HTS clients must be given are: the process of HIV testing and their right to decline testing

Non-reactive results

It means that the test indicates that HIV antibodies were not found in the blood or oral fluid sample. Anyone whose result is nonreactive to a rapid HIV test (including a self-test) does not need further testing but should be supported to re-test if they have had a recent potential HIV exposure or are at on-going HIV risk.

Service Provider

In the context of HTS is an individual who offers service for HTS after undergoing training using HTS Training curriculum

Sexual Partners

Individuals who have any form of sex, whether vaginal, anal, oral sex with the index client. These include casual and steady sexual partners.

Rapid Results Initiative (RRI)

It is a systematic and intensive 90-120 days coaching/mentorship/campaign initiative for producing tangible results in a specific problem area.

Social Behavior Change (SBC) Strategies

Social and Behaviour Change (SBC) is the systematic application of interactive, theory-based, and research driven processes and strategies to address social and gender norm change and behaviour change at the individual, community, and social levels, including cross cutting use of strategic communication.

Executive Summary.

The Kenya HIV Testing Services (HTS) operational manual, 2022 highlights the key changes as follows:

I. Shift from two test algorithm to three test algorithms to increase the positive predictive value (PPV) as the country prevalence decreases to below 5%.

II. Introduction of the HTS eligibility Screening Tool to enhance targeted testing and increase testing efficiency.

III. Introduction of new intervention such as HIV self-testing (HIVST), index testing and Social Network Strategy (SNS) for general, Key and Vulnerable populations, Men and Adolescents.

IV. Introduction of HIV Recency testing surveillance for the newly identified HIV positive client of consenting age.

V. Inclusion of the HIV syphilis dual testing algorithm for the pregnant women and their partners.

VI. Emphasis on 6 core principles (6Cs): Consent, Confidentiality, Counselling, Correct results, Connection – linkage to prevention, care and treatment, Creating an enabling environment.

VII. Guidance on re-testing recommendations for various sub-populations is updated and clearly outlined. This includes retesting of all newly diagnosed PLHIV before enrolment into care and treatment.

VIII. 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 behavioural interventions (EBIs).

IX. Provides a clearer definition of pathways of referral (connection) from testing to treatment for those who test HIV positive, to prevention for those who test HIV negative and to other post-test services for those with such needs as eMTCT, VMMC, FP and TB.

CHAPTER 1: BACKGROUND

Globally, 38.4 million people are estimated to be living with HIV in 2021 (UNAIDS, 2022). Kenya continues to scale up HIV prevention, care, treatment, and support services, making good progress in reducing the number of new HIV infections and reducing AIDS related mortality over the years. According to Kenya 2021 Estimates, 1,356,806 Adults and 78,465 children are estimated to be HIV infected in Kenya.

The Kenya AIDS Strategic Framework II (KASF II) 2020/21-2024/25 sets ambitious targets for HIV prevention, care and treatment to be achieved by 2025. KASF II aims to reduce new infections by 75% and AIDS related mortality by 50% by 2025. Further, Kenya has adopted the ambitious United Nations 95-95-95 global targets with the expected results of ensuring that 95% of people living with HIV know their status, 95% of people diagnosed are put on antiretroviral drugs, and 95% of those on ARVs achieve viral suppression by 2025.

Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 indicates that 83% of women and 73% of men aged 15-64 years who are HIV positive have been identified. Out of which,96% of these population is on care and treatment.

Despite the great strides towards pandemic control, there are various populations at high risk and disproportionately bearing the burden of infection in Kenya among them being the Adolescent and Young People (contributing 42% of all the new infections), young women (AGYW) contributing 30% new HIV infections every year and the members of Key population. The Kenya Modes of Transmission study (2008) demonstrated high incidence rates among stable heterosexual couples and among key populations (PWID, MSM and SW).

Lower and higher prevalence is reported among specific populations and in certain geographical locations. KENPHIA 2018 showed geographical variation with reported HIV prevalence of as low as <0.1% in Garissa County, to as high as 19.6% in Homa Bay County (Figure 1.1).

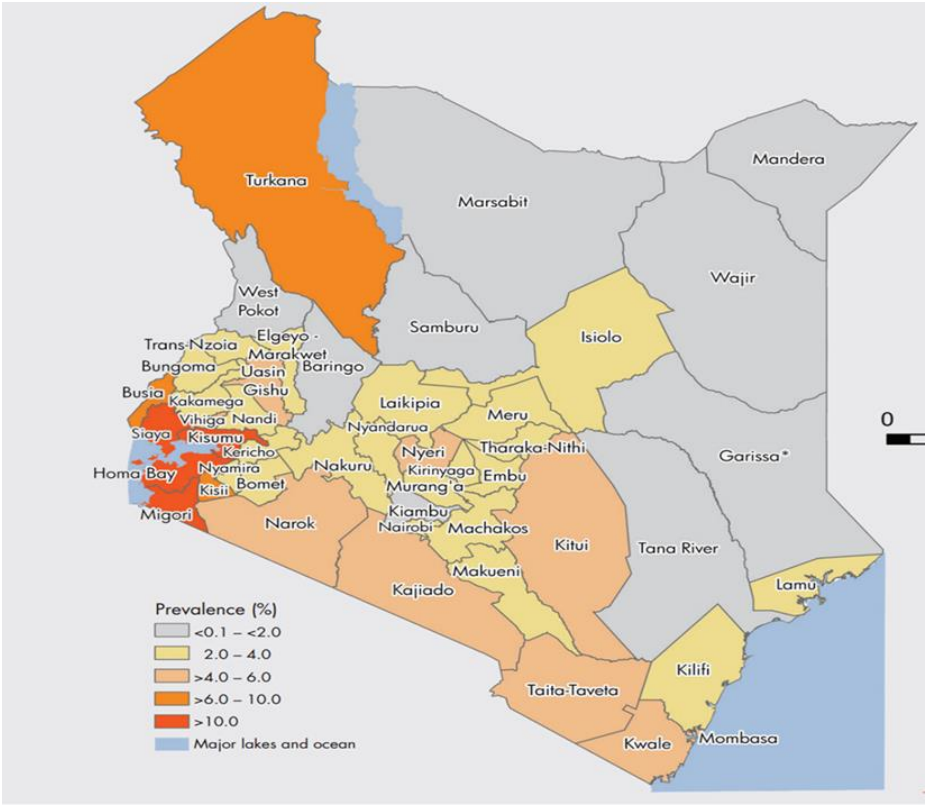
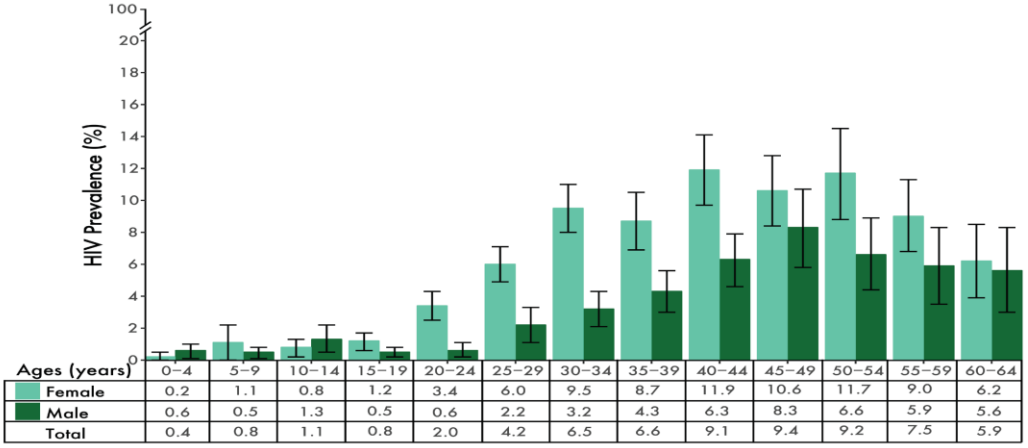


Figure 1.1: County HIV prevalence of adults aged 15-64 years -KENPHIA,2018

HTS is the gateway to HIV prevention, care and treatment. Kenya has made significant progress towards achieving universal knowledge of HIV status. In 2018, 79.5% of adults 15-64 years old living with HIV had correct knowledge of their HIV status, with a higher proportion of women than men knowing their status (82.7% versus 72.6%) (KENPHIA 2018). Through HTS, 96% of adults 15-64 who are HIV positive and knew their status were linked to care, treatment and support services in 2018 (KENPHIA 2018).



Ages (years)	0–4	5–9	10–14	15–19	20–24	25–29	30–34	35–39	40–44	45–49	50–54	55–59	60–64
Female	0.2	1.1	0.8	1.2	3.4	6.0	9.5	8.7	11.9	10.6	11.7	9.0	6.2
Male	0.6	0.5	1.3	0.5	0.6	2.2	3.2	4.3	6.3	8.3	6.6	5.9	5.6
Total	0.4	0.8	1.1	0.8	2.0	4.2	6.5	6.6	9.1	9.4	9.2	7.5	5.9

Figure 1.2: Prevalence of HIV among persons aged 0-64 years by age and sex-KENPHIA, 2018

1.1 Genesis and milestones of HTS

The realization that HTS is the only entry to prevention, 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 centres (then popularly known as Voluntary Counselling and Testing (VCT) sites) increased from three in 1998 to nationwide coverage of about 3,000 by 2013. Currently there are more than 8,000 testing sites in the country (KHIS, 2020). As part of the strategies to expand access to and uptake of HTS, Kenya adopted provider-initiated HIV testing and counselling (PITC) approach to augment the existing client-initiated approach (NASCOP, 2008). This was followed more recently by adoption of HIV self-testing, index testing and social networking strategies.

This operational manual 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 II 2020/21- 2024/25 and Kenya Health Policy framework (2014-2030).

HIV Testing services encompasses different strategies delivered in two main settings:

1) **Community-based** (Outreach services, and home-based testing and counselling)
2) **Facility-based** (static sites integrated within hospitals and clinics)

1.2. Objectives of the HTS operational manual and target audience

The Overall objective of this operational manual is to provide comprehensive guidance for the delivery of quality HTS in all approaches and settings in Kenya through;

- Offering guidance to HTS operations
- Providing guidance for strengthening linkage to prevention, care and treatment and other post-test services
- Defining various HTS strategies for different settings and types of populations.
- Defining key and target populations who will benefit from HIV testing services
- Outlining data collection, reporting mechanisms and utilization
- Providing guidance on HTS promotion
- Providing guidance on quality control and assurance
- Describing responsibilities of various players in HTS policy formulation/review and implementation

The operational manual is targeted for a range of users: HTS providers, Policy makers, partners and communities at national, county and sub-county levels.

1.3. Policy framework

Different documents were used to inform the review for this manual including but not limited to;

- WHO HTS guidelines (2019)
- International Labour Law
- KENPHIA 2018
- KASF II 2020/21-2024/25
- Kenya HIV Prevention Roadmap,2014
- The Constitution of Kenya, 2010
- The HIV and AIDS Prevention and Control Act (HAPCA), 2006
- The Sexual Offences Act, 2006
- The Children's Act, 2001
- The Public Health Act (Cap 242)
- The Medical Laboratory Act, 1999
- The Science and Technology Act, 1980

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.

CHAPTER 2: SETTINGS, APPROACHES AND STRATEGIES FOR HIV TESTING SERVICES

HIV testing services (HTS) have changed over the years in response to the evolution of the HIV epidemic globally and in Kenya. Client-centred approaches have been developed for a variety of strategies to address the needs of diverse populations and accommodate geographic differences. This chapter describes the settings and approaches for HTS in Kenya and discusses HTS strategies that are used in different settings.

2.1 Settings for HTS

In Kenya, HTS is delivered in two broad settings: community-based and facility-based settings.

Community-based settings include all places that offer HTS to clients outside a health facility. This includes:

- Workplaces
- Institutions of higher learning
- Drop-in centres (DICEs)
- HIV prevention centres
- Voluntary Counselling and Testing centres (VCTs)
- Integrated outreach sites
- Homes

Facility-based settings include all service delivery points that are within health facilities and offer HTS to clients as they seek other services. This includes but not limited to:

- Inpatient departments, both adult and paediatric
- Outpatient departments, including TB, STI, VMMC, Post Rape Care (PRC), SRH specialists' clinics
- Nutrition clinics
- Labour and Delivery Ward.
- Maternal and child health clinics, including antenatal care clinics where EMTCT services are offered
- HIV Comprehensive Care Clinics

Different populations may access HTS in different settings, thus it is recommended that ministry of health offer a mix of HTS strategies and delivery models to suit the target populations.

2.2 Approaches to HTS

Within the two settings above, two approaches are utilized to expand options available to clients while increasing opportunities to achieve the 1st 95%. These approaches are;

I. **Client initiated testing and counselling (CITC)** This is where the client seeks and initiates HIV testing in the community or at a health facility on his/her own volition.

II. **Provider initiated testing and counselling (PITC)** This is where a service provider offers HIV testing to clients, regardless of the reason for the visit. PITC places the responsibility of initiating HTS on the health provider, rather than the client. PITC service is offered with an "opt-out" option based on informed choice and consent.

2.3 HTS strategies

a) Strategic shift from general testing to targeted testing.

The robust HTS program has enabled Kenya to achieve over 80% identification of PLHIV. However, efficient identification of the unidentified PLHIV as the last mile identification requires innovative interventions in addition to the conventional HTS strategies. Targeted HIV testing is the major strategic shift, involving index client listing of contacts, HIV self-testing and use of HIV screening tools (Annex 1) to identify people at risk of HIV infection as eligible for testing, except in the case of ANC/PNC, couples and key populations.

b) HTS Strategies

The major HTS strategies in the context of the last mile identification innovations are:

i. HIV Self-Testing (HIVST)
ii. Index Testing
iii. HIV prevention centres:
iv. Social Network Strategy (SNS)
v. Integration of targeted testing to all health service delivery points
vi. Provision of universal HIV testing only to selected populations for strategic prevention purposes. This includes
    - ANC/PNC clients- Provision of testing to all pregnant and breast-feeding women and infants in line with PMTCT guidelines
    - Key populations (KP) - provision of HTS to all key populations on quarterly basis in line with KP guidelines.

1. **HIV self-testing (HIVST)** involves an individual collecting his/her specimen, performing a test using a HIVST kit, and interpreting the results. This may occur in a private space within a health facility, at home, or in any other convenient place, and can be done alone or with a trusted person. HIVST can be accessed through CITC or PITC and should be available both in community and facility settings. HIVST can be delivered through two distinct approaches to reach these different target populations and the approaches vary in terms of the level and type of support provided. These approaches are:
    a. **Directly assisted HIVST** refers to when trained providers, peer educators or community health volunteers (CHVs) give an individual an in-person demonstration before or during HIVST on how to perform the test and interpret the test result. This approach can be used to support self-testers with disabilities, low literacy levels, and individuals who may require or request direct assistance in the form of in-person demonstrations and explanations before, during and/or after testing. This is especially recommended for self-testers aged 15 to 17 who will require additional support and counselling.
    b. **Unassisted HIVST** refers to when an individual obtains and uses an HIVST kit by following instructions for use provided by the manufacturer without the help of a trained provider or peer.

HIVST kits can be delivered through different channels depending on the target population (primary distribution where one picks the HIVST for self-use while secondary distribution where one picks the HIVST for sexual partners) as detailed in the figure below:

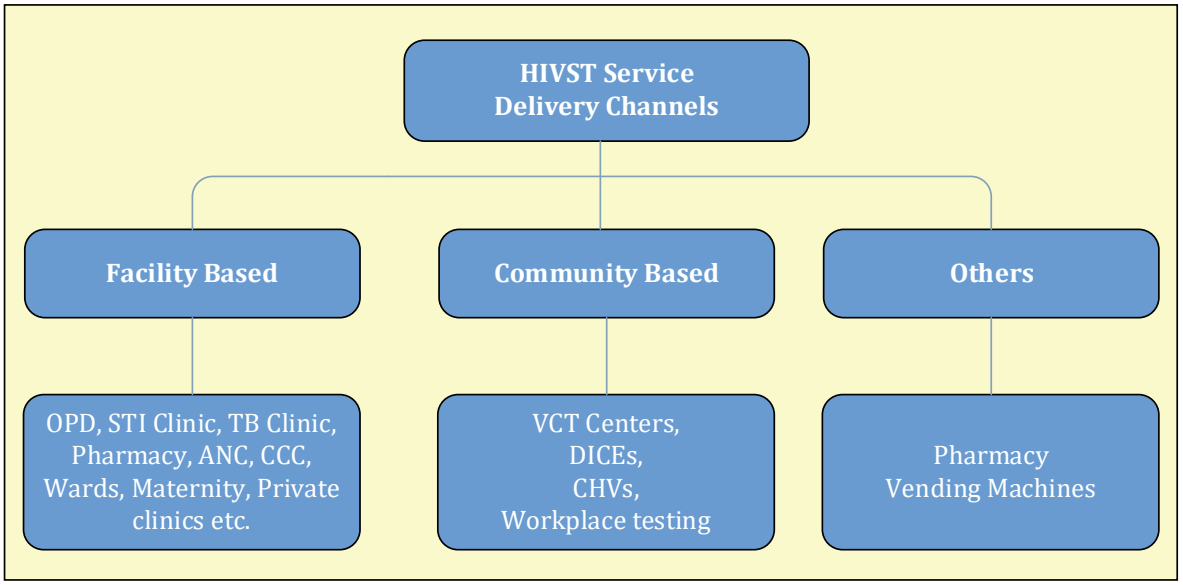


Figure 2.1: HIVST kit and service delivery channels

2. **Index testing:** This is a voluntary service offered to clients testing HIV positive. It involves HTS providers discussing with clients who test HIV positive the need for any sexual partners, injecting partners and children to also be tested and learn their HIV status. This is because they may have been exposed to HIV along with the index (HIV positive) client. With a written client's consent (Annex 2), HTS providers agree with the index client that either the index client will disclose their status to their contacts and refer them to the facility to be tested, or the provider will assist in notifying and informing the contacts of the possible exposure. In case of assisted index testing, this will be done without revealing the index client's identity and contacts will be invited for HIV testing. In special cases, such as the ANC/PNC setting, HIVST kits may be provided to the index to give to their partners.
3. **HIV prevention centres:** These are conventional centres for voluntary counselling and testing that are in the community and which offer a range of integrated HIV prevention services. The goal of HIV prevention centres is to increase knowledge of HIV status among individuals in the community who are healthy and may not otherwise go to a health facility, thus providing an entry point to HIV prevention interventions for those testing HIV negative, and to care and treatment for those testing HIV positive. The strategy is aligned with the CITC approach. The strategy is currently targeting the AYP, Men, fisherfolk and PWD.
4. **Social Network Strategy (SNS):** Providers offer PLHIV additional, self-guided options to informally extend links to HIV testing and other services to a broader set of social, sexual and injecting network members who have an elevated risk of HIV infection. It can be conducted through online and coupon-based referrals. Does not require PLHIV/index client to name, or even know the names of these contacts to make referrals. They can make confidential or anonymous referrals; this strategy has been successful among the Key population and can also be used to reach men, AYP, vulnerable and general population.
5. **Health facility HTS prioritization:** In health facilities, HTS should be offered to patients and non-patients visiting a health facility, but a risk-based approach should be adopted to screen and facilitate prioritization of testing. Providers should undertake a thorough risk assessment using a HTS eligibility screening tools to identify clients at risk and those eligible for a HIV test. Clients who test HIV positive should be linked to care while those who test HIV negative and at risk should be linked to HIV prevention services. Clients who are not eligible for testing should receive HIV prevention messages and be offered services, as appropriate. Regardless of risk, HTS should be offered only to clients who consent testing. However, effort should be made to reduce the number of clients who opt-out.
    a. **ANC, PNC and maternity wards for EMTCT:** HIV testing services are routinely offered to pregnant women attending antenatal services and to postnatal mothers within a health facility with the aim of interrupting HIV transmission to the unborn/ new-born child while facilitating early entry into a EMTCT programme for care and treatment for the HIV positive mother.

b. **Provision of HTS in community-based settings** is consistent with the Ministry of Health (MoH) Community Strategy (Kenya MoH, Health Sector Reform Secretariat) and the National Health Sector Strategic Plan-III. HTS has been classified as a level one activity of the health care system in Kenya which is in line with the KASFII 2020/21 -2024/25 Strategic Objective of strengthening integration of community and health systems. HTS strategies in community-based settings include;

i. **Home-based HTS (HBHTS):** HBHTS is a provider-initiated strategy that takes place in the community and seeks to improve access to and uptake of HTS by making it more convenient and removing structural and logistical barriers (Bateganya et al., 2010; Negin et al., 2009; USAID/AIDSTAR-One, 2009). Under this strategy, HTS providers go to the home of potential clients and initiate HTS. The HBHTS strategy has potential for attracting first time testers, reducing stigma associated with HIV testing, and promoting index testing.

In order to achieve maximum benefits from the implementation of the HBHTS strategy, it is advised that:

- Priority is given for high HIV prevalence and incidence areas with low testing coverage
- Focus be given to the clients identified through Index client testing
- There is adequate infrastructure for referrals and linkages to comprehensive post-test support services within the area of coverage, including care clinics.
- There are strong collaborations with community leaders and workers, including community health volunteers, to facilitate community entry and create linkages to community-based HIV prevention and treatment services
- For all clients testing HIV positive, The HTS provider should physically escort the client to the facility for linkage.

ii. **Drop-in centres (DICEs):** These are safe spaces located in strategic locations to provide comprehensive HIV prevention services specific to Key and Vulnerable populations in an environment that is friendly to them. The services provided include, but are not limited to HTS, STI screening and treatment, FP services, TB screening, cervical cancer screening, peer education, condom and lubricant promotion and distribution, medically assisted therapy (MAT), care and treatment. For this DICEs HTS strategy, it is recommended that peers among the key and vulnerable populations are identified and trained to offer these services and engage in outreach and tracing clients lost to follow-up when appropriate.

iii. **Outreach HTS:** This HTS strategy refers to services offered outside of a static community-based site or health facility, and includes mobile, workplace or higher learning institution-based workplace programmes. This strategy aims to enhance access to HTS among hard-to-reach populations, including key populations that have limited access to health care systems due to structural, policy, legal or geographical barriers such as distance from DICEs, HIV prevention centres and health facilities. Provision of outreach HTS in Kenya includes the following:

- Mobile trucks with counselling rooms
- Pitching tents for use as counselling 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) in hotspots and dens.
- Utilizing existing community facilities such as community halls, churches, schools and other institutions or hired rooms/premises at market centres
- Innovative strategies such as 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 the Kenya HTS operational manual with special attention to ensuring that the rights of all clients are protected. Appropriate linkage to treatment and prevention services should be given high priority. Key and Vulnerable population should be linked to DICEs for access to information and other necessary services, such as condoms, lubricants and harm reduction (MOH/NCHADS/UNICEF, 2007).

iv. Workplace HTS: This is a strategy in which HTS is offered in formal or informal workplaces and may be organized through employers or organizations who wish to ensure their employees have access to quality HTS. It is important to note that workplace programmes are not compulsory or mandatory.

To reach the hard-to-reach population, Kenya in collaboration with private sector is considering establishing HIVST vending machines in workplaces, malls among others to distribute HIVST kits and help employee learn their status. Table below shows summary of strategy, settings, approaches and targeted populations.

Summary of HTS strategies, settings, approaches and targeted populations/ services delivery points:

STRATEGY	SETTING	APPROACHES	TARGETED POPULATION
HIV Self-testing HIVST	Health facility and Community	CITC PITC	Pregnant and breastfeeding women Key Population Adult men Adult women Emancipated minor Persons with Disability Vulnerable populations
Index testing/ aPNS	Health facility and Community	CITC PITC	Pregnant and breastfeeding women Key Population Adult men Adult women Emancipated minor Persons with Disability Vulnerable populations
Voluntary Counselling and Testing VCT	Health facility and Community	CITC	Pregnant and breastfeeding women Key Population Adult men adult women Emancipated minor Persons with Disability Vulnerable populations
Social Network strategy (SNS)	Community	CICT PITC	Key Population Men; Adolescents and young persons
Integration of targeted testing to all health service delivery points, HTS settings and approaches using population-appropriate screening tools.	Health facility and Community	PITC	Pregnant and breastfeeding women Key Population Adult men adult women Emancipated minor Persons with Disability Vulnerable populations

***Note**: HIV testing should be offered to both the survivors and the perpetrators of physical and sexual violence because this violence is associated with HIV and with other HIV risk factors. Women and men who report a history of intimate partner violence (IPV) 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).*

In cases of sexual violence against children where the perpetrator is the parent or guardian, children's survivors of sexual violence can be tested without the consent of their parents or guardians, however they should be given age-appropriate counselling and referrals.

CHAPTER 3: POPULATIONS TARGETED FOR HTS

To achieve the KASF II (2020/21 – 2024/25) goal of attaining universal health coverage and the 2030 agenda for sustainable development, HTS should be offered to all age groups, genders, and population types. However, special attention should be placed on harder to reach populations and on populations where the HIV epidemic is concentrated. According to the KENPHIA 2018 preliminary report, this includes adolescents and young people, men, key populations, and other vulnerable groups who may have higher HIV incidence or lower HIV testing rates and ART coverage. Chapter describes the populations targeted for HTS in Kenya.

I. Key Populations

Key populations are group of people who, due to specific higher risk behaviours are at increased risk of HIV, irrespective of the epidemic type or local context. Also, they often have legal, cultural and social barriers related to their behaviour which increases their vulnerability to HIV and can make it more difficult to obtain testing in facilities. In Kenya, these populations include men who have sex with men (MSM), people who inject drugs (PWID), female sex workers (FSW) and transgender. The Key Populations Testing Guidelines 2014 states that the members of key populations should be tested at least quarterly due to their higher risk behaviours.

II. Infants and children

KENPHIA 2018 established an HIV prevalence of approximately 0.7% among children age 0-14 years. There is need to scale up provision of HTS for children in order to identify all those infected or exposed to HIV for prevention purposes. Since infants and children get exposed to HIV primarily from their HIV-positive mothers, it is imperative for all HIV exposed infants and children to be tested to determine their HIV status early enough and link them appropriately to HIV prevention, care and treatment.

Upon caregivers' consent, every HIV-exposed infant should receive age-appropriate HIV testing as per chapter 4 of the Kenya HTS operational manual so that ART or prophylaxis can be started immediately to prevent morbidity and mortality. The Ministry of Health is increasing HTS coverage among children, especially those with a known exposure to HIV through index testing in MCH, nutrition clinics, in-patient department and other service delivery points.

It is important to establish the exposure status to HIV for all infants presenting for immunization and other health services so as to promote early identification of HIV Exposed Infant (HEI) for Early infant diagnosis (EID). Caregivers should 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 counselling and other psychosocial support.

III. Adolescents and Young people (AYP)

Kenya HIV Estimates 2021 shows that adolescents (10-19 years) and young people (15-24years) contributed 5,294 cases (16.5%) and 11,229 cases (35.1%) respectively of new HIV infection. The estimates further show that 42% of adult new infection occurs among the adolescent and young people. Therefore, to reduce risk of new infections among adolescents, HTS should be provided to all adolescent as an entry point to HIV prevention and treatment. Emancipated minors, can also access HTS without guardian/parent consent (HAPCA, 2006)

The main mode of HIV transmission is unprotected heterosexual intercourse, however adolescents and young people may also be exposed to HIV through injecting drug use, sex work and anal sex (UNICEF, 2010). Early sexual debut, intergenerational sex, coerced sex (e.g., defilement), low rates of condom use, and biological vulnerability during adolescence also increase risk of HIV infection among adolescents and young people. Due to the risk factors that adolescent and young people are exposed to, it is important to offer HTS to all adolescents and young people who are screened eligible for a test and offer prevention services to the negatives and care and treatment to the positive ones.

IV. Adult men and women

All adults screened and are eligible for testing should be encouraged to know their HIV status and that of their partners and be offered HTS. Client education on the importance of knowing their HIV status will increase uptake of HIV prevention, care and treatment services.

Men

The KENPHIA 2018 preliminary report states that 79.5% of adults living with HIV aged 15-64 years knew their HIV positive status. Notably, men were significantly less likely than women to have tested for HIV and to know their status (72.6% of men versus 82.7% of women).

Since it has been more difficult to reach men using facility-based HTS setting due to poor health seeking behaviour, MOH is recommending the use of targeted HIV testing strategies that reach men in the community and workplace setup.

Women

Facility-based setting have been highly successful among women hence the need to scale up in the context of targeted testing to achieve 95-95-95 goals and epidemic control. HTS must be routinely offered to pregnant women seeking Maternal neonatal and child health (MNCH) services within a health facility with the aim facilitating early entry into eMTCT programme.

V. Couples/Partners

During couples testing, each partner should be given an equal opportunity to talk and ask questions during the pre-and post- testing sessions. Couples should be encouraged to disclose their results to other family members. The HTS service provider should screen for potential intimate partner violence (IPV) and make appropriate referrals before couples testing. Information about elimination of mother-to-child transmission (eMTCT) and family planning (FP) services should be provided.

It is recommended that HTS providers encourage individuals to test together with their sexual partners. Uptake of couples and partner testing remains low in many settings despite its benefits and high impact for HIV prevention and treatment. The HTS provider should facilitate adequate referrals as appropriate.

VI. Discordant couple

HIV discordance for a couple refers to a relationship where one partner is HIV positive while the other partner is HIV negative. The HIV positive partner in the Discordant relationship should be counselled and referred for HIV care and treatment services, while the HIV negative partner should be counselled and refereed for HIV prevention services.

The prevention package should include HIV testing and counselling and provision of pre-exposure prophylaxis (PrEP) for the HIV negative partner. It is important to note that there is substantial evidence that HIV transmission risk is minimized when the HIV positive partner is taking ART and has achieved undetectable viral load. The prevention package may also include evidence informed behavioural interventions such as EBAN-K (A behavioural risk reduction intervention for discordant couples), VMMC and support groups.

VII. 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 addresses their specific needs in a conducive environment. Some of these provisions include incorporating Kenyan sign language, braille, and ramps for those using wheelchairs and crutches. Where possible there should be HTS 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
- Implementation should consider human resource capacity for dealing with PWDs for service provision
- Integrate HTS in institutions and organizations working with PWDs

VIII. Sexual and Gender-Based Violence

Sexual and gender-based violence (SGBV) is one of the life-threatening forms of violence. In Kenya, data shows that 45% of women and 44% of men age 15-49 years have experienced physical violence, and 14% of Kenyan women age 15-49 years have experienced sexual violence (State Department for Gender, 2019). In addition, 32% of young women aged 18–24 years and 18% of their male counterparts reported experiencing sexual violence before the age of 18 (UNAIDS, 2018).

HIV testing should be offered to both the survivors and the perpetrators of physical and sexual violence because it increases vulnerability for HIV acquisition and transmission. Women and men who report a history of intimate partner violence (IPV) 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).

In cases of sexual violence against children where the perpetrator is the parent or guardian, children's survivors of sexual violence can be tested without the consent of their parents or guardians, however they should be given age-appropriate counselling and referrals.

IX. Vulnerable and higher-risk populations

Groups of people in Kenya who are at an increased risk of contracting HIV due to their unique circumstances may be considered vulnerable or higher risk populations.

These include:

a. Vulnerable Population
   i. Fisher folk
   ii. Truckers
   iii. People in Prison setting
   iv. Discordant couples

b. Other High-risk population
   i. Widows and widowers
   ii. Orphaned and vulnerable children
   iii. Families and children living in the streets
   iv. People in closed settings (displaced persons, refugees and migrants)
   v. People who abuse alcohol
   vi. Miners/Sand Harvesters
   vii. Uniformed Officers
   viii. Migratory Population

MOH has put in place strategies to ensure the populations listed above have equitable access to HTS. This is because these populations are exposed to circumstances that make them more vulnerable to HIV infection.

CHAPTER 4: TESTING SERVICE PACKAGE

4.1 Core principles of HIV testing service

Consistent with international policy and technical standards, NASCOP emphasizes that HTS in Kenya should focus on a client centred approach. HTS should never be coercive or mandatory and it should always be guided by the 6 core principles (6Cs) as listed in figure 4.1:

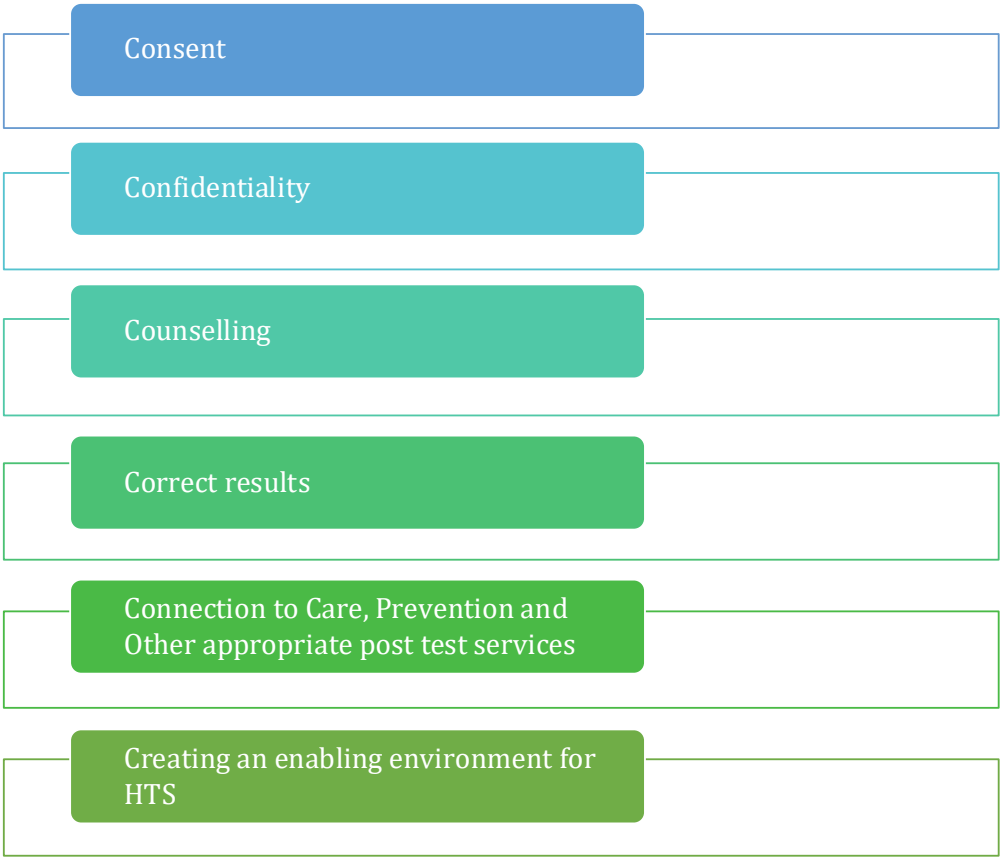


Figure 4.1: Six Core Principles

These core principles are described in detail below:

1. Consent

All people receiving HTS must give informed consent to be tested. Informed consent in the context of HTS is the process of giving adequate information to clients to facilitate proper decision-making prior to obtaining permission for conducting HTS. Two key pieces of information that all HTS clients must be given are:

I. The process of HIV testing
II. Their right to decline testing.

Additional pre-test counselling is described in more detail in a later section of this chapter. Consent can be written or verbal and must be voluntary. This is true in all situations, including, but not limited to the special circumstances below:

- **Antenatal care:** Pregnant women visiting ANC should be offered HTS, and be informed that they have an 'opt-out' option. Their choice to 'opt-out' should not affect access to other healthcare services.
- **HIV self-testing (HIVST):** When offering HIVST, it should not be assumed that people who request or report HIVST are providing or have implicitly provided consent for HTS, they should also provide consent.
- **Index testing strategy:** Index clients must give written consent before contact elicitation; the contacts must also give consent before testing.
- **Children and adolescents:** Children and adolescent should be tested with the written consent of a parent or guardian. Those above 7 years of age need to give assent after the parents give consent. A child who is pregnant, married, a parent or is engaged in behaviour which puts him or her at risk of contracting HIV may in writing directly consent to a HIV test (HIV & AIDS Prevention and Control Act (HAPCA) 2006).
- **Persons with disabilities:** A person with a disability that prevents them from giving consent may be tested with the consent of their guardian, a partner, a parent or an adult offspring. A medical practitioner may perform the HIV test if the persons referred to in the previous statement are either absent or unwilling to give consent. For those with a disability that does not prevent them from giving consent (e.g., visual and hearing impairments), providers should communicate effectively through interpreters or other means to facilitate consenting.

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.

The only circumstances where consent for a HIV test is not a requirement are:

- When a person is required to be tested for HIV under the provisions of a written law and on presentation of a written court order. If this occurs, results should only be given to the client and to the legal authority.
- When a person is unconscious or unable to give consent due to altered mental status and the test is medically necessary for a clinical diagnosis for the benefit of the client.
- When it is medically necessary to test a child who may have been exposed and there is a non-consenting parent or guardian.

In situations where consent is not required, all other core principles for HTS must be upheld.

2. Confidentiality

HTS must be confidential. This means that what the HTS provider and the client discuss is not disclosed to anyone else without the consent of the person being tested. The service provider has an obligation to hold in confidence all their client's medical and personal information.

Confidentiality must be maintained when conducting all types of HIV testing and in all settings. All HTS service delivery points should ensure that the policies, training and infrastructure needed to uphold client confidentiality and privacy are in place and adhered to. HTS records and information, just like any other health records, should be kept confidential in all circumstances. Client's names will be used to facilitate referral to other services and test results may be shared with other health care workers providing services to the client (shared confidentiality). However, a person's HIV status should only be discussed in settings that maintain confidentiality. Written documents should be stored in lockable cabinets accessible only by authorized personnel while electronic medical records should be stored in password protected computers. A provider who does not maintain confidentiality commits an offence under the HAPCA (2006).

3. Counselling

Counselling is an interaction between the HTS provider and the client to facilitate informed decision making and get the most benefit from the HIV testing service package. Everyone is entitled to adequate, correct information and counselling before HIV testing. This includes pre and post-test counselling, referrals and linkage to prevention, care and treatment services. It is recommended that pre-test counselling should focus on providing information to facilitate informed consent while the post-test counselling should be tailored on the outcome of the test and the individual client needs, including referrals and index testing. Post-test counselling is a critical component of client's linkage to treatment, retention and reengagement to care. Risk assessment and risk reduction counselling should be provided to all clients as part of HTS package. r services.

Regardless of how counselling is provided, quality assurance mechanisms, as well as supportive supervision and mentorship, should be in place to ensure the provision of high-quality pre- and post-test counselling.

4. Correct results

HTS providers should strive to provide quality HIV testing services. Quality assurance (QA) mechanisms must be in place to ensure that clients receive the correct results. These should include both internal and external measures. In addition, to protect against false positive and false negative results, HTS providers must adhere to the National HIV testing algorithms.

In case of inconclusive results, a client should be retested after 14 days. If results remain inconclusive even after the 14-day test, the individual should be reported as HIV-negative and should be advised to retest after 3 months.

5. Connection to prevention, treatment and other appropriate post -test services

Connection refers to HTS referrals and linkage to prevention and treatment. HTS should include facilitated referrals tailored to the individual clients to appropriate and effective post-test services, including HIV prevention and treatment support as described below:

- Those who test HIV positive should be linked to HIV treatment immediately so that treatment is initiated as soon as possible. All clients testing HIV positive must be provided with facilitated referral and confirmed linkage.

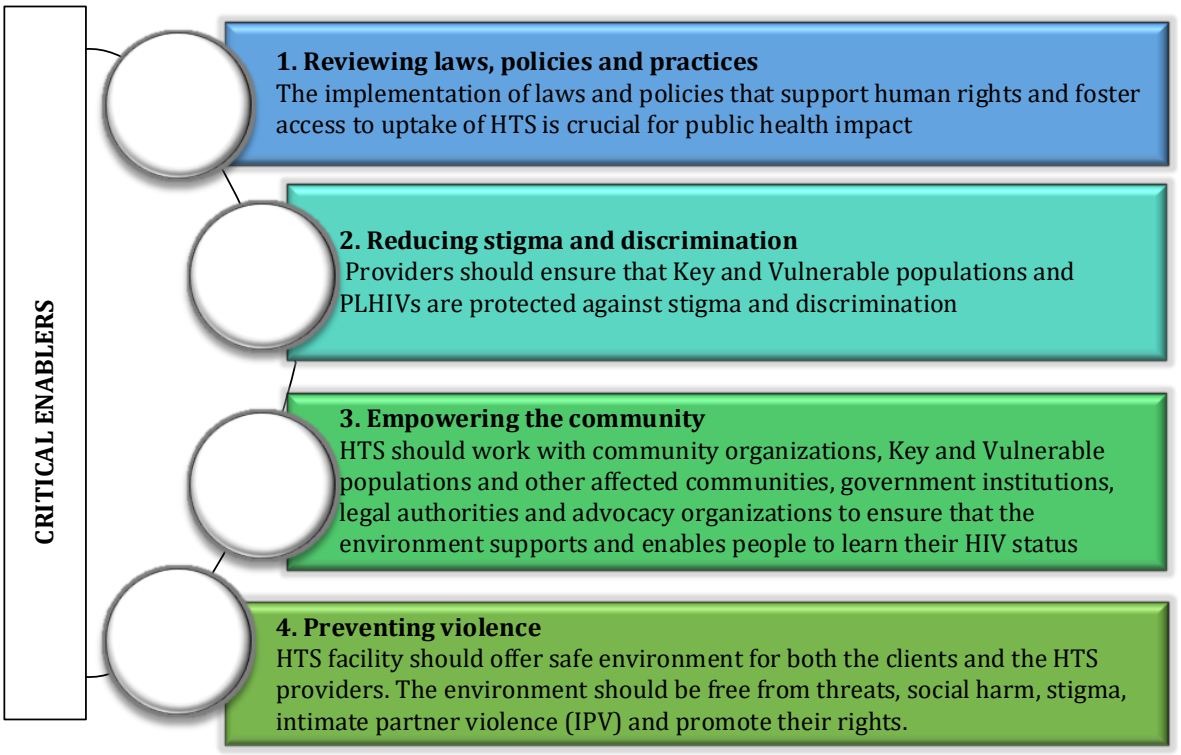
NOTE

- It is the responsibility of the HTS provider to ensure all positive clients have been linked to treatment.
- It is the responsibility of HTS provider who is retesting at the receiving facility to confirm linkage to the referring facility.
- Confirmed Client linkage should be documented in the HTS Lab, Referral and linkage register (MOH 362).

- Those who test HIV negative and are at risk of HIV infection should be linked to effective prevention interventions such as PrEP.
- Clients in need of other post-test services, such as sexual and reproductive health (SRH) or TB services, should also be linked, as described in Chapter 5 of the Kenya HTS operational manual.

6. Creating an enabling environment for HTS

Enabling people to make an informed and healthy choice to access HIV testing and engage in HIV treatment or prevention is a core public health function. The following are key areas to consider when creating an enabling environment for clients seeking HTS:



4.2 HIV Testing service package

The primary components of the HTS package are:

- Pre-test counselling
- HIV testing
- Post-test counselling
- Assessment of other health related conditions, such as TB
- Referral and linkage to appropriate health services

These 5 components make up the minimum service package of HTS. The package is aimed at enabling clients to understand their HIV risk, take the HIV test, develop a risk reduction plan, and access appropriate referrals. This package will be delivered by utilizing the approved HTS protocol, as summarized below (Table 4.1).

Before pre-test counselling, conduct HTS eligibility screening for all populations except ANC/PNC clients, Children, couples and key populations to establish if the client is eligible for HTS or not

Table 4.1: Steps in HTS service package protocol

Step 1: Provision of pre-test counselling
Key areas to be addressed during pre-test counselling: • HIV information and patient education • Conduct risk assessment • Emphasize importance of HIV testing • Address the option to opt out • Provide information on other testing strategies (HIVST, index testing and/or SNS) • Explain HIV testing procedures. • Discuss the importance of disclosure to partners and other family members • Obtain informed and voluntary consent • Explain the benefits of ART. • With the consent of index client, note sexual, drug injecting partners and children mentioned
Step 2: Perform HIV test
• Provide accurate HIV diagnosis as per the approved National testing algorithm • Provide same day HIV test results and provide appropriate linkage. During the 15 minutes as you wait for the test results: • Discuss Combination Prevention e.g., PrEP, PEP, Risk Reduction, STI treatment, condom information and demonstration, VMMC, Elimination of Mother to Child Transmission of HIV (eMTCT) • Screen, provide information and referrals for; Intimate Partner Violence (IPV), STI and cancer screening, Tuberculosis (TB), Family planning/contraceptive needs, etc. • Establishing number of sexual contacts and biological children for the purpose of index testing. • Document in the HTS, Lab, referral and linkage register (MOH 362). Discuss further on index testing and HIVST as you perform the second and the third test, as per the national algorithm, for the clients who test positive with the screening test

Step 3: Post-test counselling

Post-test counselling

- Check if the client is ready for results and help them to interpret.
- Check what the client understands by the results.
- Allow the client to share his/her initial reactions and verbalize their initial feelings.
- Explore and acknowledge client's immediate feelings and concerns.

Offer necessary support

NEGATIVE RESULT

- Explain test results.
- Review implications of being HIV negative.
- Support clients to develop a Specific, Measurable, Attainable, Realistic and Time bound (SMART) risk reduction plan
- Provide information on methods to prevent HIV acquisition.
- Provide male and/or female condoms, lubricant, and guidance on their use.
- Emphasize on importance of knowing the status of sexual partners and information about the availability of partner and couples testing services.
- Referral and linkage to relevant HIV prevention services

Explain the need for repeat testing for people who test negative but report risky behavior within the prior 4 weeks (i.e., unprotected sex with a partner of unknown status or Known HIV positive status); if they test HIV negative again after 4 weeks and are at ongoing risk of HIV acquisition, they should be advised to return for testing every 3 months (Table 4.10) (e.g., ongoing risk, recent exposure).

Positive results

- Review implications of being HIV positive.
- Help the index client to cope with emotions arising from the diagnosis.
- Discuss immediate concerns and help for the client to decide who in his or her social network may be available to provide immediate support.
- Discuss positive living.
- Explain importance of immediate linkage to HIV care and treatment, including undetectable = untransmissible (U=U)
- Provide clear information on ART and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to access ART
- Refer clients who turn HIV positive to CCC for linkage to treatment.
- Revisit index testing and HIVST to determine partner notification plan/approach (refer A guidance document for the delivery of HIVST and aPNS in Kenya).
- With the consent of index client, Obtain contact information of index client contacts.
- Conduct Intimate partner violence (IPV) assessment
- Capture locator information (Annex 3)
- Obtain a written consent to contact the index clients contact/s (Annex 2)
- Discussion of the risks and benefits of disclosure to partners; couples counselling should be offered to support mutual disclosure.

Encourage and offer HIV testing for sexual partners, injecting partners, biological children, and other family members, which can be done through couples testing, family testing and/or assisted partner notification service.

Step 4: Assessment of other health related conditions

- Conduct assessment for risk of other ailments
- Assess risk for sexually transmitted infections (STIs) and opportunistic infections that would also require notification

Step 5: Referrals and linkage

- Obtain accurate locator information from the index client (physical location, phone number)
- Physically escort the client for re-testing and linkage to ART. If the client chooses a facility far away that physical escort is not possible, provide a facilitated referral (*The HTS provider will utilize the national directory to reach out to the facility the client has selected and initiate referral and linkage communication. The HTS provider agrees with the referral facility on the day of arrival of the patient for linkage. If the patient doesn't arrive on the agreed date, the referral facility calls the testing provider to continue with the follow up)*

NOTE

1) **It is the responsibility of the HTS provider to ensure all positive clients have been linked to treatment.**
2) **It is the responsibility of retesting counsellor at the receiving facility to confirm linkage to the referring counsellor/facility.**
3) **Confirmed Client linkage should be documented in the HTS and linkage register (MOH 362).**

- Document the Sexual/injecting partners and biological children of the index client for follow up in the index testing register
- **Document referrals and issue a copy of referral form to client. Additionally update referrals in the MOH 362 for both prevention services and treatment services.**
- Ensure all clients are enrolled to care and document the CCC number in the linkage register (MOH362)

Step 1: Pre-Test counselling

Pre-test counselling may be provided to an individual, a couple or a group presenting for HTS in a concise manner. The objectives of the pre-test counselling session are to:

- Introduce and give information on importance of testing for HIV
- Explore the client's risk of HIV infection.
- Address the option of opt-out
- Explain the benefits of couple testing, index testing and SNS where applicable.
- Obtain informed and voluntary consent for HIV testing
- Provide an explanation for the HIV testing process
- Discuss the importance of disclosure to partners and other family members.
- Provide information on the benefits of knowing one's HIV status, including outcomes for people on ART.
- Provide information on available post-test services, including referrals

Step 2: HIV Test

The goal of HIV testing is to:

- Provide accurate HIV diagnosis as per the approved National testing algorithm
- Provide same day HIV test results and provide appropriate linkage.

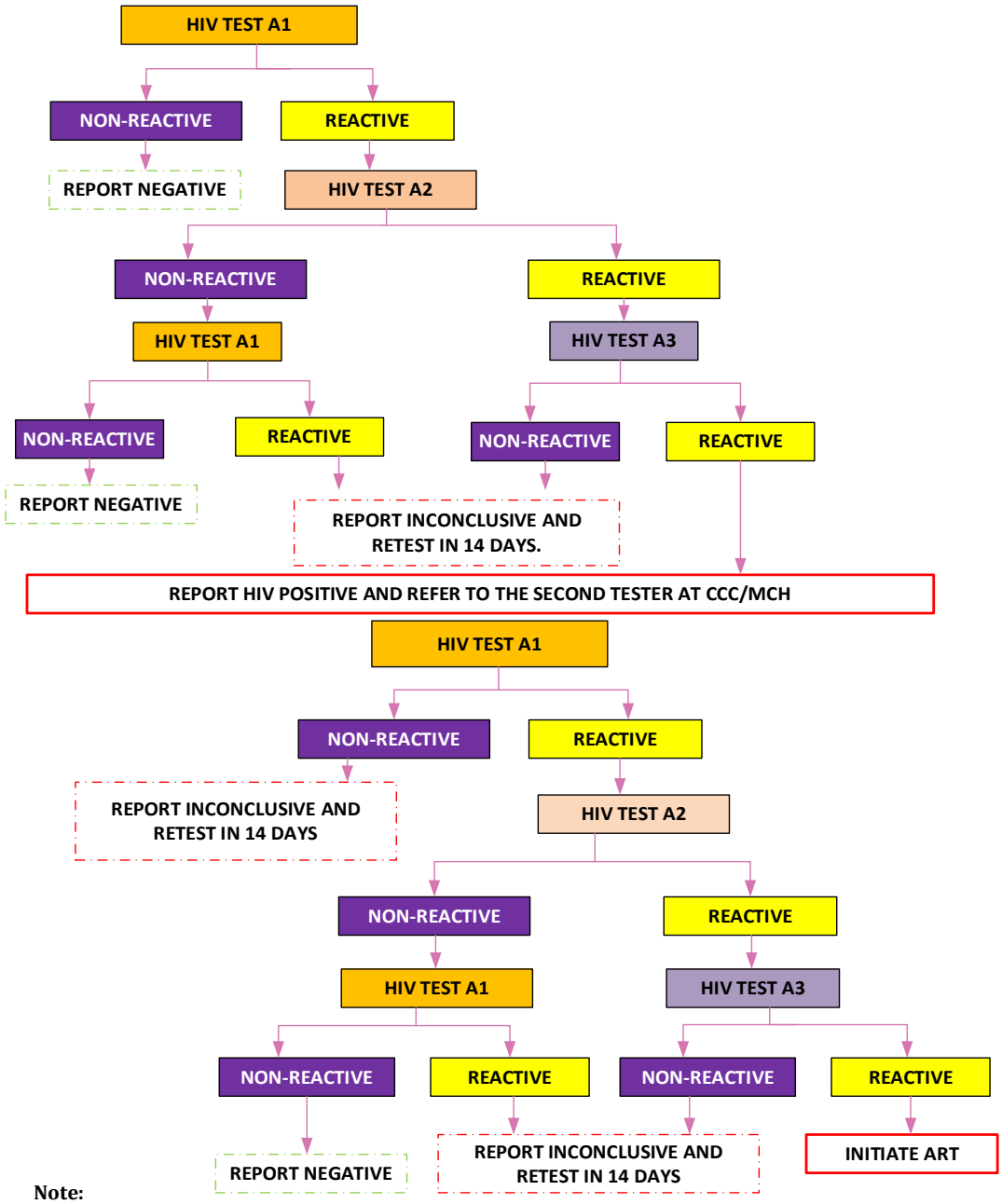
Table 4.2: Key Terms in HIV testing

Terminology	*Definition*
Assay	*A synonym of test kit; in the case of HIV, all the components of a test kit used to identify HIV p24 antigen or HIV-1/2 antibodies.*
Testing strategy	*A sequence of tests conducted on assays to achieve a specific objective, such as screening for infection or diagnosis of infection.*
Testing algorithm	*When specific products are populated into a testing strategy, it is a testing algorithm. A specific product is defined with a product name, product code(s), a manufacturing site and a regulatory version. The testing algorithm is likely to change depending on which specific products are verified for use together and are procured.*
HTS positivity	*The proportion of HIV-positive results among those undergoing HIV testing.*
Discrepant test results	*When the test results for two or more assays do not agree. For example, Assay 1 is reactive, but Assay 2 is non-reactive.*
Repeat testing	*When the same specimen is tested again on the same assay when the initial result is reactive or test results are discordant. The assay is repeated to rule out biological false reactivity. For assays that utilize capillary whole blood, another prick may be needed to collect adequate specimen volume, but it must be in the same testing event.*
Retesting	*When a second specimen from the same individual is tested again following the same testing algorithm. This is not in the same testing event – for example, retesting 14 days later after a HIV-inconclusive status, retesting every quarter for people taking PrEP or retesting to verify a HIV-positive diagnosis prior to ART initiation (Table 4.10).*
HIV-inconclusive status	*When the testing strategy cannot provide a positive or negative HIV-status. This is different from discrepant test results.*
Confirmatory testing	*Use of any assay that definitively confirms an initial reactive test result, providing either a HIV-positive or HIV-negative status. Supplemental testing is sometimes referred to incorrectly as confirmatory testing; there are very few HIV assays that can definitively rule out HIV infection (HIV-negative).*

The HIV test should be performed according to the approved National testing algorithm and strategy. The diagram below illustrates the serial testing algorithm (Figure 4.1). In some instances, clients may be referred to another on-site HTS provider or laboratory for the test. Anyone receiving HIV test should be encouraged to receive their HIV test results in the same session regardless of where the HIV test is conducted.

This three-test strategy as well as retesting aims to ensure that at least a 99% PPV is maintained and false positive misdiagnosis is avoided.

All people newly diagnosed with HIV should be retested to verify their HIV status prior to starting ART using the same testing algorithm. Retesting is conducted by a different testing provider.



Note:

- The use of DNA PCR as a supplemental assay is no longer recommended
- For inconclusive HIV status, if reactivity remains the same after 14 days the individual should be reported as HIV-negative and advised to retest after 3 months

Figure 4.2: HIV Testing service Algorithm

HTS Results interpretation

RESULTS	INTERPRETATION
A1-	HIV-NEGATIVE
A1+; A2+; A3+	HIV-POSITIVE
A1+; A2-; Repeat A1+	HIV-INCONCLUSIVE (retest after 14 days). If reactivity remains the same after 14 days the individual should be reported as HIV-negative
A1+; A2-; Repeat A1-	HIV-NEGATIVE
A1+; A2+; A3-	HIV- INCONCLUSIVE (Retest after 14 days). If reactivity remains the same after 14 days the individual should be reported as HIV-negative

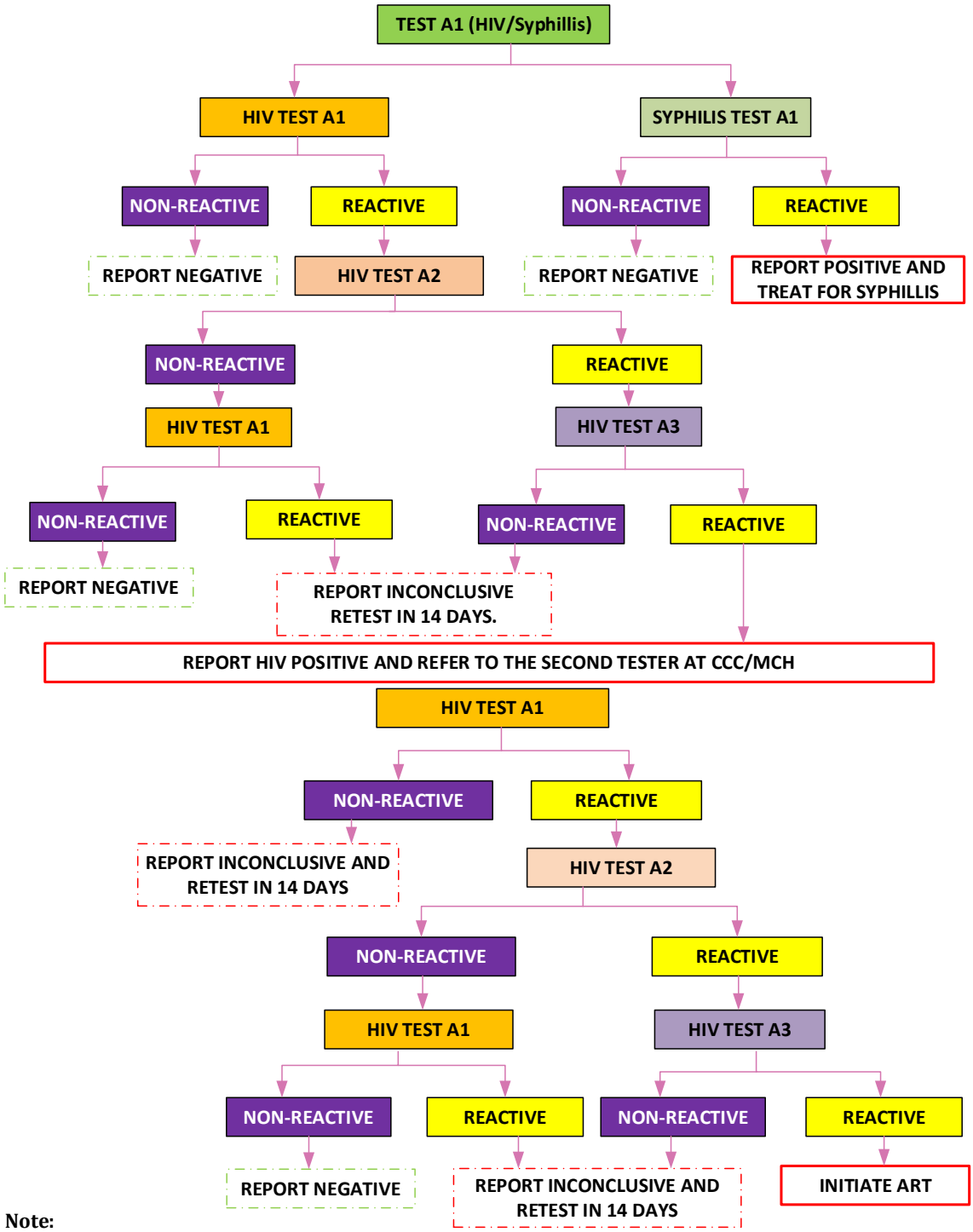
ii. **Dual HIV/Syphilis testing algorithm**

Since 2015, WHO is committed to triple elimination of mother-to-child transmission of HIV and congenital syphilis and hepatitis B virus (HBV). In line with the WHO recommendations, the Ministry of Health in Kenya developed the eMTCT framework aiming at elimination of MTCT of HIV, syphilis and HBV, further pushing the agenda for integrated service delivery (refer to the eMTCT framework).

This operational manual provides guidance on HIV and syphilis testing. For Hepatitis B testing refer to the Kenya HIV Prevention and Treatment Guidelines, 2022. The HIV/syphilis dual test is used as the A1 (HIV/TP) test (Figure 4.2). It is recommended for:

- All pregnant women presenting for the initial test at ANC in any trimester including labour and delivery
- All pregnant women presenting themselves for third trimester and had a negative HIV/Syphilis test result during the 1st trimester.
- All breastfeeding women presenting for the first time in the post-natal period and were never tested during ANC, labour and delivery.
- Partners accompanying pregnant women for the first-time during ANC, labour and delivery or post-natal period.
- It is important, however, not to use the rapid dual HIV/syphilis test for:
- women and partners with HIV taking antiretroviral therapy (ART);
- women and partners already diagnosed with and treated for syphilis during their current pregnancy; and
- Retesting for HIV.

See Figure 4.3 for the full algorithm when considering HIV and syphilis (TP) results concurrently.



Note:

- The use of DNA PCR as a supplemental assay is no longer recommended
- For inconclusive HIV status, if reactivity remains the same after 14 days the individual should be reported as HIV-negative and advised to retest after 3 months

Figure 4.3 Dual HIV/syphilis testing algorithm

RESULTS	INTERPRETATION
A1 HIV- TP-	HIV negative, syphilis negative
A1 HIV- TP+	HIV negative, syphilis positive
A1 HIV+ TP-	Report syphilis negative and proceed with A2 for HIV
A1 HIV+ TP+	Report syphilis positive and proceed with A2 for HIV
A1 (HIV+); A2+; A3+	HIV-positive
A1(HIV+); A2-; Repeat A1+	HIV-inconclusive (retest after 14 days). If reactivity remains the same after 14 days the individual should be reported as HIV-negative
A1(HIV+); A2-; Repeat A1-	HIV-negative
A1(HIV+); A2+; A3-	HIV- inconclusive (retest after 14 days). If reactivity remains the same after 14 days the individual should be reported as HIV-negative

HIV self-test (HIVST) algorithm

HIV self-testing (HIVST) is a process whereby an individual collects his or her own specimen (oral fluid or blood), performs a HIV rapid diagnostic test and interprets the result, often in a private setting, either alone or with someone he or she trusts. HIVST is intended as a HIV screening tool that has the potential to meet the needs and address challenges of increasing knowledge of HIV status. It is a complementary strategy to increasing knowledge of HIV status and uptake of prevention, care and treatment services.

HIV self-testing is a screening test and is not sufficient to make a HIV-positive diagnosis. A reactive (positive) self-test result (Assay 0) should therefore be confirmed using the national testing algorithm by an HTS provider. A person testing negative is advised to re-test after 3 months if they have been exposed to HIV in the 4 weeks prior to the testing or are at an ongoing risk.

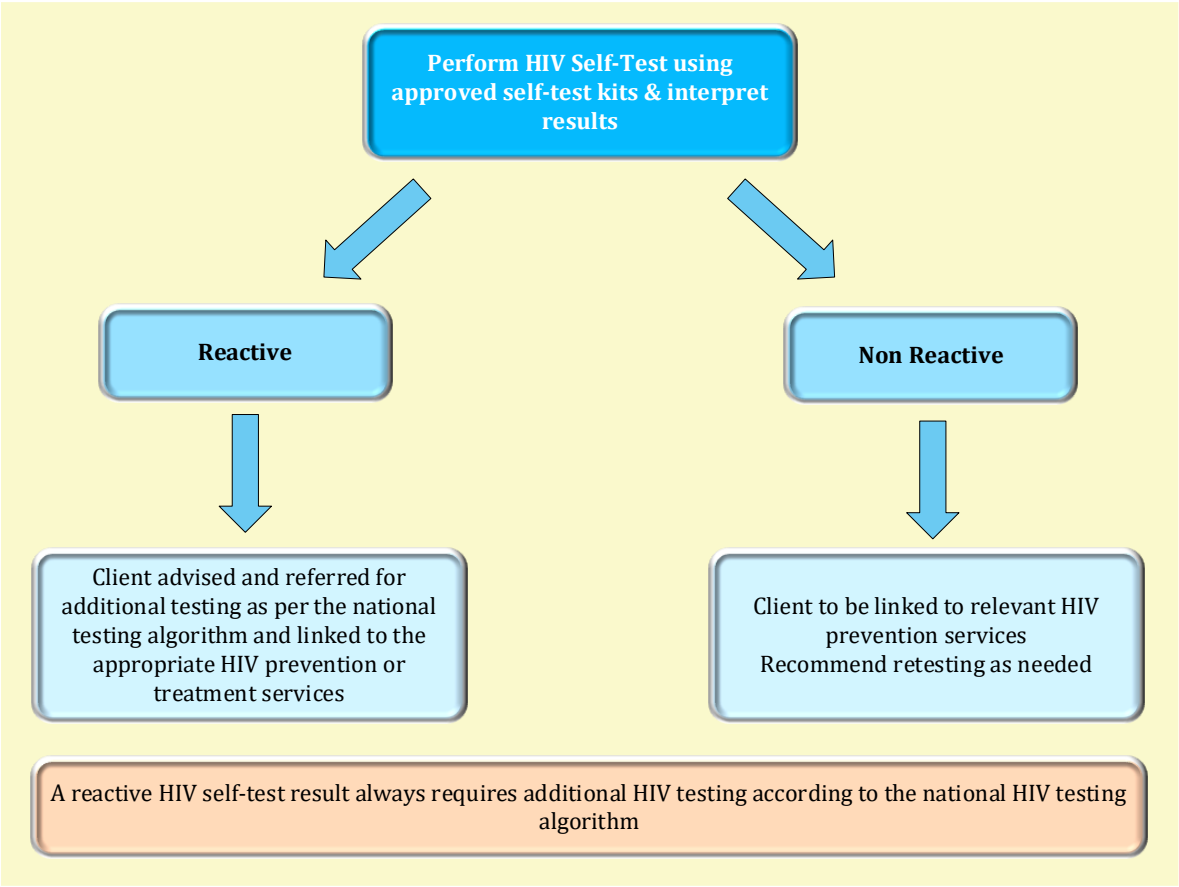


Figure 4.4: HIV self-Testing Algorithm

Early Infant diagnosis

For HIV-exposed infants, DNA PCR testing for HIV as early as possible is recommended so that ART can be started immediately. Nucleic acid testing (NAT) technologies that are developed and validated for use at, or near to, the point of care can be used for early infant HIV testing. Addition of NAT at birth to existing early infant diagnosis (EID) testing approaches can be considered to identify HIV infection in HIV-exposed infants.

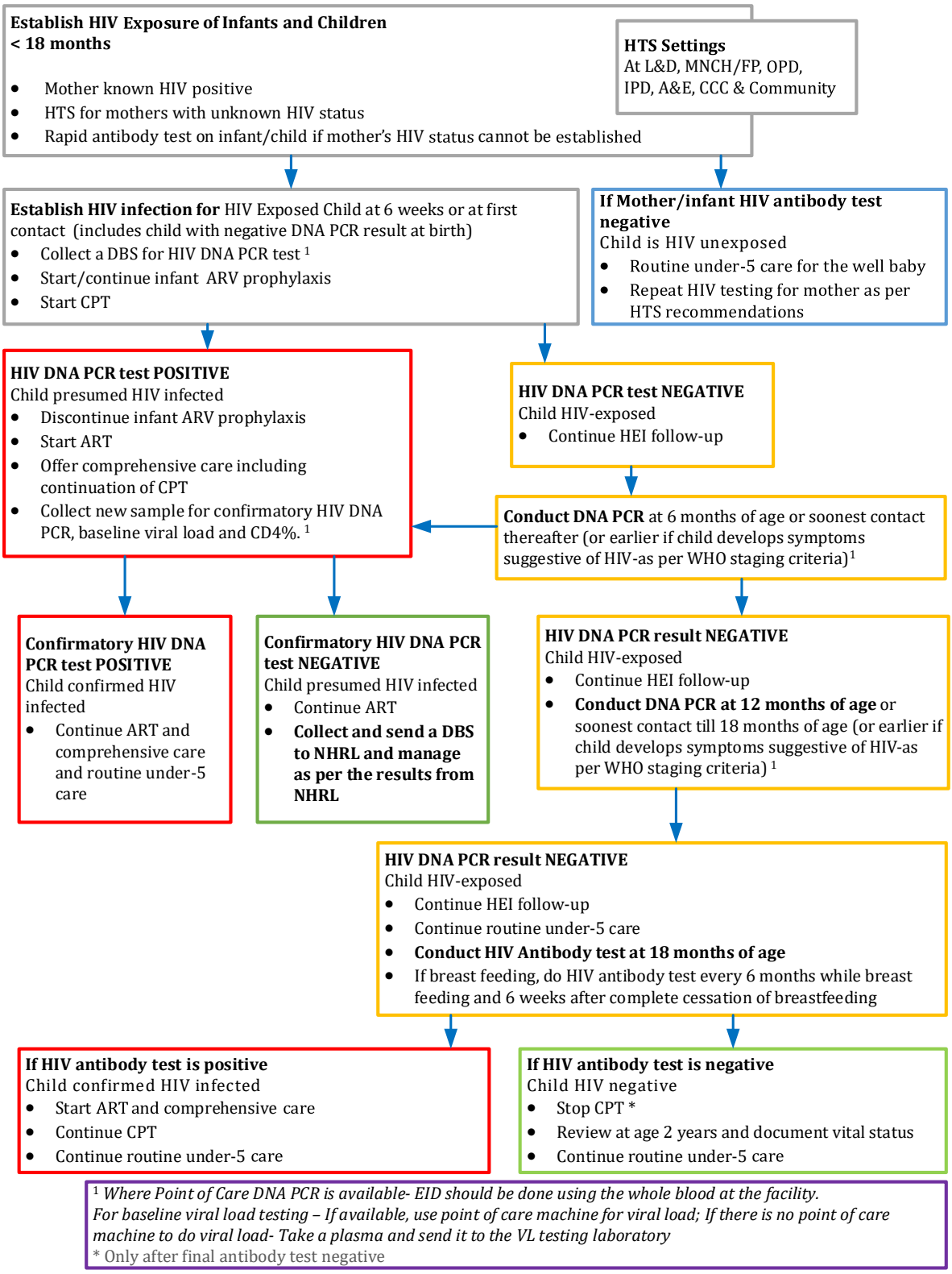


Figure 4.5: Algorithm for Early Infant Diagnosis in Infants and Children < 18 months of age

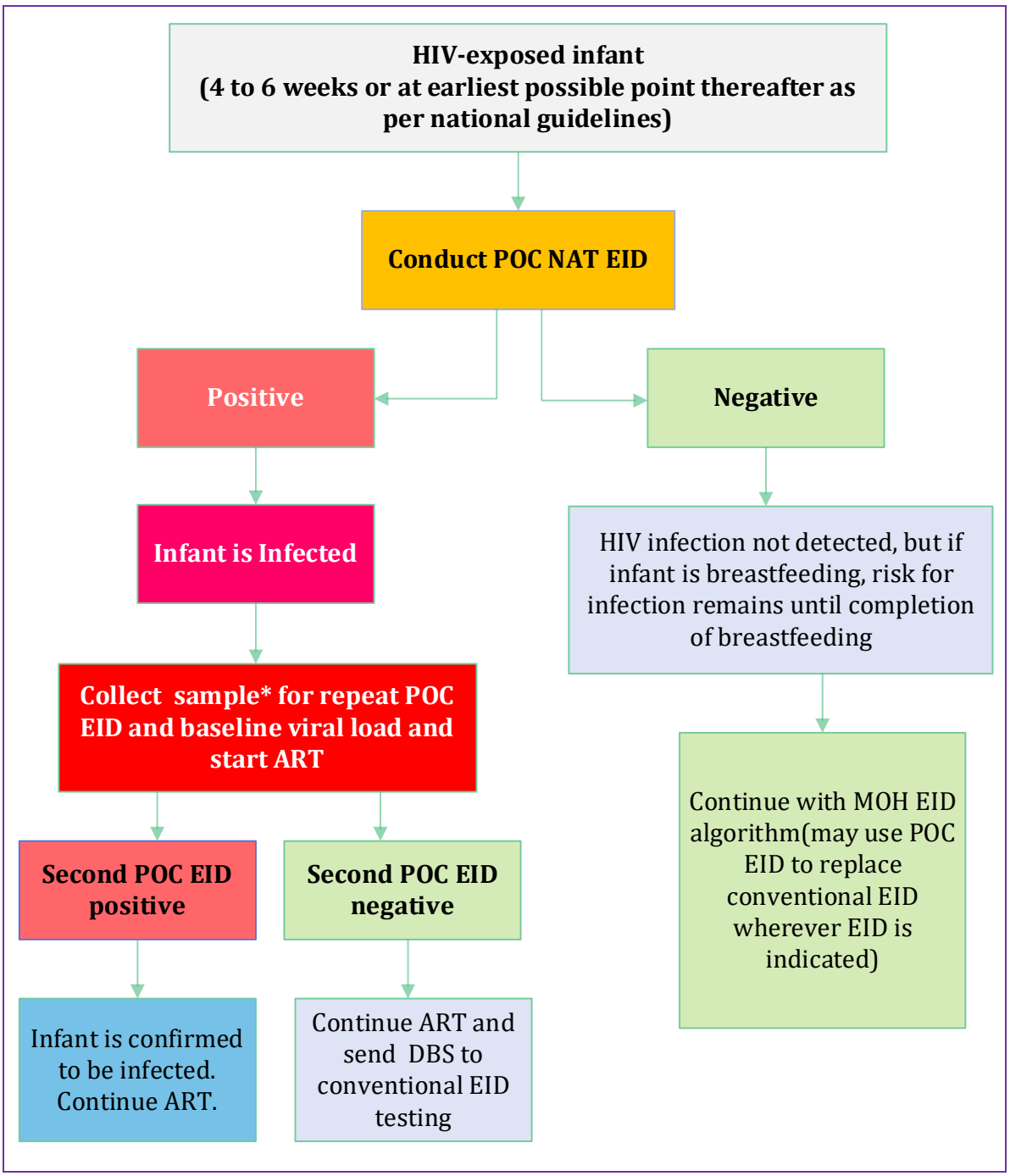


Figure 4.6: Point of care Algorithm for Early Infant Diagnosis

4.3 Testing Algorithm Review

Accurate HIV test results are essential since they are the entry point to treatment and prevention strategies. Algorithm-based testing instead of a singular test is preferred to enhance test results' diagnostic PPV. The testing strategy and algorithm used influence the accuracy of the HIV status reported. Against this backdrop, WHO recommends verification of testing algorithms before widespread roll-out (WHO, 2019).

The current practice of selecting a national testing algorithm based on evaluations performed at a single point of time or in a single population is inadequate. Although WHO-prequalified HIV rapid diagnostic tests (RDTs) met the recommended sensitivity and specificity criteria in the prequalification evaluations and in-country verifications, several reports from different countries indicate much poorer performance in real-world settings. Besides, not much is known about shared false-reactivity results among various RDTs. The use of the same antigen (Ag) preparations in the production of different tests (This has become common due to rebranding or relabeling arrangements among test manufacturers) can lead to shared cross-reactivity, but this may not be the only reason. Even low levels of shared cross-reactivity, or marginally substandard performance of one RDT, could significantly impact the performance of an algorithm. (Kosack et al., 2017). In an ideal algorithm, tests should not share the same false reactivity (WHO, 2021).

Therefore, it is important that after testing algorithms have been adopted and implemented nationally, they should be reviewed frequently to determine if test is performing as expected and if any changes need to be made to the algorithm. Lack of guidance on a regular reassessment of tests used in the country is still a major concern. People falsely declared positive or negative because of reduced performance of assays or inappropriate HIV testing impact current prevention and treatment strategies in resources-constrained settings like ours (Aghokeng et al., 2009).

Moreover, many HTS guidelines assume that a population is serologically stable over time, as once adequate test performance is established through the initial validation, no ongoing assessment of test specificity or sensitivity is required. Evidence across more than 22 programs in 10 countries suggest that this is not the case (Klarkowski et al., 2013)

In addition, certain tests may fail to identify HIV infection by certain HIV variants circulating in certain regions. Particular variants may become common in certain populations due to migrations and displacements (Aghokeng et al., 2009). Given this, policy-makers need to re-examine the current guidance for determining and monitoring a test algorithm. Regular evaluations for known tests are important to ensure that HIV testing algorithms are effective (Aghokeng et al., 2009). As a country, there will be two-level of algorithm review once it is enacted

1. Yearly review using post-market surveillance protocol and proficiency testing data
2. If the prevalence changes significantly or after every five years, there will be a full algorithm review whose results will inform the revision of national HIV testing guidelines to adopt and scale up new WHO-recommended HIV testing strategies and algorithms. Such a review will give guidance to the testing assays and combinations that HTS will adopt.

Step 3: Post-test

Post-test counselling for people who test HIV negative involves the following:

- Explore the implications of testing HIV negative
- Discuss and come up with a SMART risk reduction plan
- Provision of male and/or female condoms, lubricant and guidance on their use
- Emphasis on importance of knowing the status of sexual partners and information about the availability of partner and couples testing services
- Referral and linkage to relevant HIV prevention services, such as needle and syringe programmes and opioid substitution therapy for people who inject drugs, post-exposure prophylaxis, pre-exposure prophylaxis and voluntary medical male circumcision (VMMC)
- Repeat testing for people who test negative but report risky behaviour within the last 4 weeks (i.e., unprotected sex with a partner of unknown status or Known HIV positive status); if they test HIV negative again after 4 weeks, people with ongoing risk should be advised to return for testing every 3 months
- Post-test counselling for people who test HIV positive:
- Explanation of the test result and diagnosis, giving the client time to consider the result and helping the client to cope with emotions arising from the diagnosis
- Discussion of immediate concerns and help for the client to decide who in his or her social network may be available to provide immediate support
- Clear information on ART and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to access ART
- Newly identified HIV positive clients should be escorted to CCC for linkage to care and treatment, clients who are unable to enroll in HIV care on the day of diagnosis Should be supported to access the same at a date of their choice
- Provision of Information on how to prevent transmission of HIV, including information on the reduced transmission risks when virally suppressed on ART
- Provision of male or female condoms and lubricants and guidance on their use
- Discussion of the risks and benefits of disclosure to partners; couples counselling should be offered to support mutual disclosure
- Encouragement and offer HIV testing for sexual partners, injecting partners and children

- Provision or referral to counselling, support and other services as appropriate, including screening and treatment for tuberculosis (TB) and sexually transmitted infections (STIs), prophylaxis for opportunistic infections, contraception, antenatal care, opioid substitution therapy, and access to sterile needles and syringes.

Post-test counselling for inconclusive result:

- Explain the meaning of an inconclusive result
- Discuss and address the client's immediate concerns
- Normalize and validate client's feelings
- Inform the client that the test will have to be repeated after 14 days
- Conduct repeat testing as per the national algorithm

The need for quality post-test counselling cannot be overemphasized. The client's uptake of post-test referral and adoption of safe behaviour is dependent on the quality of the post-test session.

4.4 HIV Recency Testing

HIV recency testing is an approach for understanding HIV transmission patterns within a population or region. It is used as part of surveillance efforts and is one of several approaches to understanding the epidemic. Recency testing is not to be used for diagnosis.

A testing algorithm using rapid tests for recent HIV infection (RTRI) and viral load (VL) testing can differentiate between infections that occurred less than 12 months and long-term HIV infections that occurred >12 months ago. By conducting recency testing among newly diagnosed PLHIV, Kenya will have a better understanding of where and among which populations more recent infections are occurring or are being diagnosed, which can contribute to more targeted HIV testing and prevention programs. Clients reported as newly HIV positive by tester 1 (A1+, A2+ and A3+) in the routine HIV testing algorithm above, will be considered for HIV recency surveillance. The algorithm to determine the recent HIV infection status using RTRI and VL testing is called the Rapid Infection Testing Algorithm (RITA) and is shown in the figure below:

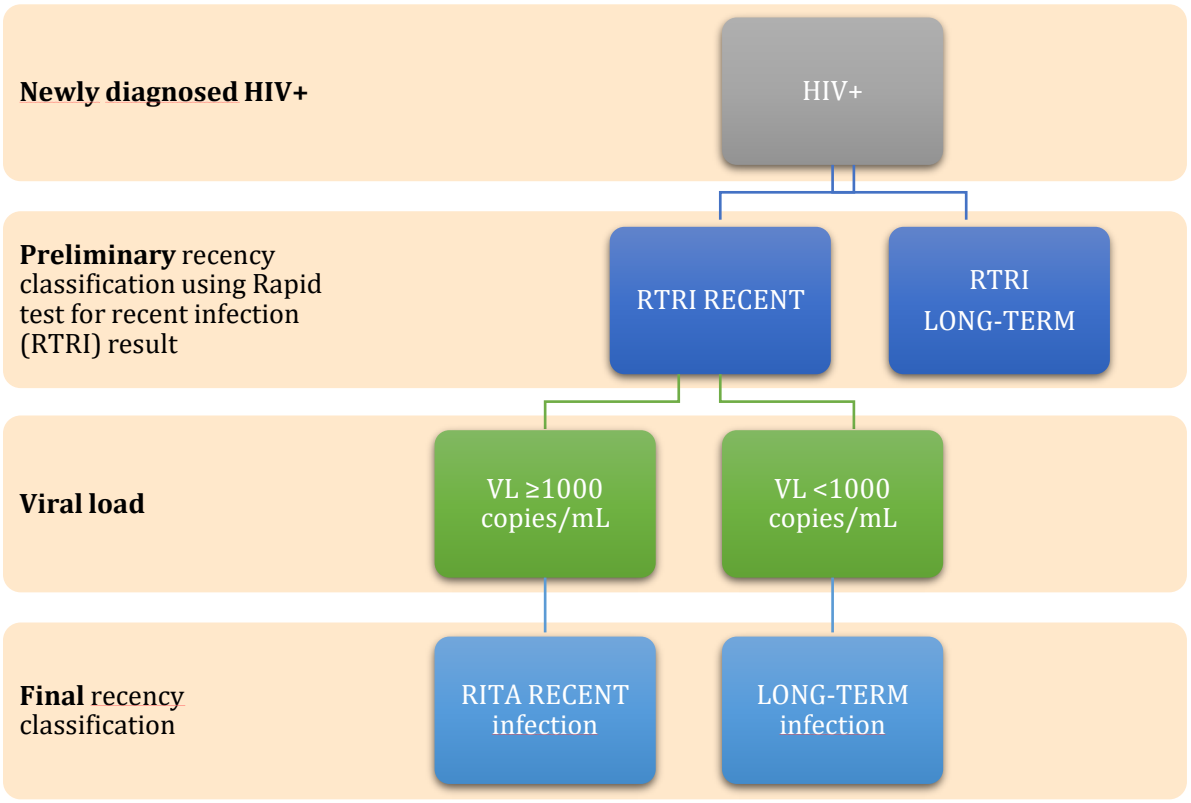


Figure 4.7: Recent Infection Testing Algorithm (RITA)

a. **Implementation of recency testing;** Depending on available resources, local context, and latest testing guidelines, recency testing may be implemented in different ways. The table below outlines the approach to HIV recency testing in Kenya.

Table 4.3: Approaches to HIV recency Testing

Area	Recommendation
Who is eligible for recency testing?	All newly diagnosed HIV positive persons of legal consenting age for HIV testing.
When should recency testing be offered?	Recency testing should be offered as soon as possible after a person is newly confirmed to be HIV positive.
Will the PLHIV receive his or her recency result?	Recency results will not be returned to the individual client. Clients will be informed that results of recency testing are relevant and reportable at the population level, not at the individual level, and results do not change HIV clinical management. Standard package of care will be based on HIV diagnosis and not on the recency test result. Community-level aggregate results may be publicly available after recency testing has been established in the community.
What type of sample is required for recency testing?	A whole blood sample, commonly venous blood, will be required to determine the recent HIV infection status of an individual. Following RTRI testing, clients who test RTRI recent will receive a VL test to confirm their recent HIV infection status.
Remnant Samples	Remnants of samples testing recent from HIV rapid recency testing will be stored for future surveillance activities. Stored samples will be anonymized.
Data Collection and Storage	Data for HIV recency surveillance will be collected according to national data management SOPs for surveillance and will be stored in the Kenya national HIV recency database. This database will consist of merged data from HTS facilities, RTRI testing labs and viral load testing laboratories. Data elements that can be obtained from this database include; • Number of newly tested HIV positive individuals per facility • Number eligible for recency testing using RTRI • Number that gives consent for RTRI testing • Number that gets tested for recency. • Number that tests RTRI recent and RTRI long term. Of those who test RTRI recent, the number who are truly recent infections based on viral load testing (RTRI recent + VL ≥1000 copies/ml are considered as recent HIV infections). The data collected is owned by MOH and will be stored at a place advised by MOH.
Reporting of HIV Recency Performance Indicator(s)	It is important to monitor indicators of performance of HIV recency surveillance. NASCOP will advise on reportable indicators from time to time. At the beginning, the reportable indicator will be HTS_REC which is the number of newly diagnosed HIV-positive persons who received a test for recent infection with a documented result during the reporting period. Data source for this indicator will be the national HIV recency database.

b. Use of recency testing data

A database and dashboard of epidemiologic data will be available to determine and monitor trends in person, place and time of the proportions of recent HIV infections among newly diagnosed PLHIV. These data can be disaggregated by routinely available demographic and HIV risk variables to inform targeted HIV testing and prevention interventions.

Recency testing will also help identify signals among hard-to-reach groups and new pockets of HIV transmission to facilitate rapid interventions to stop the chain of transmission and strategically support epidemic control in Kenya. Inclusion of recency status into existing surveillance databases for instance the case-based surveillance database for more complete description of newly diagnosed cases can be used.

Step 4: Referrals and linkage

Linkage is the first step towards onward services. Without linkage to care and treatment, being tested and learning one's HIV-positive status have limited value. Similarly, those who test HIV- negative and are at ongoing risk need linkage to prevention services. Also, those with a reactive HIVST need to be linked for additional testing to establish HIV status and connect to additional services, as needed.

HTS sites, testers and counsellors are responsible for ensuring linkage. They need to provide post-test service packages that includes up-to-date post-test counselling messages and evidence-based strategies and support tools to facilitate linkage depending on the context, setting and population.

Documentation for referral uptake should be done using nationally approved HTS referral tools and tracking should be done by the HTS providers, CHVs or peer educators to ascertain if the clients accessed the referral services. Linkage should be documented in the HTS register.

Table below summarizes recommended services and interventions that people living with HIV and those who test HIV-negative may be linked to:

Table 4.4: Linkage to HIV Treatment and prevention

Who is to be linked	
Linkage to retesting	After the rare case in which an individual could not be diagnosed on the same day and is given an inconclusive status, linkage to retesting is needed after 14 days.
Linkage to Further testing	After a reactive HIVST, linkage to further testing using national HTS algorithm is recommended
Linkage to ART	For all people diagnosed with HIV, it is recommended that treatment is offered and ART be initiated as early as possible preferably within 2 weeks. Treatment may be deferred for patient with Tuberculosis and cryptococcal meningitis (refer to the Kenya HIV Prevention and Treatment Guidelines, 2022).
(Re)Linking to ART	For all people with HIV who know their status and are not currently taking ART. This includes: • People diagnosed with HIV before the test and treat era who never started treatment • People who were offered ART but who were not yet ready to start • People who started ART but later discontinued.
Linkage to HIV prevention	For those who are HIV negative and at ongoing risk and not accessing prevention services should be linked to HIV prevention interventions
Measuring linkage	Monitor linkage to treatment initiation within 14 days of diagnosis, however allow follow up of unlinked clients up to 90 days of a HIV-positive diagnosis. Note: • **Beyond the 90 days of unsuccessful follow up, the client is declared Lost To Follow Up or declined ART.** • **It is the responsibility of the HTS to document and demonstrate tracing effort in the defaulter tracing register.** For HIV negative clients link to HIV prevention services based on assessed risk

A combination of interventions is needed to improve linkages to prevention, care and treatment, particularly to minimize loss to follow-up between HIV testing, on one hand, and care and treatment, on the other. This needs attention especially for people living with HIV who are reached outside of health facilities, in settings where ART is not available onsite and for populations that may face barriers to services. Such groups include key populations, men, young people, migrants and displaced populations, and people who are very ill or have advanced HIV disease.

Depending on need, approaches to improve linkages include:

- Integrating and co-locating services (providing HTS, ART and other related services in a single facility) whenever possible
- Implementing quality improvement approaches
- Peer outreach and support models

4.5 Retesting and disclosure recommendations

a) Retesting

Retesting can refer to performing a second test on a different sample after an individual

- Tests positive using the national algorithm, or
- Has an inconclusive test result using the national algorithm described in Figure 4.1.

In the first scenario, retesting occurs prior to initiating ART to verify the positive result, and in the second scenario, retesting is done 14 days following inconclusive results.

Retesting can also refer to testing that occurs at a later date after the initial test is negative because there is ongoing behaviour that place a person at risk for HIV. The following are the recommendations for HIV retesting in different populations and settings in Kenya:

Table 4.5: HIV Retesting Recommendation

Scenario/population	Recommendation for retesting
General population	Re-test every two years. Screening to be done on contact with HTS service provider.
Key populations (FSW, MsM, TG, PWID)	Quarterly risk-based screening and testing (Targeted testing).
Vulnerable Population	Retest biannually
Negative partner in discordant	Re-test at the initiation of ART for the HIV positive partner, Retest every three months until viral suppression is achieved. Once viral suppression is achieved, Retest at 6months and 12 months then annually if the positive partner remains virally suppressed.
Pregnant women	Test in first trimester or first contact; Re-test in the third trimester and, during labour and delivery.
Breastfeeding mothers	Re-test 6 weeks after delivery, at 6 months then every 6months until complete cessation of breast feeding.
Persons who had a most recent (e.g., less than one month) risk exposure to HIV	Test at initial presentation and re-test at 4 weeks. For negative clients retest at month 3 after which usual guideline should apply.

Scenario/population	Recommendation for retesting
STI symptomatic patients or patients with symptoms suggestive of acute HIV	Test at initial presentation and re-test at 4 weeks, for negative clients retest at month 3 after which usual testing guidelines apply
Individuals on Pre-exposure prophylaxis (PrEP)	Test at initiation of PrEP; Retest at Month one, Re-test at month 3 then retest after every 3 months

Disclosure of clients' 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. This is different from index testing. An important goal of HIV status disclosure is to obtain support that enhances access to care and may help a client overcome personal challenges. Another important goal is to inform sexual or injecting partners that they may have been exposed to HIV and would benefit from HIV testing if they do not know their status. Some clients may face situations of stigma, discrimination or violence so the health care provider should encourage and support the client to disclose, but it should not be treated as if it is an event that must happen. If the client voluntarily consents to assistance, a health care provider may disclose patient HIV results to another provider for purposes of further care/management. In this situation, all information should remain confidential.

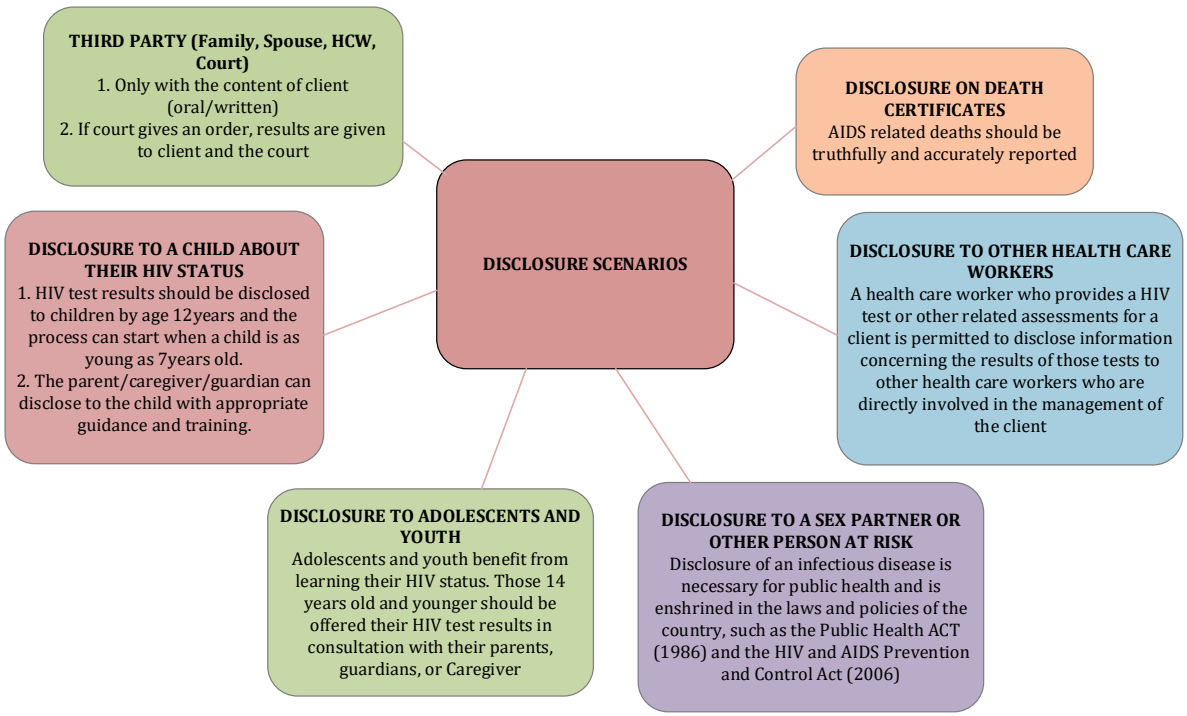


Figure 4.8: Disclosure scenarios

a) Disclosure to Children living with HIV about their HIV status

HIV test results should be disclosed to children by age 12 years and the process can start when a child is as young as 7 years old. The parent/caregiver/guardian can disclose to the child with appropriate guidance and training. HTS providers, parents, guardians, and caregivers 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 step-by-step disclosure depending on the child's level of understanding of concepts of ill health and HIV infection. HTS service providers should offer to assist with disclosure in case difficult questions arise. For children up to 14 years, test results will also be given to the parents/guardians who provided consent for testing them. Parents, guardians, and care may then disclose to the child; they should be guided on disclosing to children their HIV status using age-appropriate language. WHO recommends that the decision about who should disclose to the child be guided by the intent to improve/promote the child's welfare and minimize the risk to his or her wellbeing and to the quality of the relationship between child and parent/caregiver. HTS providers should also be available to provide ongoing support and counselling for the family, as necessary.

b) Disclosure involving adolescents and youth

Adolescents and youth benefit from learning their HIV status. Those 14 years old and younger should be offered their HIV test results in consultation with their parents, guardians, or caregivers. Post-test counselling 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 for HTS, but where they wish to receive the results in the company of their parents/guardians they can choose to. Adolescents and youth should be counselled about the potential health benefits of disclosing their HIV status to significant others, including their parents/guardians and sexual partners. They should be 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 HTS providers to disclosure.

c) 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 a 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 or adult offspring, or a health care worker who is directly involved in the treatment or counselling of that person. If a 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.

d) Disclosure to other health care workers

A health care worker who provides a 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.

e) Disclosure to a sex partner or other person at risk

HTS 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) who are at 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 sex partners or other persons at risk, a medical practitioner may encourage the partners at risk to consider having couple HIV test with the partner without disclosing the status of the HIV positive partner. 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. It is important to recognize that if a person has an undetectable viral load, there is no risk of HIV transmission to sexual partners.

Index testing, which is inclusive of assisted partner notification, is different from disclosure because the identity of the HIV positive person is not revealed to anyone. Index testing is recommended to identify people living with HIV who do not know their positive status. Assisted partner notification is discussed in detail in the NASCOP APNS guidelines (HIV Self-testing and Assisted Partner Notification Services, 2019).\

Disclosure of the identity of the positive partner may be important in certain situations and encouraged. For example, 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 if the positive partner is not taking ART and virally suppressed. HIV post-test counselling 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; 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. Counsellors and HTS providers should be prepared to address the unique challenges that may arise during couples HTS.

f) 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.

4.6. Special consideration for testing

There are certain specific circumstances when HIV testing can be done without consent and have not been included in the usual settings, approaches and strategies as explained below.

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 HIV testing. However, the person being tested should receive their test results and adequate counselling should be done in an appropriate setting. The clients should also be provided with the necessary referrals and linked to care if HIV positive.

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. It is recommended that HTS be offered alongside blood donation services and that results should be 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 counselling 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 surveillance must be delivered in line with national testing guidelines and other relevant policy guidelines. Caution 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. Measures should also be put in place to ensure that participants receive appropriate post-test referrals and are linked to appropriate prevention and care services.

CHAPTER 5 INTEGRATION OF SERVICES

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 health system levels (WHO 2008). One or more service providers can offer integrated services within the same service delivery points (SDP).

5.1. Bidirectional HTS integration

Integrating services aims 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 spent. It is recommended that health service delivery points include HTS because of the potential benefits of offering HIV testing in these settings. Additionally, in settings where HTS is the primary service, other health services should be provided along with HTS. Thus, the integration of HTS is bidirectional.

Integration entails HTS being offered to those seeking other health services and other health services are offered to those presenting for HIV testing.

This Integration will lead to early detection of HIV and quality health care for people who are testing for HIV and maybe living with HIV leading to reduction of HIV transmission and making services more cost-effective. In addition, HIV self-testing is an important intervention that can be used to integrate HTS into different care settings that may not have the capacity to test for HIV.

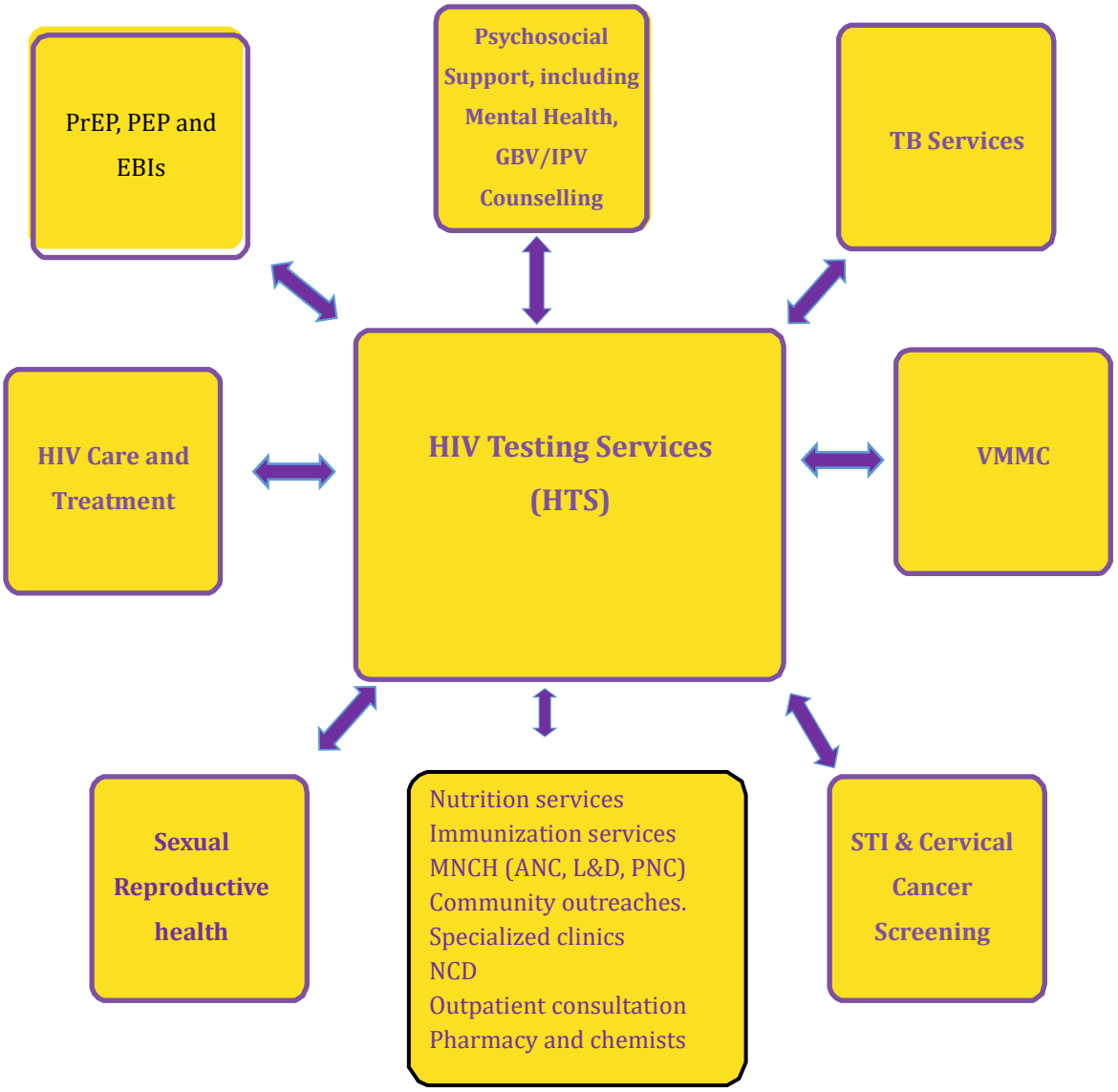


Figure 5.1: Bidirectional HTS integration facility and community settings

5. 2. Minimum package of services provided at HTS delivery points

The following services should be provided as a minimum package at HTS delivery points located at the community and health facility level. All HTS should be equipped with the necessary skills to provide these integrated services.

- Contraceptive services.
- Tuberculosis screening, testing and referral for prevention and treatment
- Psychosocial support.
- Gender-based violence/Intimate partner Violence risk assessment and appropriate referrals
- STI screening and referral or treatment
- Condom demonstration and distribution
- Cervical cancer screening
- Pre-exposure prophylaxis (PrEP)
- Post-exposure prophylaxis (PEP)
- Voluntary medical male circumcision (VMMC).
- Other HIV prevention services
- Referral for Nutrition services, Immunization services, Pharmacy and chemists
- Referral for MNCH (ANC, L&D, PNC)
- Referral for Community outreaches.
- Referral for Specialized clinics
- NCD

5.3. Integrating HTS into healthcare service delivery points

Healthcare service delivery points should integrate HTS and offer it to clients alongside the services noted in figure 5.1 above in health facilities. These service delivery points include but are not limited to the following: all outpatient and inpatient settings, maternal neonatal and child health clinics, family planning clinics, STI clinics, TB clinics, antiretroviral therapy clinics, VMMC clinics, post-rape care and sexual assault clinics. At these SDP, it is important to follow all national guidelines if a person tests positive. Specific service delivery points where integration is critical are described below.

5.3.1 Sexual Reproductive Health.

Evidence shows that 58% of married women and 65% of sexually active unmarried women use contraception (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, where HTS is being provided (UNAIDS and WHO 2007, WHO 2014, eMTCT Strategy 2013). All HTS SDPs are encouraged to identify clients with unmet family planning needs and refer or provide them with FP services where feasible, emphasizing long-acting reversible contraceptive methods. This will facilitate adherence to WHO guidance that states, "Women and adolescent girls living with HIV should have access to and be able to use the full range of available contraceptive options for which they are medically eligible."

SRH services Including post abortion care (PAC) should incorporate HTS into their services. In addition, HIV self-testing kits can be used as a screening tool to reduce the burden of testing at the FP clinics and those at ongoing risk should be referred for HIV Prevention services.

5.3.2 Maternal Neonatal and child health care

The overall national HIV prevalence is 4.5% while the mother to child transmission is as high as 10.8% (HIV estimate, 2020). Kenya has committed to the triple elimination of HIV/Syphilis/HBV transmission from mother to child.

HTS should be offered in all MNCH services

Community and facility-based HTS service providers should identify pregnant women and refer them for early antenatal services. If a woman presents to a HTS SDP with a child, She and the child will be screened and tested if they are eligible and both referred to other health services as appropriate.

Knowledge of HIV status is also essential for the partners of women seeking maternal and child health services to make appropriate decisions about their families' health. Health providers should encourage pregnant and postpartum women to bring their partners for couple HTS or access HTS outside the MNCH clinic setting, including using HIV self-testing, if this is preferred. It is recommended that Partners to PMTCT client be tested with a dual test as assay one during initial test. HIV test should also be offered to HIV exposed infant during immunization and other scheduled clinic visits.

5.3.3 Tuberculosis services

TB is the leading cause of death among people living with HIV, hence the integration of HTS into TB service delivery. Screen all clients receiving HTS for TB symptoms using the TB Active Case Finding tool. The Integrated Guideline for Tuberculosis, Leprosy and Lung Disease recommends that all clients presumed to have TB or diagnosed with TB receive a HIV test. Refer all clients presumed to have TB to the clinical team for TB diagnostic workup. Link to TB care and treatment all clients diagnosed with TB. Link all clients diagnosed with TB and HIV to TB HIV care and treatment.

5.3.4 Sexually transmitted infections (STIs) services

STIs are associated with increased HIV transmission and acquisition. All persons who are diagnosed with an STI should be offered HTS as recommended in Table 4:10 on Retesting, and persons who receive HTS should be screened for symptoms of STI and appropriately referred for management or treatment. Providers should trace and link partners of index client to appropriate HIV prevention and or treatment service. HTS providers are also encouraged to demonstrate and distribute condoms to clients seeking STI services to promote increased use and prevention of STIs and HIV.

5.3.5 Cervical cancer screening

Cervical cancer is the leading cause of cancer-related deaths in Kenya and the second most common cancer among females (GLOBOCAN, 2018). The causative agent of cervical cancer is human papilloma virus (HPV) which is sexually transmitted, and research has shown that women with HIV are more likely to have progressive disease when compared to those without HIV. Therefore, it is recommended that all women who are screened for cervical cancer are offered HTS.

HTS should also integrate cervical cancer screening, especially among women above 25 years of age who have not been screened before or who test HIV positive at any age. If cervical cancer screening is not available at HTS delivery points, HTS providers should encourage all women especially those above 25 years old, to seek cervical cancer screening from trained health providers in reproductive health clinics and other service delivery points.

5.3.6 Voluntary Medical Male Circumcision (VMMC)

Male circumcision has been proven to prevent HIV transmission by up to 60%. Therefore, voluntary medical male circumcision (VMMC) should be offered to all uncircumcised men seeking HTS as a package under combined prevention strategy among other services. HTS is routinely recommended and provided for all men seeking circumcision and aged 15 years and above as per the VMMC approved consent form. However, for the young males aged 7-14 years, Consent from the parent/guardian and assent from the minor is required before HTS except for the case of emancipated minor.

HIV positive men are not eligible for VMMC as a prevention strategy for HIV. However, where an HIV positive uncircumcised male requests for circumcision for other benefits, such a person should be counselled on the risks of such surgery and be advised to do a viral load. It is advisable that only virally suppressed clients can undergo male circumcision.

5.3.7 Gender-based violence services

Survivors of rape or defilement should be offered HIV testing services. Those who initially test negative should be provided post-exposure prophylaxis (PEP) and emergency contraception, as per the guidelines to reduce the risk of HIV acquisition and unwanted pregnancies, and retest 4 weeks after the exposure, if negative retest at 3 months thereafter as per the guideline. Individuals at risk of GBV/IPV who seek Health services should be screened for HTS/GBV/IPV. HTS providers should be trained on GBV/IPV screening and management to promote the integration of GBV response to HTS

5.3.8 Hepatitis

Hepatitis B virus (HBV) and hepatitis C virus (HCV) are significant health problems in Kenya, and anyone being treated for HBV or HCV should be tested for HIV. All persons receiving HTS services who are suspected of having viral hepatitis or members of populations at risk for hepatitis should be referred for HBV and HCV testing. Populations at risk include PWID, MSM, FSW, MSW, transgender and healthcare providers due to exposures to blood borne pathogens via needle sticks injuries. Screening for viral hepatitis should be done for members of these populations using a national standardized screening tool.

5.3.9. Specialized services

Persons seeking specialized services such as nutrition services, specialist clinics (Dental, NCDs, rehabilitative services, mental clinics etc.) Chemist/Pharmacy should be offered HTS services by providers trained on HTS. This can be made more efficient through leveraging on innovations such as HIV self-testing. Similarly, persons seeking HTS should be provided with the appropriate specialized services they require.

5.3.10. HIV Prevention services to HTS

All persons accessing HTS in all settings who test HIV negative should be offered HIV prevention services based on their needs. These include behavioural, Biomedical and structural interventions. Those who test HIV positive should be linked to HIV care, treatment and support services.

CHAPTER 6 HUMAN RESOURCES

The critical role of human resources in the provision of high-quality HTS cannot be overemphasized. Kenya has a resource of well-trained health care workers, but there is a huge disparity in distribution across the country. Through task-shifting, specific tasks can be delegated to lay health workers, which is recommended to increase access to HTS. This chapter describes the requirements of the personnel involved in the provision of quality HTS.

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

6.1. HTS service providers

Quality HTS can be provided by the following individuals:

Health care providers who have undergone training based on any of the NASCOP approved curricula and have been certified by NASCOP. This includes all qualified medical personnel from health care training institutions. HTS training could occur as:

- HTS pre-service training from a recognized medical training institution
- HTS in-service training in PMTCT
- HTS structured on the job training (OJT)

Non-medical (lay) providers who have undergone the HTS training using approved curricula and have been certified by NASCOP may conduct HIV testing. This category of providers should have completed at least a diploma level course in social or health sciences before training in HTS. They can be engaged to work in community or health facility settings where task shifting is applied to tasks such as HTS, linkage and retention in HIV care, ART adherence counselling and support group management.

Additional mandatory requirements:

i. All those trained on HTS should undertake observed practical sessions to master competency for a period of one month.
ii. All HTS providers should undergo refresher training once every two years:
    a. To update their skills to work with different populations
    b. To stay abreast of new developments in HIV and HIV testing in particular
iii. All HTS providers should undertake proficiency testing annually and attain a satisfactory level.

6.2. Who can train HTS providers?

Trainers must have a minimum qualification of a diploma in social or health sciences, be a NASCOP certified Trainer of Trainees (TOT) and be proficient in HTS.

All institutions conducting HTS trainings must have a valid biennial approval by NASCOP based on assessments using the nationally approved tool. All HTS training must be conducted in accordance with the nationally approved curriculum. Laboratory personnel TOTs should conduct training on the technical laboratory component.

6.3. Roles and responsibilities of staff within the facility

There are various personnel involved in ensuring provision of high quality HTS services, including but not limited to health managers and in-charges, HTS providers, laboratory in-charges, health records and information officers (HRIOs), laboratory supervisors, HTS mentors and all qualified health care workers. It is recommended that all staff work as a team to ensure provision of high quality HTS at all times. It is also important that everyone clearly understands their roles in order for teams to deliver services efficiently and effectively. The table below summarizes the different roles and responsibilities of the personnel.

Table 6.1: Roles and responsibilities of different staff and cadres involved in HTS

Staff/Cadre	Roles and responsibilities
HTS Providers **Facility in-charges**	Provide high-quality HTS, including: • Create demand for HTS through mobilization and health talks. • Conduct appropriate risk assessment and reduction counselling • Conduct HIV tests and give correct results. • Provide appropriate referrals and linkages to prevention and treatment programs through patient escort where possible and tracking of the referred clients • Manage HTS commodities in accordance with the national guidelines • Complete documentation of the client and testing data using the nationally approved tools and timely report • Within the community, coordinate post-test clubs and support groups • Facilitate evidence-informed behavioral interventions (EBIs) • Participate in HTS refresher trainings at least every two years as above • Observe infection prevention as per guidelines in all HIV Testing Services. • Participate in Quality assurance • Oversee planning, staffing deployment, monitoring and evaluation of HTS. • Ensure HTS services are promoted in the facility through support and administrative supervision • Ensure adequacy of commodities for HTS • Communicate HTS performance targets to the HTS providers • Ensure availability of conducive space for providing HTS • Facilitate timely reporting for HTS and commodities to the relevant offices • Provide regular administrative support supervision • Receive and review facility reports for decision making
HIV, AIDS and STI Coordinator (CASCO)	• Coordinate day-to-day HTS activities • Organize and conduct multidisciplinary support supervision for HTS. • Assist HTS providers in creating demand for services • Provide mentorship to the HTS service providers • Coordinate HTS commodities in liaison with the laboratory and pharmacy commodity managers. • Facilitate and ensure the adequacy of commodities for HTS, the preparation of commodities consumption reports. • 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 the performance of HTS

Staff/Cadre	Roles and responsibilities
	• Facilitate client feedback on the quality of services • Ensure HTS providers are trained according to the approved requirements • Liaise with the laboratory manager for proficiency testing program and corrective measures undertaken where necessary • Organize for observed practice by the HTS supervisors and mentor. • Supervision and assessment of HTS training institutions. • Ensure proper management of HTS data in liaison with the HRIO • Conduct regular data/service quality audits and support supervision
Health records and information officers (HRIOs)	• Ensure adequate supply of data collection and reporting tools for all HTS delivery points in the facility • Orientate all the HTS providers on the HTS tools • Analyze HTS data for decision making for service improvement at the facility level. • Collate data from the facility and report to the relevant sub-county offices. • Conduct regular data quality audits and support supervision
Medical Laboratory Managers	• Provide technical support to HIV testing. • Ensure quality assurance for HIV testing • Ensure all HTS providers are enrolled on a proficiency testing program and corrective measures undertaken where necessary. • 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 corrective actions • Ensure accountability for HTS commodities • Ensure timely reporting for commodities consumption and accurate projection • Ensure proper storage and management of testing commodities as per the SOPs. • Ensure that HTS providers receive regular debrief sessions to mitigate burnout in order to maintain the provision of high-quality HTS services • Provide mentorship of HTS providers through individualized or group sessions in the SDPs • Perform observed sit in sessions to ensure adherence to HTS SOPs.
HTS mentors	• Provide timely feedback to the HTS providers on their performance • Inform the patients on the benefits of HTS. • Initiate/refer HTS to all eligible patients.
Other Health workers	Participate in demand creation for HTS services
Community	• Take up the HTS services • Provide feedback on the quality of HTS

CHAPTER 7 COMMODITY MANAGEMENT

Commodity security is critical for the success of HTS. An effective commodity management system must be put in place to ensure access to and effective use of HIV rapid test kits (RTKs) at both service delivery points and store. Commodity management for HTS should follow well established principles but must be flexible and responsive to the varied settings and services offered.

7.1 Quantification

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

In addition to quantifying for HTS commodities, the counties should also 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 use of RTKs.

7.2 Commodity Management at county

Commodity management at county level entails commodity reporting, facility ordering, resupply and distribution planning. At the facility level, facilities determine the quantities to order within their drawing rights so that they are re-supplied as per their consumption. All HTS SDPs should compile and submit monthly summaries of the consumption and stock balance of the RTKs 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 (MoH643) for all the RTKs. At the end of the month, these documents shall be used to generate data for F-CDRR compilation. The completed F-CDRR (MoH 643) form includes up-to-date information on the stock available across the facility (e.g., in lab storage and at all HIV testing points), the consumption plus adjustments (e.g., positive, negative and losses), and the number of tests done across all SDPs in the facility.

The F-CDRR (MoH 643) should be submitted to the sub-county medical laboratory Coordinator (SCMLC) by the 5th day of the following month. SCMLCs/SCHRIO will collate F-CDRR reports for all the facilities in the sub-county and uploads in KHIS/HCMP. NASCOP, county and all stakeholders can access the data in KHIS. Reporting on consumption of commodities is done through Kenya Health Information Software (KHIS2) and is coordinated by responsible personnel at all levels, in collaboration with implementing partners.

At the county level, orders management for test kits is done by the county commodity TWG. The TWG utilizes the FCDRRs from facilities to allocate RTKs based on their consumption and stock at hand using the Health Commodities Management Platform (HCMP). The allocation list is then shared with the National Allocation TWG committee for approval. The National Allocation TWG validates resupply order for counties with approvals, seeks clarification where necessary, and generates the final allocation list.

The final allocation list is shared with the Kenya Medical Supplies Authority (KEMSA), who then picks, packs and distributes the RTKs directly to official health facilities with MFL code in the counties. KEMSA should send the final distribution list to NASCOP and County director of health before initiating the distribution. At the facility level, the HTS commodities should be received by designated personnel using clear written guidelines on receiving procedures. Any discrepancies should be documented immediately and communicated to the KEMSA central store.

KEMSA should share a copy of proof of HIV test kit delivery with the County Director of Health (CDH) to inform the county of the actual quantities supplied to facilities in that county. The CDH should also share the same list with the County and Sub-County Medical Laboratory coordinators (CMLC & SCMLCs) who will monitor the RTKs consumption. The CMLC should give an update of what was supplied to the county TWG. KEMSA then uploads the proof of delivery to the Health Commodities Management Platform (HCMP) dashboard for everyone to reference after every distribution cycle.

Laboratory commodity & information flow

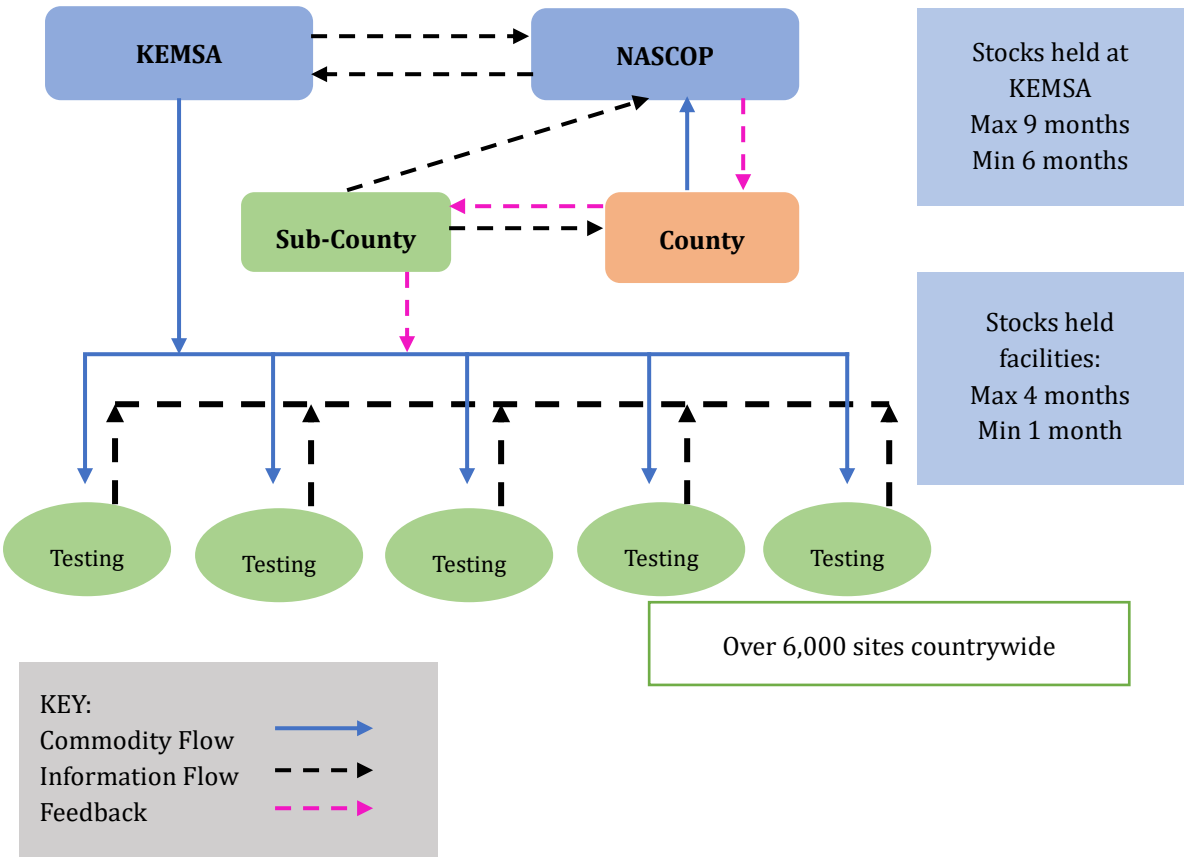


Figure 7.1: Commodity Consumption and Supply Chain Flow Chart

7.3 Procurement

KEMSA is the government agency primarily responsible for procurement of HIV test kits in Kenya, based on funding provided through Government of Kenya (GoK), Global Fund, Presidential Emergency Fund for Aids Relief (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. 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 HTS in Kenya shall be approved and registered for use by the relevant regulatory body in the country.

For KEMSA, procurement will be done in accordance with existing GoK/MoH procurement regulations, and in consultation with NASCOP. NASCOP shall provide 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 HTS commodities (gloves, disinfectants, etc.) should also meet 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.

7.4 Warehousing and distribution management

KEMSA shall distribute test kits directly to the health facilities, based on the approved 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 an update on monthly stock balances in its warehouses to NASCOP, list of HTS 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 HTS planning and 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 HTS related supplies including the commodity data tools, consumables and QA materials.

Peripheral re-distribution: At the county level, the CMLC, CASCO and other health officials should assess the stock status of their facilities at least quarterly. Facilities with 5 Months of stock should be closely monitored while 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. Where redistribution of RTKs is required, standard procedures and documentation should be utilized. 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.

7.5 Storage

Test kits and other HTS commodities should be stored and managed as per the Laboratory commodity management guidelines, which, at a minimum, follow the manufacturers' 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.

7.6 Quality logistics management

Quality logistics management aims to ensure that commodities are in the right condition and are available at the HIV testing points when needed. It also aims to achieve cost efficiency through minimizing expiration of HTS kits and other commodities. Measures to ensure high quality logistics management include:

- **Utilization of a "pull" system:** Commodities are supplied based on facility reports that reflect current consumption and stocks.
- **Timely and accurate reporting at all levels:** Counties will be expected to compile electronically the aggregated consumption, physical stock, and orders from their various facilities and then justify facility orders based on the data provided by 10th of every month.
- **Commodity audits:** Regular comparison of service and commodity data should be done to evaluate the utilization and reporting for HTS commodities. These audits will also help to identify stock outs, kits that are expiring or missing, and provide corrective actions.
- **Use of standardized reporting tools:** To ensure data is collected and reported routinely, standard national inventory management and commodity tools should be used for reporting.
- **Regular supervision exercises:** Counties should undertake regular supervision checks on commodity management system in health facilities within their county. They should also conduct data quality assessment and hold meetings with SCMLC, SCASCO and facility in charges to evaluate their data quality and develop data improvement plans.
- **Inventory management:** Specific inventory management SOPs exist and should be adhered to.

CHAPTER 8: QUALITY ASSURANCE FOR HTS

Quality assurance (QA) is a systematic and planned approach to monitor, assess, and improve quality of services on a continuous basis. The Constitution of Kenya 2010 (Bill of Rights chapter 4, article 43) states that every citizen has the right to the highest attainable standards of health.

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). QA should be an integral part of all the HTS and should be implemented in all aspects, including testing, counselling, management of commodities, human resource and data management. In addition, all stakeholders should have a systematic and planned approach to monitor QA on a continuous basis.

8.1 Benefits of Quality Assurance

Quality assurance has the following benefits for HTS:

- Ensures that the client gets a correct test result
- Ensures coherence and smooth functioning through various levels of service delivery
- Ensures the needs and expectations of clients and communities are being met
- Focuses on processes and how service delivery can be improved
- Enables standardization to ensure an acceptable level of quality services
- Encourages a multidisciplinary team approach
- Lowers the operational cost for delivery of services

8.2 Components of HTS Quality Assurance

The components of quality assurance identified below should be put in place to ensure that maximum benefits of HTS QA are realized.

8.2.1 Certification of HTS providers and continuous professional development

Health service providers who receive HTS pre-service training will be certified by the health training institutions while those who undergo in-service HTS training will be certified by NASCOP (See Chapter 6. Human Resources for HTS). It is recommended that those health service providers who undergo pre-service training undertake practical sessions to acquire competency in HTS. Non-medical HTS providers who undergo HTS training must have NASCOP certification and should possess a minimum of diploma qualification in a social science or health sciences.

After training, all HTS providers should receive continuous professional development in HIV management services. Professional development for health care workers should be monitored through a Continuous Professional Development (CPD) scheme in line with the relevant professional bodies. It is recommended that all HTS providers undergo continuous professional development through biennial refresher hands-on trainings to ensure competency is maintained. These refresher trainings are geared towards providing updates to HTS providers, including in areas such as new policies, research, procedures, and technologies. The refresher will be done using standard NASCOP curriculum through NASCOP trained TOTs and shall be certified by NASCOP and updated in the database.

Mentorship of HTS providers should be done by current experienced HTS providers and technical persons using the nationally approved tools. Technical support for HTS should also be provided regularly by the county and sub-county teams. Trained providers who have not practiced for more than a year should undergo refresher training and provided a certificate or other verifiable record of training before being allowed to resume HTS delivery.

8.2.2 Internal quality assurance at service delivery points

Quality assurance should be an integral part of HTS and should be implemented through simple and practical approaches at all levels.

Internal quality assurance at service delivery points focuses on the Core Principles of HTS which are summarized in Chapter 4, HTS Package and are known as the 6 C's: Consent, Confidentiality, Counselling, Correct results, Connection-linkage and Creating an enabling environment. HTS providers follow a defined protocol to uphold quality HTS and the 6 C's and this is supported by the following QA practices:

8.2.2.1 Counselling support supervision

Supervision/debriefing is an opportunity for HTS providers to come together, discuss and process issues that arise during HTS with a qualified and experienced HTS supervisor either during group or one-on-one sessions. Supervision/ debriefing should be offered by a trained and qualified counsellor supervisor to HTS providers on at least a quarterly basis. Counselling support supervision/debriefing is important for preventing 'burn out' of individual HTS providers and maintaining high quality communication between providers and clients.

It should be noted that counsellor support supervision is different from administrative support supervision offered by the health management teams. It is the responsibility of CASCO/SCASCO to ensure that all HTS providers receive quarterly support supervision. HTS counsellor supervisors are NB: To be trained as a counsellor supervisor, a person should have a minimum of 3 years' experience in offering HTS.

8.2.2.2 Counsellor self-assessment

Counsellors should use standardized NASCOP approved self-assessment forms to monitor the quality of their own service provision over time. The counsellors will be expected to fill self-assessment form and analyses them by the end of the month (Annex 4). Improvements should be done on the weak areas identified for quality service provision.

8.2.2.3 Client satisfaction surveys

HTS sites and facilities should administer client satisfaction surveys on quarterly basis to gauge the quality of their service delivery from the client's perspective. Questions may be brief, self-administered or/ and community members may be employed on a voluntary basis to help administer the interviews, which may address topics such as waiting time, cleanliness, counsellor attitude, and overall satisfaction with the service (Annex 6). The HTS coordinator analyses the client feedback data which is shared with HTS providers and the clients. Adjustments should be made to improve the quality of HTS provision. Facilities should also provide suggestion boxes for collection of anonymous client feedback at any time, and face-to-face client feedback should also be encouraged.

8.2.2.4 Observed practice

Observed practice is achieved when, with the consent of the client, a HTS provider is observed during the process of service provision. A plan needs to be in place on the implementation of observed practice in all HTS settings and should be done by a trained and experienced counsellor supervisor or more experienced counsellor which is shared and agreed upon by other counsellors. The observer should do it in person during the HTS session. Feedback is given directly to the HTS provider by the observer, who should use a NASCOP HTS observed session supervision tool (Annex 5) 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 HTS providers can learn from if they receive constructive feedback. Confidentiality should be observed by all parties. Each HTS provider should undergo observed practice on quarterly basis.

8.2.3 External quality assessment (EQA)

Measures will be implemented to allow for the external assessment of the quality of services at SDP. These measures will assist in identification of testing sites performing below standards so that corrective actions can be instituted to improve their performance. EQA is monitored in five complementary ways:

i) Proficiency Testing (PT)

This is an evaluation to determine the competence of a service provider. PT involves the distribution of characterized blinded panels to all enrolled service providers at least twice a year. NPHL through Kenya National External Quality Assurance Service (KNEQAS) coordinates the HIV PT EQA scheme through enrolling individual HTS providers in collaboration with the counties, production of the HIV rapid PT panels, evaluation of PT performance and provision of technical guidance on corrective interventions. Testing should be done in accordance with the national HIV testing algorithm and adhering to HIV testing SOPs. Results obtained should be submitted to KNEQAS for performance evaluation using the channels determined by the scheme.

KNEQAS shall prepare a summary of PT participants' performance per county to enable the CMLCs to execute appropriate corrective actions at facility level. Feedback reports outlining the performance and suggested / trouble shooting procedures will then be prepared and made available through the HIV PT online system (http://rhtpt.or.ke/). 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. The HTS supervisors are encouraged to make use of PT results to design corrective action to support participants.

HTS 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 HTS service delivery. PT panels addressed to participants who transferred or are on leave should be processed and tested by any other certified HTS service provider who is not enrolled on PT to avoid wastage, this will also present an opportunity for PT enrolment for the trained HTS service provider who had not enrolled.

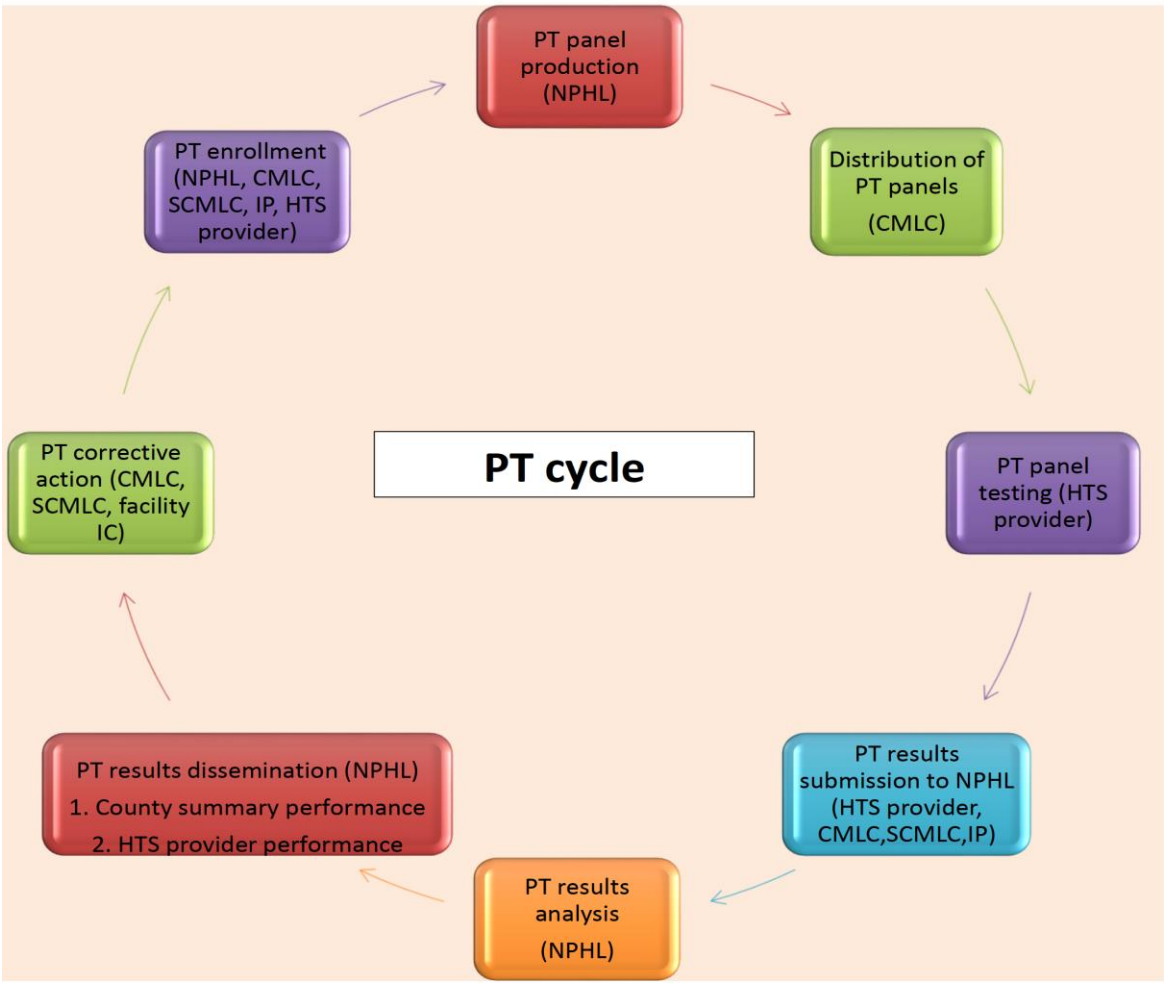


Figure 8.1: Proficiency testing cycle

ii) On site quality management (QM) assessment

On-site QM assessments involve periodic site visits to systematically assess the HIV testing practices at service delivery points. The visits focus on how the sites monitor their operation and ensure testing quality; they also provide information for internal process improvement. On-site visits provide opportunities to identify gaps or deficiencies, institute corrective interventions and collect information for planning and implementation, monitoring and continuous improvement.

They are also necessary to confirm that all SOPs and other testing protocols are available and adhered to including QC, troubleshooting procedures, record keeping, observation of staff performance, test kit management, and kit performance data. When necessary, it can provide the opportunity to administer observed PT to service providers who perform testing.

For onsite quality management assessment, NPHL implements HIV Rapid Test-Continuous Quality Improvement (RT-CQI). RT-CQI is a comprehensive package of quality assurance and improvement activities. RT-CQI increases the implementation of best practices at the site level using Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklist.

Key areas in RTCQI:

- **Guidelines and policies on quality assurance and improvement of rapid HIV testing**
- **Enrollment of all testers to the national proficiency testing scheme**
- **Strengthening systems for internal quality control at all testing points.**
- **Monitoring adherence to national testing algorithm**
- **Quartey RHT site assessments and implementing required interventions**
- **Certification of HIV service delivery points based on the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklist**
- **Post-marketing surveillance for RHT**

Site assessments are conducted at least quarterly and the aggregate percentage scores are used to provide a level-rating (Figure 8.2) that guides the need for improvement and assesses the sites readiness for national certification. Site certification is coordinated by NPHL using trained national auditors.

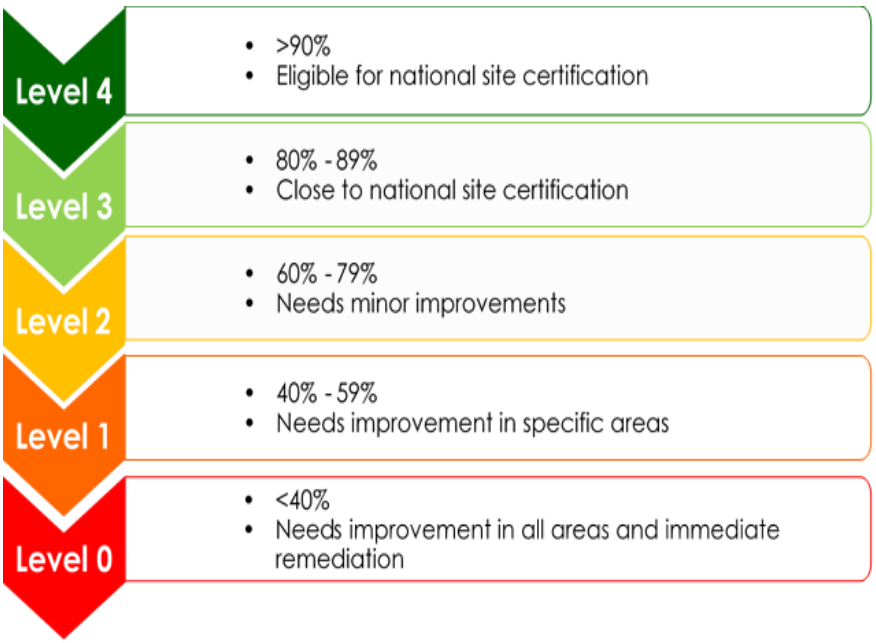


Figure 8.2: SPI-RT Assessments Pre-certification Levels for Testing Sites

iii) Use of HTS standardized tools for quality monitoring and improvement

Data from the standardized MOH HTS tools (both electronic and paper) should also be analyzed for use as part of ongoing quality monitoring and improvement. All routine HIV testing services data must be recorded in the HTS Register (MOH 362) -Test Kit name, Lot number, expiry date, individual test results, final results and all other columns.

Testing done in other settings must be completely documented in the appropriate registers such as ANC, Labour and Delivery, PNC, VMMC, GBV, KP and TB.

This has the capabilities of monitoring:

- Adherence to the national HIV algorithm
- Test performance (Agreement between the three testing assays and test results invalidity levels
- Change in trends of HIV positivity rates
- Test kits management

Site level supervision is the responsibility of the facility in charge, subcounty, county and national supervisors. A laboratory manager/HTS supervisor assigned by the facility in-charge will sign as the supervisor in the HTS Lab register MoH 362. These data should be analyzed on a periodic basis and corrective action done in a timely manner.

Each facility should have a functional working HTS specific work improvement team (WIT), to handle continuous HTS quality improvement projects.

iv) Data quality management

Data is critical in informing and directing programme activities and provision of quality HTS. Quality data should be accurate, complete and timely in order to make informed decisions. Standardized tools for HTS data collection and management are 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 also be done at the various levels and feedback provided to all stakeholders.

v) Service Quality Audit (SQA)

The HTS programmes will conduct Service Quality Audits (SQA) whose objective is to assess whether the services offered to clients meet the expected standards of care. National SQAs should be conducted semi-annually while county/sub-county level SQA should be conducted every quarter. Service quality gaps identified through SQAs are addressed using tools like plan, do, study and act (PDSA).

8.3 Quality Improvement Teams (QIT)

At the national level, the QIT 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. HTS facilities should have their own QA systems in place in accordance Kenya HIV quality improvement framework (KHQIF,2014). It is the role of the QIT teams at all levels to address clients' complaints within the facility.

QIT membership should take into consideration the representation of all stakeholders at various levels. Individual HTS providers are also responsible for delivery of high quality HTS to clients and communities, according to the defined standards. Whenever possible, QA for HTS in health facilities should be integrated into other ongoing QA activities at the facility. QIT teams should undergo periodic training on quality improvement strategies at least biannually.

8.4 Infection Prevention and Control

All biosafety and infection prevention control measures should be adhered to, and biosafety guideline and SOPs should be available in all service delivery points. Infection prevention control measures should be followed in all HTS settings and these may change under different prevailing circumstances, such as COVID-19. The testing facility shall ensure availability of personal protective equipment (e.g., masks, gloves, lab coats), appropriate disinfectants, and running water and soap to ensure optimal infection prevention to service providers, clients and the community. Waste segregation and disposal should be practiced in accordance with the recommended biosafety guidelines.

Control measures should be followed in all HTS settings. Sharps should be disposed in designated sharps containers. HTS 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 (HBV). PEP protocols should be available in all the testing sites, and the testing room should be well ventilated and illuminated. The above shall apply to both facility-based HTS and community-based HTS settings.

8.4.1 HTS In the Context of emerging public health threats.

HIV testing is a highly personalized health service that often involves close contact between clients and providers.

The HTS providers shall comply with the laid down HTS protocols and guidance during service provision. However, in the event of emerging public health threats, appropriate adjustment will be made in accordance with the provided policy guidance.

8.5 Laboratory and Test Kit Quality Assurance Processes

8.5.1 Adoption of new technologies

The National Public Health Laboratory (NPHL) through NHRL will provide leadership in the adoption of new HIV testing technologies as they become available. NPHL will analyse 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, NPHL will build capacity through refresher training.

8.5.2 Evaluation of HIV test kits

Evaluation of HIV test kits shall be done according to the country's regulation. The national HIV algorithm will be assigned and approved by a committee of national experts appointed by MOH. No test kits will be allowed for use in Kenya unless it has been evaluated and approved by the relevant bodies.

8.5.3 Post market surveillance

Once a product is placed on the market, its quality, safety and performance must be monitored to ensure that diagnostics continue to meet standards. The Ministry of Health in Kenya has established a system for post-market surveillance of HIV rapid kits that supplements the obligations of manufacturers, who must also conduct their own post-market evaluation activities. The reports from post market surveillance will be discussed with relevant stakeholders.

In this context post-market surveillance consists of:

- Proactive post market surveillance
- Reactive post market surveillance

Proactive post-market surveillance (to identify any problem before use) before and after distribution of test kits to testing sites.	**1. Lot testing** ➢ Pre-distribution lot verification testing Lot/batch verification is done to obtain evidence-based appraisal of any new kits against the ones in use to ascertain performance consistency between different lots/batches from the same manufacturer and reliability of test kits being received. The activity provides immediate means of corrective actions in case of significant variations in performance. NHRL will be responsible for new lot/batch verification prior to the release of kits from KEMSA into circulation in the counties. ➢ Post distribution lot verification testing NHRL will carry out a quarterly random assessment of the HIV test kits that are used in the country. This should be done every quarter at least one month post kit distribution. 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. 2. **Evaluation of EQA/ QC data** Data on the quality, safety and performance of in vitro Diagnostic (IVDs) in the post-market phase may also come from on-going external quality assessment schemes (EQAS), also known as proficiency testing. These programmes collect testing results from testing sites that receive the same blinded specimens to test. Lot numbers used to test these specimens should be recorded to make these useful data sets that can be used to give feedback to regulatory bodies.
Reactive post-market surveillance (when a problem has been identified during use of the HIV rapid test kits)	This is carried out through reporting and evaluation of complaints, including reports of adverse events, and any required actions to correct the problem and prevent recurrence.

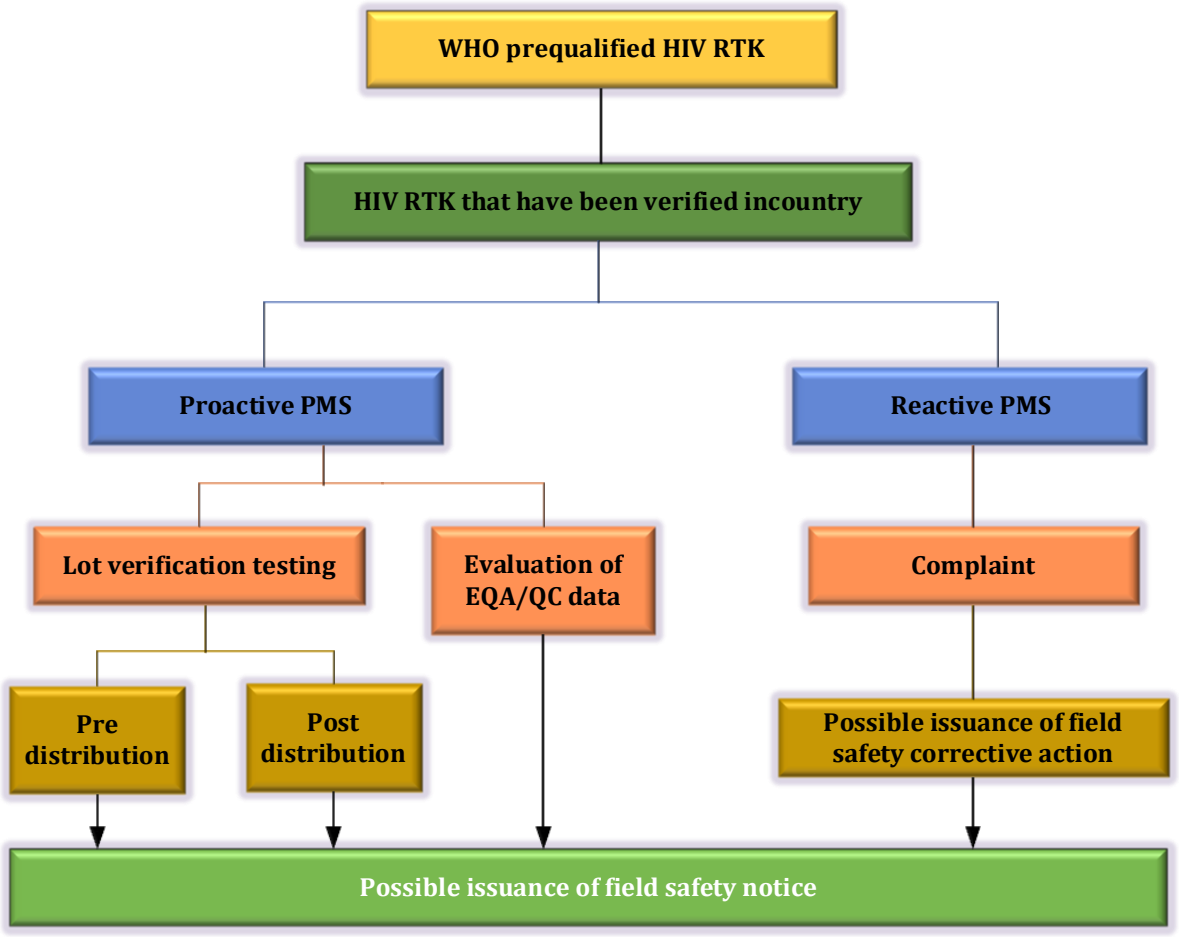


Figure 8.3: Procedure for Post market surveillance

CHAPTER 9 HTS PROMOTION

9.1 Introduction

Promotion of HTS is geared to engage and empower individuals and communities with information to help them make informed decision on HTS uptake and influence behavior change to reduce risk of acquiring and transmitting HIV.

All HTS providers, health promotion officers, mobilizers, and any person undertaking demand creation for HTS should embrace HTS and health promotion as an entry point to HIV prevention or treatment.

The HTS communication should be done in the context of combination Prevention and provide potential users the opportunity to make informed choices without discrimination. Service providers should not assume that clients already have information about HTS but provide HTS information at all times. Additionally, there is emphasis on differentiated HTS provision and application of targeted approaches hence demand generation should also take the same approach.

9.2 Overall Goal

To increase demand, uptake, and enhance utilization of HTS for sustained social and behaviour change to contribute towards the elimination of new HIV infections, stigma, and discrimination in Kenya.

9.3 Objectives

1. To increase knowledge and awareness of HTS among the general, key, and vulnerable populations
2. To scale up demand for and utilization of HTS
3. To foster an enabling policy and social environment for HTS uptake

9.4 Guiding Principles

It is important to adopt public health, human rights, and a people-cantered approach when developing HTS promotion strategies. Similar to other HIV prevention and treatment interventions, a human rights-based approach gives priority to issues concerning universal health coverage, gender equality, and health-related rights including accessibility, availability, acceptability and quality of HTS. The following principles should be adhered to:

I. Human rights-based: All communication will be respectful of the rights of beneficiaries without causing any harm such as stigma and discrimination.

II. Results-oriented: Effective communication will entail correctly answering the question; 'what do we want to achieve with a given communication activity or intervention?'

III. Evidence-based: All communication will take into consideration existing research in answering the 'what', 'why', 'where', 'when', and 'how' questions. In addition to pre-testing, messages will be post-tested and periodically reviewed and updated if new evidence emerges.

IV. Audience-centred: All communicators are expected to adapt the communication interventions to local context and language, and respond to changing needs and preferences of the target group including persons with disabilities.

V. Participatory: This implies the involvement of concerned national, county, and local stakeholders as well as peer educators and social workers, and beneficiaries in all stages of communication planning, message development, implementation, monitoring, and evaluation.

VI. Multi-pronged approach: A mix of behavioural communication interventions will be implemented simultaneously targeting different levels of influence and depending on resource availability. Efforts will be made to build on the success of prior interventions.

VII. Sustainability and ownership: Communication strategies will be steered by the national, county and communities' leadership through the county health management team and integrated within county health program initiatives.

9.5 Focus areas for HTS Promotion

To ensure maximum impact on HTS promotion activities, the following five key areas should be addressed:

I. Demand creation

II. Advocacy

III. Capacity building

IV. Coordination and implementation of HTS promotion efforts

V. Monitoring and evaluation of HTS promotion interventions

1. Creating demand for HTS

Demand creation entails increasing knowledge and awareness of, and motivation to seek HTS which is often low among those most in need of testing such as adolescents and young people, men, and key populations. Human-centered design approach can be applied to develop HTS demand creation strategy that is targeted and tailored to specific populations and geographical zones.

1.1 Approaches for HTS demand creation

Peer-led interventions have been proven to improve HTS uptake. Some of the evidence-based Social Behavior Change (SBC) Strategies that can be applied in demand creation for HTS include: Interpersonal Communication, use of Information Education and Communication (IEC) materials, digital media, mass media and promotional events as shown in figure 9.1.

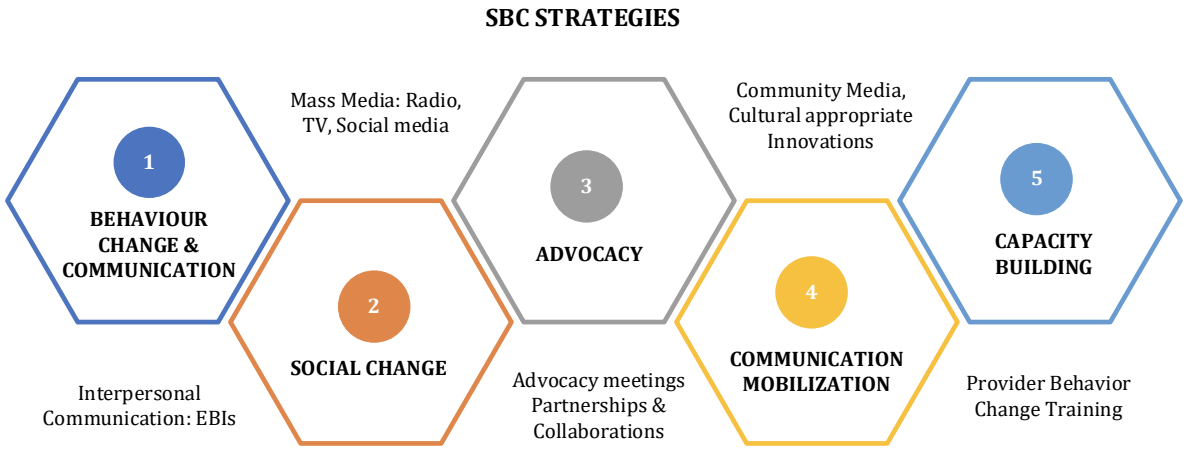


Figure 9.1: Social Behaviour Change Strategies

- **Inter-personal communication (IPC):** This is a strategy in which the **client is seen as an expert** on his or her life, desires and goals, while the facilitator (health promotion officer/peer educator/CHV/Health service provider/mobilizers) serves as a guide who can assist clients in reaching their goals or setting new goals. The IPC can be done through one-on-one sessions or small group sessions.

  In IPC **Autonomy and respect** for a client's decisions are paramount. The facilitator allows the client to lead the conversation and offers reflective feedback. Client-centred counselling emphasizes sharing knowledge, respecting individuals' experiences in the context of their social realities, acknowledging and, as appropriate, involving others who influence individuals' lives, and building opportunities for autonomy and success.
- **Information materials:** Information should be available in various formats to suit the diverse needs of target audiences. The IEC materials should be targeted and tailored to address specific barriers or needs of the target population. Examples of IEC materials include: Fliers, Posters, T-shirts, Banners and brochures.
- **Digital media:** Depending on target audience preference, the following platform can be utilized to increase awareness: Facebook, Twitter, Instagram, Telegram, WhatsApp, Tik-tok, Snapchat, You Tube, websites. The channels can also be applied as referral tools to drive traffic to HTS service delivery points. Digital platforms that use video-based information and

counselling messages have proven to improve HTS uptake. Evidence show that audio-recorded messages have little or no effect on HTS uptake.

- **Mass media:** This is above the line communication aimed at reaching large numbers of individuals in a broad geographical area at one point in time. It is more effective in reaching populations with higher prevalence or incidence rates. It can be conducted periodically to sustain HIV testing behavior and increase awareness about HTS to a large population at the same time. It includes newspaper, radio and Television advertising
- **Promotional events:** A promotional event is an occasion that draws a particular community attention to a particular product or products. Examples of events that can be deployed to promote HTS include road shows, community theatre activations.

1.2 Communicating about emerging/new research and national guidelines

Besides continued conventional demand creation for HTS, there are new areas in this guideline that require new messaging/ IEC materials:

Emerging/new research or guideline	HTS Promotion objective
Shift from **two test algorithms to three test algorithms**	Messages should focus on the reasons for new guidance, dispel myths that the past algorithm for HIV tests may have been incorrect
Introduction of HTS Screening Tool.	Create awareness to service providers on the availability and the need to utilize Screening Tool for enhanced targeted testing and increase in identification
Introduction of new approaches such as Social Network Strategy (SNS) for key population, AYP and men, vulnerable and general populations	Create Awareness and demand for Social Network Strategy (SNS) for key population, AYP and men, Vulnerable and general populations
Population targeted approach	Create demand especially in the HTS priority populations (Key population, AYP and men and other vulnerable populations)
Recency testing	Create awareness about recency testing, Rationale of Recency Testing in HTS, Eligibility for recency testing, Benefits of Recency testing at individual and community level, HIV Recency Surveillance in context of routine HTS, Client rights and informed consent in the context of recency testing
HIV syphilis dual test algorithm for the pregnant woman and their partners	Awareness for both Service providers and clients is needed to understand the reasons and benefits for dual test
Inclusion of the roles of the national and county governments relating to HTS communication and coordination structures	Create awareness of the new structures and advocacy for the resource allocation

Emerging/new research or guideline	HTS Promotion objective
Emphasis on 6 Cs during HIV Testing Services (HTS).	In addition to the earlier 5 Cs, create awareness on the additional 6th C which stands for creating an enabling environment HCW need to be made aware of the 6 Cs and importance of the same. The clients on the other hand need to know importance of all the 6 C and what they mean
Use of self-testing to increase access to knowledge of HIV status in Kenya.	Awareness and demand creation for Self-Testing as an alternative for testing, Emphasis should be on messaging around confirmatory test, availability in pharmacies
Re-testing recommendations for various sub-populations	Awareness will be key to help newly diagnosed anticipate and understand reasons for retesting.
Integration relating to PrEP, 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 behavioural interventions (EBIs).	Awareness for Integrated services that's **aims to** promote uptake and demand for other post-test services for those with such needs, e.g., eMTCT, VMMC, FP, TB and other prevention interventions.

2. Advocacy

Advocacy is a key strategy for gaining buy-in from leadership, community and other stakeholders. This buy-in is necessary to create a conducive environment for policies and programs and increase resources for HTS activities at the county and national levels. It may take place at the local community, county, and national levels. Emphasis should be placed on advocating for HTS with the following groups:

Table 9.1: Reasons for targeting specific leaders and groups with HTS advocacy

Group	Reasons for targeting
Religious leaders (national, county, community)	Motivate and educate constituents; Obtain buy-in for demand creation activities in the community
Community and opinion leaders	Reducing stigma and discrimination; Empowering the community, including ownership and leadership; Violence prevention and response; Health systems strengthening
Political leaders	The influence policy change, Secure government buy-in, and support; obtain financial resources, Health systems strengthening
Business community	Integrate HTS into workplaces; motivate and educate the workforce
Education sector	Integrate HTS into school health programs; mainstream HTS into the education sector, motivate and educate youth
Administrative personnel	Ensure conducive environment, ensure stable infrastructure and administrative support for activities; reduce stigma and discrimination

3. Capacity Building

Capacity building in the context of HTS promotion entails improving communication and demand generation skills for HTS providers and key stakeholders at all levels. This will help in ensuring quality demand creation and services delivery. Capacity-building activities should be led by the national and County governments, specifically NASCOP, NACC and supported by various stakeholders including communities and partners.

Coordination and implementation of HTS promotion activities

- National level coordination: The Ministry of Health through NASCOP and NACC will be responsible for providing direction on HTS health promotion across the country through identifying target audiences, as well as national communication priorities, based on the latest available research data.
- County and sub-county coordination: Counties will be responsible for adapting already developed communication and education strategies from the national level to ensure they are locally relevant. The counties will also be responsible for ensuring that communication is cascaded through local channels and the community strategy.
- Facilities: Facilities will be responsible for the implementation of the strategies, led by the facility management teams. This will be done in collaboration with the counties and sub counties team.

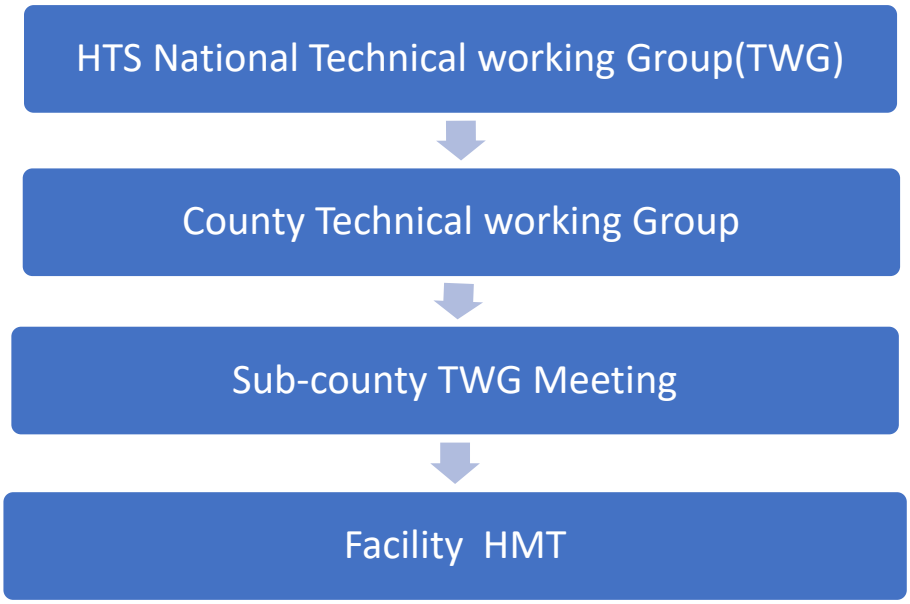


Figure 9.2: Structures for coordination and implementation of HTS/PrEP promotion activities

4. Monitoring HTS demand generation efforts

As part of continuous quality improvement in demand creation activities, healthcare providers, health promotion officers and mobilizers should regularly consult with community stakeholders/clients to determine the most acute needs and desires of HTS. The team should fill-in the data collection and referral tools and submit on a monthly basis.

The team should take stock of the communication materials available and put in place a clear dissemination and follow up plan by continuously looking at available stocks. The national program will undertake an annual awareness assessment to inform the areas that require additional demand creation support.

CHAPTER 10 MONITORING AND EVALUATION

Successful implementation of HTS services requires effective coordination, coupled with robust monitoring and evaluation (M&E) systems. M&E is critical at all levels of the health system to ensure effective and efficient HTS delivery.

10.1. Coordination

The coordination of HTS services is multi-faceted and multi-level, with responsibilities spanning national, county and facility level structures. At each level, various bodies are responsible for different functions as listed in the table below.

Level	Body/Institution	Roles and responsibilities
National	NACC	• Strategic guidance on the HIV response • Multi-sectoral coordination • Resource mobilization • Advocacy and engagement of civil society • HTS promotion and demand creation activities
	NASCOP	• 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 and demand creation activities • Standardization of QA tools • Data Quality Audits • Service Quality Audits (SQA) • Accreditation of training institutions

	NPHL	• National quality assurance
		  ○ EQA through PT
		  ▪ Test Kit validation
		  ▪ New lot verification
		  ○ RTKs 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 for counties in HIV testing
		• Performance monitoring and reporting on HIV testing quality indicators

Level	Body/Institution	Roles and responsibilities
	Supply chain institutions	• Procurement, warehousing and distribution of HTS commodities
	Health information systems (HIS)	• Development of data collection and reporting systems • Data warehousing and management • Registration of M&E tools • Data quality audits
County	CHMT	• 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 HTS commodities • Storage and redistribution of HTS commodities • Printing and distributions of M&E tools and the nationally recommended IEC materials • Infrastructure for HTS services • Data/service quality audits • Participate in QA • HTS promotion and demand creation activities • Assessment and recommendation for/against accreditation of institutions • Resource mobilization
	Sub-county HMT	• Supervision of service delivery • Data/Service quality audit • Reporting through KHIS • Provision of Corrective Action Preventive Action (CAPA) • Enrollment of participants in QA • HTS promotion and demand creation activities
	Health Facility	• Provision of quality HTS services • Performance monitoring and reporting • Commodity management and reporting • Human resource management • Data/Service quality audit • Participate in QA • HTS promotion and demand creation activities
	Community level	• Community mobilization and advocacy • Provision of quality HIV services within their scope. • Data collection and reporting • HTS promotion and demand creation activities

10.2. Importance of Monitoring and Evaluation

Monitoring and Evaluation (M&E) involves systematic and continuous data collection, analysis, interpretation and reporting at all levels. This information is essential for the effective management and improvement of HTS. Whereas monitoring involves the regular or 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 HTS. Both monitoring and evaluation are critical components of Kenya AIDS Strategic Framework II (KASF II).

Up-to-date monitoring of HTS allows for prompt identification and resolution of the challenges and successes of HTS programme. M&E allows for observation of programme trends, 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 and form the basis for research at the service delivery, county, national, or international level. For these reasons, it is critical that the quality of data is assured at all levels.

Monitoring in HTS include but not limited to:

- Key Indicators evaluated periodically. It involves reviewing data collected from routine service delivery to inform programmatic decisions. This may include;
    - Commodity consumption trends
    - Service uptake among different populations
    - Positivity and linkage trends
    - Testing algorithm performance trends
    - Training
    - Quality of testing performance.

10.3. Data Collection Tools, Demand and Information Use

Monitoring and evaluation require the following data collection tools. It is the responsibility of the county government to ensure continuous availability of these national M&E tools at all service delivery points:

- Routine National HTS data collection tools
  - MOH 362 -HTS Lab & referral and Linkage Register
  - MOH 405 - Antenatal register
  - MOH 333 - Maternity Register
  - MOH 406 - Post Natal Register
  - Index testing register
  - SNS registers
- HTS Client Referral Forms
- Reporting and summary forms:
  - MOH 731 – Summary Tool
  - MOH 643 – Facility Consumption Data Reporting & Request (FCDRR)
- Electronic Medical Record (EMR) systems and applications.
- Periodic surveillance data tools
- KHIS tools

Once data has been collected and analyzed, it is critical that data is used for decision making. Programme monitoring and evaluation will be conducted through cascades. Data can help in determining service uptake, coverage and resource allocation for different subpopulations. It is the responsibility of HTS service providers and managers at all levels to understand and use HTS data to improve the services.

HTS 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.

The national, Counties and all stakeholders have the responsibility to build capacity for data analysis and use the data to make improvements for health service providers and managers in their counties. Data sharing forums are encouraged at facility, sub-county, county and national levels where data are reviewed. Data review will be done using dashboards annually at the national level, quarterly at the county/subcounty level and monthly at facility level. Data demand and data reviews will be done to track quality for re-programming based on gaps identified.

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

10.4. Data and Service Quality Audits and Data Quality Improvement

Data Quality Audit (DQA) is the process of assessing whether data is fit for the intended purpose. In the context of HIV, data is gauged against the seven dimensions of data quality as defined in the national DQA guidelines: accuracy, completeness, reliability, precision, timeliness, integrity and confidentiality. The frequency of DQAs will vary: national level DQAs shall be done annually under the leadership of NASCOP; county and sub-county level DQAs shall be done quarterly led by SCHMT and CHMT and the facility level DQA should be done on monthly basis led by HRIO or the designated person. The conduct of DQA in HTS shall be in accordance with the national DQA guidelines with regards to planning, team composition, indicator selection, sampling of health facilities, frequency, service level assessed, data transmission, analysis, report writing and dissemination of results.

Data Quality Improvement (DQI) refers to the strategies and interventions aimed at improving the quality of data. Following every DQA, the audit team should develop a data improvement plan in consultation with the health facility staff. The sub-county management team shall be responsible for the follow-up of DQI plan implementation. Actualization of DQI plans at the facility level can only be actualized through collaboration among, clinical/service delivery staff, data management personnel and health facility management. HTS DQI activities shall be conducted in line with the national DQA guidelines.

10.5 Ethical issues to consider when handling patient records

The Data protection ACT (N0.24 of 2019) provides for protection of personal data and privacy of individuals concerned. For this reason, the health care provider shall observe confidentiality as follows:

Information from HTS should be treated with the same level of confidentiality that all medical records are given in both paper and electronic platforms. 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 locations that are only accessible to authorized persons. For all electronic medical records and Mobile Applications for HTS, protection should be enhanced through encryption, authentication and access control measures. All authorized officers handling all records should ensure protection of clients' Personally Identifiable Information (PII) through de-identification before preparation of any reports.

10.6. Data Flow

Data should flow from the service delivery points up to Kenya Health Information System (KHIS) where all stakeholders have access, as illustrated in Figure 10.1. Data collection occurs at the facility-level service delivery points (SDPs) and at the community-level, using pre designed ministry of health approved tools. Data collected from the two levels is submitted to the facility health records and information officer or to the facility in-charge for aggregation and either directly uploaded into KHIS or submitted to the sub county health records and information officers for uploading into the national repository (KHIS) if the facility does not have the capacity to do this. Data should be uploaded in KHIS by 15th of the subsequent month.

For health facilities with EMR or any other form of electronic system, patient level data is either entered at service delivery points or entered retrospectively into the system and sent automatically to the central repository (Data Warehouse (DWH)). An auto-populated summary reporting form (MOH 731) can also be uploaded into KHIS through an interoperability layer, which also enables exchange of information between the individual level data system (DWH) and the aggregate data system (KHIS).

Standardization of data in the manual and electronic data collection and reporting systems are ensured by customizing the manual tools into EMRs as service modules. The EMR system has the advantage over the manual system in that it can perform and generate additional data more effectively and efficiently. Given its advantages, electronic data collection and reporting have been recommended for adoption country wide.

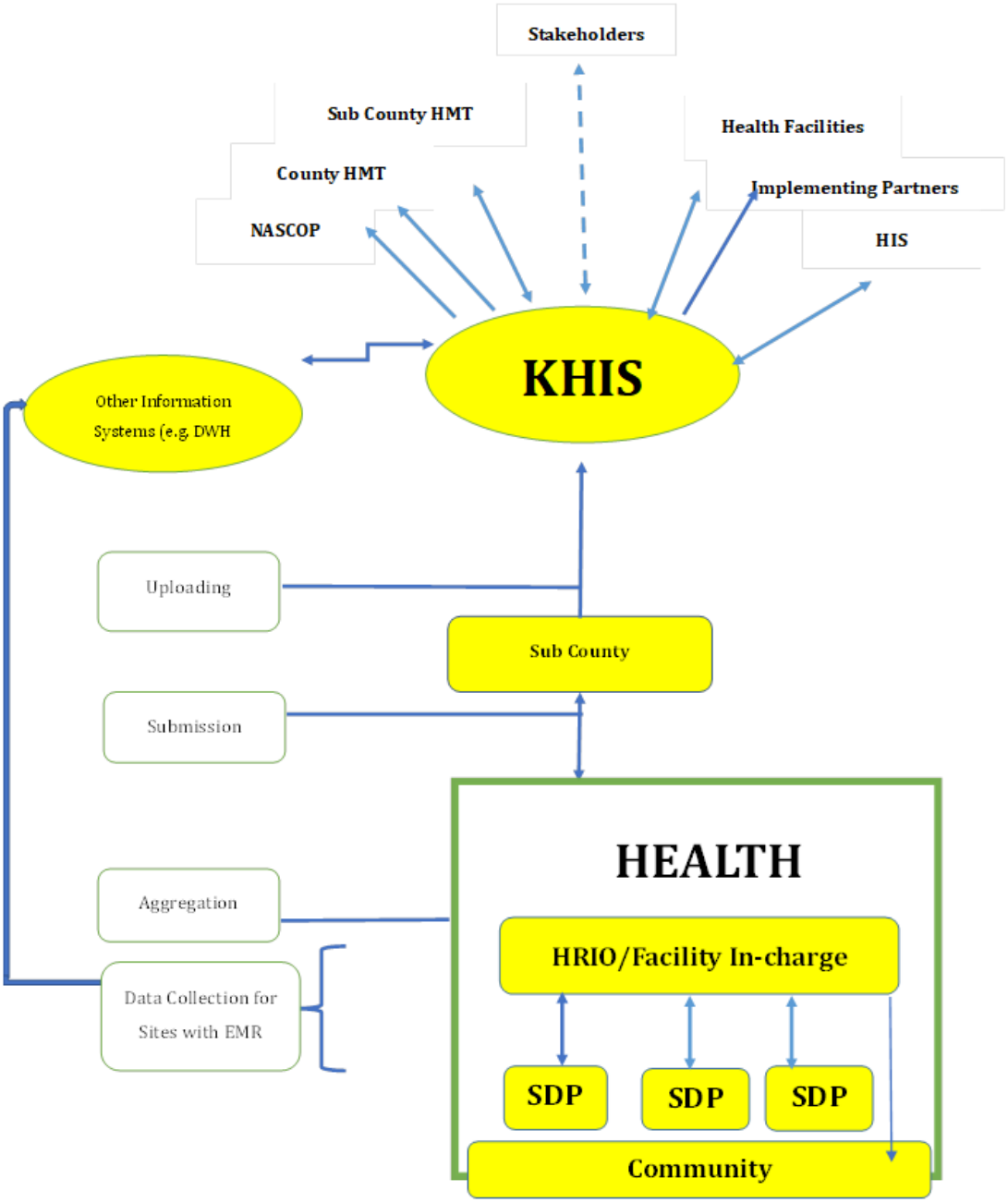


Figure 10.1: Data Reporting Flow

10.6. Evaluation

HTS Service evaluation entails assessing whether services offered to clients meet the expected standards of care as well as measuring the status of HIV response in the country. Areas that require improvement are identified and corrective measures/ actions are recommended to the service providers and managers. Evaluation can be continuous or periodic. Some of the evaluation exercises include but not limited to:

- Sentinel studies done by NASCOP and with partners to evaluate/answer specific questions
- Annual HTS program reports on KHIS data
- Routine population-based survey e.g., KDHS, KENPHIA
- Annual HIV estimates

10.7 Surveillance

As the Kenya epidemic matures, there is an increasing demand for data to better monitor the dynamics in the epidemic and the gains made over 20 years of investment in HIV programming.

The current HIV surveillance system has relied heavily on periodic and cross-sectional surveys and programmatic data collected in aggregate form which poses a challenge in describing the epidemic.

Second generation HIV surveillance provides an opportunity for the country to monitor and understand the dynamics of HIV epidemic in the country over time which guides in formulation of targeted interventions and evaluation of their impact. This is achieved through regular, systematic collection of data, analysis and interpretation of information from different data sources. For all the three major types of HIV surveillance currently in use in the country, HIV testing services is the entry to the surveillance system.

10.3.1 Types of surveillance being implemented in Kenya include

1. Case based surveillance- This involves the capture of individual-level information from persons diagnosed with HIV infection. Case based surveillance measures and characterize persons newly diagnosed with HIV, their immune status at diagnosis, number and characteristics of persons living with HIV. It also provides information on progression of PLHIV from diagnosis, entry into care and treatment, use of ART, retention, viral suppression and exit(death)
2. Recent HIV infection surveillance: This refers to Newly or recently acquired HIV infection as detected by a given laboratory method or assay. An HIV infection is termed as recent when it has occurred within the past 12 months. It determines the proportion of recent HIV infections, monitors trends of recent HIV infection among newly diagnosed PLHIV by demographic, geographic and HIV risk variables. RITA assays are used in detection of recent HIV infections.

3. ANC sentinel surveillance -This involves collection, analysis and interpretation of HIV serology status data among pregnant women attending antenatal care. It aims to monitor the levels and trends of HIV epidemic in this group by geographic and demographic parameters with an aim of developing targeted HIV Prevention programs.

10.3. 2 Data sources

Sources of data for HIV surveillance depends on the data management systems in a country. In Kenya this includes the laboratory information systems, EMRs, HTS registers, ANC register, Maternity register, PNC register, NASCOP EID and VL website.

10.3.3 Role of HTS providers and Health care workers in HIV surveillance

Health care providers are vital in HIV surveillance because they are the first point of contact for the client. They are therefore responsible for ensuring successful implementation by providing accurate information to clients about their participation in HIV surveillance as outlined in the protocol, HIV sample collection, testing, data collection and reporting. Specific roles include

- Obtaining informed consent from clients participating in the surveillance as outlined in the protocol
- HTS providers shall provide the primary conventional HIV test, which forms the entry to surveillance depending on the HTS results.
- Maintenance of the data collection systems
- Ensuring quality data is captured in the data collection and reporting tools
- provision of timely reports
- Ensuring infection prevention during HIV surveillance activities
- Maintaining confidentiality of patient level data
- Provide HIV test results to the client based on the surveillance protocol.

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ANNEXES

Annex 1: HTS screening Tool

MINISTRY OF HEALTH
NATIONAL AIDS & STI CONTROL PROGRAM

HTS Screening Tool

1	Has the adult/adolescent been tested for HIV Before? If yes, what was the HIV result? If positive, probe the Date of ART initiation (Client not eligible for HIV testing) If Negative, when is the most recent HIV test? Follow the HTS retesting guideline for the different population, proceed to 2 and conduct a risk assessment.
2	If negative or status unknown, Determine behavioural risk of HIV acquisition by asking the following questions: • Pregnancy for females • Is the client using PrEP • Unprotected sex within the last 3 months • Unknown status of the sexual partners • Multiple sexual partners • intergenerational relationships • Symptoms of sexually transmitted infection (refer to MoH syndromic chart) or history of STI • Assessing history of recurrent illnesses without resolution of symptoms, acute or chronic febrile illness (symptoms ≥ 14 days) and any other conditions suggestive of HIV • Presumed to have TB
3	Possible Risk exposures: • Defilement • Traditional /non-medical procedures e.g., scarification, plastic tooth extraction, Circumcision, uvulectomy etc.
4	If Risk noted or clinical assessment suggest HIV, eligible for testing
5.	If No risk noted and assessment does not suggest, not eligible

Annex 2: Index testing Consent Form

MINISTRY OF HEALTH

NASCOP INDEX TESTING CONSENT FORM

I……of Telephone Number……...and I.D number……... (where patient is under the age of 18 years, state the age of the patient) ……. and accompanied by ……..…. (If accompanied by guardian, also indicate the name and ID details of guardian)

Do hereby willingly consent/assent as follow:

1. That I have been counselled to the best of my satisfaction on the benefits of Index testing
2. That the provider has also stated to me the other options available to encourage my partner (s) or children to get tested;
3. That from my assessment, based on the information shared by the Provider, no possible or eminent risk is likely to occur from the shared contacts;
4. That the decision to share my partner(s) contacts is made freely, willingly and voluntarily;
5. That the provider undertakes that they will maintain privacy and confidentiality and my identity will at no time be revealed to my partner(s);
6. That the provider undertakes that all contacts shared will only be used for the sole purpose of contacting my partner(s) for HIV testing and due diligence will be exercised to protect this data;
7. I affirm that I was given an opportunity by the undersigned medical provider to ask all questions and they were answered satisfactorily and I therefore agree without coercion to share the contacts.

…… ……..

Patient's Signature and date Service provider

……...

Relative/Guardian (In case of Minor)

Annex 3: Patient locator form

PATIENT LOCATOR FORM

Name:_____ HTS No. _____ Date_____Sex:_____

Date of birth _____ Name of facility: _____

County: _____

Patient Residence and Tracer Information

Name commonly called:_____

Phone No:_____ Phone owner:_____

Workplace: _____ Occupation: _____

Religious affiliation and location: _____Marital status:_____

Fill for children testing positive only

Child orphaned (Both parents dead) Yes/No: _____

Mother alive Yes/No: _____Father alive Yes/No: _____

Who is the caretaker? _____Number of siblings: _____

Which parent is aware of child HIV status? _____ Child attending school Yes/No? __

If yes, name of school _____ Standard/ Form: _____

Is there anyone in the child's family enrolled in this PSC (who and relationship)

Name of parents:
Father's name:_____ Mother's name:_____

Caretaker (if no parents present)

Name:_____Relationship: _____

Spouse or next of kin

Name: _____Relationship: _____

Name commonly known or called: _____

Phone number:_____ place of work:_____

Residential address:_____

Other personal contacts (Treatment supporter/close family/friends

Name: _____ Relationship: _____ _____

Name commonly known or called: _____

Phone number:_____ Place of work:_____

Residential address:_____

Social Demographics

Number of children: _____ Name of well-known child: _____

Whom do you stay with? _____

To whom have you disclosed your HIV status? (List all)

Locator information

If we need to find you, where should we go first? (Home/place of work)

Who can help us locate you?_____

Is there any support group/community organization through which we can contact you (Mention home and location)

Below fill the set up that is applicable
Urban set up

County:_____ Sub County: _____

Town: _____ Stage:_____

Estate: _____ House number: _____

Road: _____Landlord:_____

Nearest church: _____ Nearest school: _____

Whom to ask for: _____

Another physical landmark: _____

Rural set up

County: _____ Sub County: _____

Location/Ward: _____ Stage:_____

Village: _____ House number: _____

Nearest Neighbour:

Nearest church: _____ Nearest school: _____

Whom to ask for: _____

Another physical landmark: _____

Description of direction to Client's place from the nearest health facility
Map (draw sketch from the most prominent landmark/features

Completed by

Name:_____ Designation: _____

Signature:_____ Date:_____

Annex 4: Counsellor self- assessment form

Ministry of Health

National AIDS and STI Control Program

HIV Testing Service Provider Self-Assessment Form

HTS Provider Name: _____ Date___/___/20_____

Facility_____ SOP_____

#	HTS Protocol Step	Score range: 0-3 0=Poor; 1=unsatisfactory; 2=Satisfactory; 3=Excellent		
1.	Did I introduce and orientate the client to the session?			
2.	Did I assess risk patterns and help the client come up with risk reduction plan			
3.	Did I prepare the client for HIV testing process			
4.	Did I prepare the client understand the meaning of possible HIV test results			
5.	Did I conduct the HIV testing processing following the laid down SOPs			
6.	Did I observe infection prevention measures?			
7.	Did I deal with the client's emotional reactions?			
8.	Did I assess for other health related conditions/services like TB, FP, PEP, PrEP, GBV, PMTCT			
9.	Did I discuss referral options with the client?			
10.	Did I discuss disclosure of test results with the client?			
11.	Did I document appropriately in the appropriate registers			

Notes: ***Filling HTS Self-Assessment Form is self-initiated and requires discipline genuineness***

How to use this tool

1. HTS Provider self-assessment tool targets providers with the main objective of improving quality in service provision
2. This form is supposed to be filled by HTS provider at least once a week (Choose 1 client that you wish to evaluate yourself with.
3. Data Compilation and analysis should be done monthly

Annex 5: HTS Observed Session Supervision Tool

County: _____ **Sub-County_____** **Observers Name: _____**	**Facility _____** **SDP: _____** **Session Number_____** **DATE: _____**

Please score as follows; 0=not done, 1=attempted with little success, 2=achieved fairly, 3= achieved successfully, NA =Not applicable

Areas assessed	Score	Comment
Availability of guidelines and protocols • Latest National HTS guidelines • Testing algorithm • SOP for Screening & Confirmatory test • Interpretation charts • Referral directory • Referral book • Working timer		
Condition of the room/tent • Cleanliness • Two small tables • Well light and arranged room • Timers/Stopwatch available, updated and use		
Pre-test Counselling • Contracting and its limitations (Timing, confidentiality, rapport) • SOLER • Counsellor sitting at a strategic position (at the exit/door) • Sitting arrangement of the counsellor and the client according to counselling standard (sits must be of the same size and colour) • Adequate use of counselling skills such as reflecting, paraphrasing, etc. • Client centred session (Clients talks more than counsellor) • Risk assessment properly done (proper screening for eligibility) • HIV Prevention is discussed (Behavioural, Medical and Structural) • *Introduced and discussed index testing* ○ *Client willingly gave out contact(s)* • *Introduced and discussed SNS* • TB and GBV/IPV Screening done • Consent for testing is done		

Testing Process • Preparation of clients for the test ○ Confirmed client's readiness to take up the test • Preparation of all requirements to conduct the test • Labelling of test kits • Pricking, drawing of blood and putting the right quantity • Infection preventions control measures e.g., gloving, waste management • Correct timing depending on the test kits good interpretation • Fill in the MOH 362 and other tools • Condom demonstration • *Confirm client's readiness to have their partners tested*		
Post Test Counselling **If Negative** • Confirmed result outcome • Addressed client's feelings, • Confirm how client plans to remain negative • Come up with risk reduction plan • Client reminded about possibility of discordance where applicable • Appropriate referral done based on need **If positive, confirm** • Client supported to understand the result • Support client to deal with immediate feelings • Discuss referral for Retesting & enrolment to Tx • Discuss positive living e.g., condom use, drug adherence, partner testing, disclosure and STI/TB screening and treatment, nutrition. • Appropriate referral done and documented **If Inconclusive,** • Test repeated and appropriate referral done • Termination		
Counsellors General Comment		
Observer General comment		
Start time_____ Stop time_____		
Name of the Counsellor: _____Sign_____Date_____		
Name of Observer: _____ Sign_____ Date_____		

Annex 6: Client Exit Form

Date:	____/___/___	County:		Sub/C:	
Site:		No.		Sex:	M: ☐ F: ☐

We are conducting an assessment with users of our health facility to find out what you think about our services. This is intended to help us improve quality of the services we provide to our clients. Your answers will be treated confidential and we thank you for your participation and honesty.

1. How long did you want to see the service provider?
   [ ] < 30mins [ ] 30mins-1hr [ ] 1-2hr
2. How was the service provider's attitude?
   [ ] Warm [ ] Neutral [ ] Cold
3. Do you feel the service provider gave you time to talk about concerns and personal issues?
   [ ] Yes [ ] No [ ] N/A
4. Did the service provider discuss the following issues with you?
   a. Benefits of knowing your HIV status?
      [ ] Yes [ ] No [ ] N/A
   b. Your HIV infection risks?
      [ ] Yes [ ] No [ ] N/A
   c. Disclosure of your HIV status?
      [ ] Yes [ ] No [ ] N/A
   d. HIV prevention options?
      [ ] Yes [ ] No [ ] N/A
5. Were you tested today?
   [ ] Yes [ ] No [ ] N/A
6. If yes, did the service provider obtain your consent before carrying out the test?
   [ ] Yes [ ] No [ ] N/A
7. Did the service provider explain to you how to read the results?
   [ ] Yes [ ] No [ ] N/A
8. Did the service provider inform you on how long it will take for the results to be ready?
   [ ] Yes [ ] No [ ] N/A
9. Did the service provider show you your test results as soon as they were ready?
   [ ] Yes [ ] No [ ] N/A
10. In your opinion, the time taken with the HTC service provider was?
    [ ] Too Long [ ] Just Right [ ] Too Short
11. How was the attitude of the other staff?
    [ ] Friendly [ ] Neutral [ ] Unfriendly
12. How would you rate the following about the site/facility?
    a. Cleanliness
       [ ] High [ ] Poor [ ] Very Poor
    b. Availability of toilets?
       [ ] Available [ ] Not Available
    c. Adequate waiting space
       [ ] Adequate [ ] Not Adequate [ ] N/A
13. Did the service provider refer you for any other services?
    [ ] Yes [ ] No [ ] N/A
14. Overall, how would you rate the services you received today?
    [ ] Very good [ ] Fair [ ] Poor [ ] N/A
15. Are there any other special comments you would wish to make?

Thank you very much for your patience and time!

Annex 7: List of contributors

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THE KENYA HIV TESTING SERVICES OPERATIONAL MANUAL

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