NATIONAL HIV TESTING SERVICES: POLICY AND GUIDELINES 2015

Prepared by the national Department of Health

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Department:
Health
REPUBLIC OF SOUTH AFRICA

A long and healthy life for all South Africans

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ACKNOWLEDGEMENTS

The HIV Testing Services, Policy and Guidelines, 2015 is the product of great collaboration among the South African government, civil society and non-governmental organisations as well as international agencies. Wide consultation and partnership in the development of these revised guidelines will go a long way to ensure the success of the rollout and uptake of the guidance included in the document.

The national Department of Health extends special thanks to all the individuals for providing support and technical expertise towards the content and finalisation of this document.

FOREWORD

Responding to HIV and AIDS is one of the most important tasks in South Africa, which is why the prevention of new HIV infections and treatment and care of HIV-infected people are the South African government's top priorities.

Recent new South African and international guidelines and recommendations prompted the review of South Africa's HIV counselling and testing (HCT) guidelines, which resulted in this newly revised document, the South African *National HIV Testing Services: Policy and Guidelines, 2015*. The *National Strategic Plan for HIV, STIs and TB 2012-2016 (NSP)* guides this response, while the *Health Sector HIV Prevention Strategy and Guidelines, 2014 -2016,* which focuses on the implementation of combination prevention, contributes to the operationalisation of the NSP. The policy is also aligned with the *National Development Plan, 2030* and the ambitious 90-90-90 targets expounded by UNAIDS.

The NSP outlines four strategic objectives that shape the HIV, STI and TB responses in South Africa. These include:

- addressing the social and structural drivers of HIV, STI and TB infections
- preventing new HIV, STI and TB infections through combination interventions
- sustaining the health and wellness of people through improved access to high quality treatment, care and support services
- protecting the human rights of and improving access to justice for people living with HIV.

Over a period of five years, the NSP aims to reach the following goals:

- reduce new HIV infections by at least 50% using combination prevention approaches
- initiate at least 80% of eligible patients on antiretroviral treatment, ensuring that 70% of patients are still alive and on treatment five years after initiation
- reduce the number of new TB infections and deaths from TB by 50%
- ensure an enabling and accessible legal framework that protects and promotes the rights of those living with HIV
- reduce stigma and discrimination related to HIV and TB by at least 50%.

Knowing one's HIV status is critical to the achievement of these prevention and treatment goals, making HTS the gateway to a complete continuum of care. A comprehensive approach, known as HIV testing services (HTS) is central to every single HIV intervention and among all target populations, and requires close collaboration with other health services. Through linkages with care, treatment and support programmes, HTS is an effective package of services that diminishes the impact of the HIV epidemic in our country. The South African Government has embarked on a deliberate effort to scale up and strengthen the quality of HTS at all public health facilities and non-health sites offering this service, and over the years, testing and counselling has improved and has progressively become more available and acceptable to our people.

The Department of Health acknowledges international trends and recommendations as described in the revised World Health Organization's (WHO) guidelines. All forms of HTS adhere to the 5Cs: **C**onfidentiality, **C**ounselling, **C**onsent, **C**orrect results and **C**onnection, or linkage to care, with all based within a human rights context. In addition to the 5Cs, however, the Department accentuates the use of a variety of approaches to HTS that will reduce the number of missed opportunities. These include provider-initiated counselling and testing, couple counselling and testing, home-to-home and infant and children counselling and testing in alignment to the revised WHO guidelines.

Effective combination of prevention interventions require strengthened biomedical interventions like the familiar prevention of mother to child transmission or medical male circumcision.

It also demands that we engage fully with changing the attitudes, beliefs, cultural practices and other barriers that thwart individual, couple, family, and community access to HTS and other prevention interventions. We recognise that prevention remains the cornerstone of our entire response to this epidemic. The programme seeks to ensure that people who test HIV-negative are encouraged and motivated to maintain their negative status, and those who test positive are supported in living long, healthy lives through positive health-seeking behaviour and the provision of appropriate services.

The National HTS programme will continue to provide an integrated service at all levels of the public health service delivery system. We encourage and support formal collaboration among public, private and non-governmental sectors.

The revision of our National HTS policy is important to keep abreast of international guidance and recommendations. More importantly, I am confident that implementation of these revised guidelines will be important in achieving epidemic control in South Africa. I strongly urge all HTS service providers to do all that is necessary to adhere to the recommendations outlined herein.

MINISTER OF HEALTH
DR AARON MOTSOALEDI (MP)

ABBREVIATIONS AND ACRONYMS

AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral (drugs)
CBO	Community-based organisation
CDC	United States Centers for Disease Control and Prevention
CICT	Client-initiated counselling and testing
DHIS	District health information system
DHS	District health system
DNA	Deoxyribonucleic acid
ELISA	Enzyme-linked immunosorbent assay
EQA	External quality assessment
FBO	Faith-based organisation
HBHTS	Home-based HIV testing service
HCT	HIV counselling and testing
HIV	human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV testing service
M&E	monitoring and evaluation
NASBA	Nucleic acid sequence-based amplification
NCD	Non-communicable disease
NDOH	national Department of Health
NGO	non-governmental organisation
OI	Opportunistic infection
OVC	Orphans and vulnerable children
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PICT	Provider-initiated counselling and testing
PLWHA	People living with HIV and AIDS
PMTCT	Prevention of mother-to-child transmission
QA	Quality assurance
QC	Quality control
QI	Quality improvement
QMS	Quality management system
RDT	Rapid diagnostic test
RNA	Ribonucleic Acid
SANAC	South African National AIDS Council
SOP	Standard operating procedure
STI	Sexually Transmitted Infection
TB	Tuberculosis
TNA	Total nucleic acid
UAT	Unlinked anonymous testing
UNAIDS	Joint United Nations Programme on HIV/AIDS
Unicef	United Nations Children's Fund
USAID	United States Agency for International Development
VCT	Voluntary counselling and testing
VMMC	Voluntary medical male circumcision
WB	Western blot
WHO	World Health Organization

DEFINITION OF TERMS

Active referral	A referral where the person performing an HIV test makes an appointment for the client or accompanies the client to an appointment, including an appointment for co-located services, and enrolment into HIV clinical care.
Acute infection	The period in which an individual becomes HIV-infected and before HIV antibodies can be detected by a serological assay.
Concentrated epidemic	A defined sub-population (e.g. men who have sex with men, transgender people, sex workers and people who use drugs) where HIV has spread rapidly compared to the general population, due to active networks with high-risk behaviours within the sub-population.
Couple HCT	When two or more partners are counselled, tested and receive their results together, resulting in mutual disclosure of HIV status.
Discordant test results	When one HIV test result in an individual is reactive and the other test result using a different HIV assay in the same individual is non-reactive.
Early infant diagnosis	Testing infants to determine their HIV status, given that HIV can be acquired in utero (during pregnancy), peri-partum (during delivery), post-partum (through breastfeeding) or via parental exposure.
Eclipse period	The period between HIV infection and detection of virological markers, such as HIV RNA/DNA or HIV antigen.
HIV status	Result from one or more assay. It refers to reports of HIV-positive, HIV-negative or HIV-inconclusive.
Inconclusive HIV test result	The first reactive test results are not confirmed by additional testing using subsequent HIV assays.
HIV-inconclusive status	The HIV status of an individual in whom the test results cannot lead to a definitive diagnosis (i.e. no clear HIV status, neither positive or negative can be assigned).
Index testing	A focused approach to HIV testing in which the household and family members (including children) of people diagnosed with HIV are offered HIV testing services; also referred to as index case HIV testing.
Indicator condition-guided HIV testing	A focused approach to test people more likely to be infected with HIV and who are identified through indicator conditions, such as sexually transmitted infections, lymphoma, cervical or anal neoplasia, herpes zoster and hepatitis B or C. These conditions occur more frequently in HIV-infected people than in uninfected people, either because they share a common mode of transmission with HIV or their occurrence is facilitated by immunosuppression associated with HIV infection.
Key populations	Refer to defined groups who, due to higher-risk sexual and drug behaviours, have increased risk for HIV irrespective of the epidemic type or local context. These are men who have sex with men, people who inject drugs, people in correctional services and other closed settings, sex workers and transgender people.
Nucleic acid testing (NAT)	Also referred to as molecular technology, for example, polymerase chain reaction (PCR) or nucleic acid sequence—based amplification (NASBA). This type of testing can detect small quantities of ribonucleic acid (RNA), deoxyribonucleic acid (DNA) or total nucleic acid (TNA), qualitatively and quantitatively.
Partner testing	This is when one person is tested and is then encouraged to bring in their partner for testing. The partner is then tested separately. Partner testing may occur with or without disclosure.
Quality assurance (QA)	A part of quality management focused on providing confidence that quality requirements will be fulfilled.
Quality control (QC)	A mechanism which, when used with or as part of a test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.

Quality improvement (QI)	Part of quality management focused on increasing the ability to fulfil quality requirements.
Quality management system (QMS)	A system to direct and control an organisation with regards to quality.
Repeat HIV testing	Refers to a situation where additional HIV testing is performed immediately after the initial test results, within the same testing visit, using the same assays and, where possible, the same specimen.
Retesting for HIV	In certain situations, individuals should be retested after a defined period of time to rule out errors and sero-conversion. These include: • HIV-negative people with recent or on-going risk of exposure; • HIV-inconclusive status; or • HIV-positive people before antiretroviral treatment (ART) initiation.
Self-testing (HIVST)	A process where a person wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him- or herself, often in private. Reactive test results must be followed by additional HTS.
Serodiscordant couple	A couple in which one partner is HIV-positive and the other is HIV-negative.
Unconfirmed HIV test results	Refers to an HIV-positive test result without a confirmatory test.
Verified	People diagnosed HIV-positive are retested before initiating ART and their HIV diagnosis is verified before initiating care or treatment.
Window period	The period between HIV infection and the detection of HIV-1/2 antibodies using serological assays, this signals the end of the seroconversion period.

1 INTRODUCTION

1.1 Background

HIV represents the primary burden of disease in South Africa, with an estimated national prevalence of 12.2% in 2012. The HIV incidence among individuals aged 15 to 49 years is estimated at 1.9%, and 2.3% among youth aged 15 to 24 years.

The country has a generalised and a maturing HIV epidemic, with the highest number of people (6.4 million) living with HIV in the world. Although the prevalence of HIV in South Africa remains high, it has been stable over the last decade, which can be attributed to the rapid scale-up and success of the antiretroviral treatment (ART) programme. It is estimated that approximately three million people are on ART, making it the largest programme in the world.

HIV testing services (HTS) *is used to refer to the full range of services that should be provided with HIV testing.*

HIV counselling and testing (HCT) is now referred to as HIV testing services (HTS) to embrace the full range of services that should be provided together with HIV testing. These services include:

- counselling (pre-test information and post-test counselling);
- linkage to appropriate HIV prevention, treatment and care services and other clinical and support services; and
- coordination with laboratory services to support quality assurance and the delivery of correct results.

The South African government has embarked on a deliberate effort to scale up HTS and strengthen its quality at all health facilities and non-health sites. With increasing availability of quality HTS and its uptake in all public health facilities in South Africa, the proportion of people who have ever had an HIV test and are aware of their status has increased from 50% in 2008 to 66.5% in 2014. In addition, 92.3% South Africans are aware of HTS services and 66.2% had actually utilised them in the past year, according to 2014 data.
The goals of the National Strategic Plan on HIV, STIs and TB, 2012-2016 (NSP) include the reduction of new HIV infections by at least 50% using combination prevention approaches and initiation of at least 80% of eligible patients on ART, with 70% retained on treatment. Knowledge of HIV status is critical to achieve prevention and treatment goals and HTS is the key entry point to a comprehensive continuum of HIV care.

1.2 Rationale for an HTS policy

There is a global initiative to accelerate universal access to HIV prevention, treatment, care and support services for people living with HIV and AIDS (PLWHA). The main entry point for the HIV continuum of care is through HTS, which has become increasingly available. South Africa has more than 4 000 public health facilities offering provider-initiated counselling and testing (PICT) and client-initiated counselling and testing (CICT). In addition, HTS is also available through non-medical sites and the private sector.
South Africa has adopted UNAIDS' 90–90–90 strategy, which calls for 90% of all people living with HIV to be diagnosed, 90% of eligible people with diagnosed HIV to receive ART and 90% of those on ART to have a suppressed viral load by 2020.
This policy guideline provides a framework for all HTS modalities that should be implemented in the country. A variety of HTS modalities should be utilised to reach targeted populations in different settings.

1.3 Goals and objectives

The overarching HTS goal is to identify people living with HIV timeously through the provision of

quality testing services for all -- including adults, children, couples and families -- and effectively link them to appropriate prevention, care treatment and support services.
The main objectives of this document are to provide guidance to the health-care worker that will ensure:

- consistent provision of high quality HTS;
- appropriate use of HTS modalities to reach different populations;
- strengthened linkages to prevention, care and treatment services; and
- strengthened quality assurance and the delivery of accurate results.

1.4 Target audience

This document is intended for clinical and non-clinical HTS service providers. National, provincial and district health facility managers and health-care providers in private and public health facilities are urged to comply with these guidelines. HTS providers engaged by community- and faith-based organisations (CBOs/FBOs), non-governmental organisations (NGOs), the private sector, educational institutions and any other HTS service providers should also adhere to these guidelines.

1.5 Guiding principles

1.5.1 A rights-based approach

A human rights-based approach that prioritises universal health coverage, gender equality and health-related rights such as accessibility, availability, acceptability and quality of services is essential for the success of an HTS programme. The national HTS programme will benefit the tested individuals and simultaneously improve health outcomes at the population level. It will also ensure access to appropriate, quality services that are linked to prevention, treatment, care and support services for those who need these services. HIV testing for diagnosis must always be voluntary, consent must be informed through pre-test information, and testing must be linked to prevention, treatment, care and support services to maximise individual and public health benefits.

1.5.2 The 5Cs

The 5Cs are the foundation of effective HTS. Consent, Confidentiality, Counselling, Correct test results and Connection are the 5Cs and are described below.

Consent: People who receive testing must consent to be tested and counselled. Clients or patients must be informed of the process for HTS and of their right to decline testing.

Confidentiality: Discussions between the HTS provider and the client should not be disclosed to anyone without the expressed consent of the person being tested. Shared confidentiality with a partner or family members or trusted others must be encouraged.

Counselling: Pre-test information can be done in a group setting, but a private setting must be provided for individuals who have questions that they do not wish to share with others. HIV testing must be followed by appropriate high quality post-test counselling.

Correct: Quality assurance (QA) mechanisms are essential to ensure that people receive a correct diagnosis.

Connection: Linkage to prevention, treatment and care services and effective and appropriate follow-up should be provided.

The 5Cs
(Consent, Confidentiality, Counselling, Correct, and Connection) are principles that apply to all HTS and under all circumstances.

1.5.3 HTS continuum of care

HTS providers shall ensure that clients are not lost in the HTS cascade. The continuum of care is depicted in Figure 1.

Figure 1: HTS continuum of care

2 ETHICAL AND LEGAL CONSIDERATIONS

2.1 Human rights

A human rights-based approach to HTS ensures that the essential elements of the programme are aimed towards realisation of rights and that those rights are used as standards. HTS must be offered in a way that is consistent with the rights described in the Constitution of South Africa and in the Children's Act. It must be ethical and be conducted within a supportive environment.
Three important human rights are described below.

2.1.1 Right to dignity and non-discrimination

Every person has inherent dignity and the right to have their dignity respected and protected. No actions should be taken against any individuals solely on the basis of their HIV status, as this will constitute stigma and discrimination.

2.1.2 Right to privacy and confidentiality

All personal information concerning a client, his or her health status, treatment or stay in a health establishment must be kept confidential, unless ordered by the court of law or done so for the advancement of client's care and treatment after following the necessary procedure.

2.1.3 Right to refuse HIV testing

Clients have the right to refuse HIV testing, without compromising their access to standard health care. There shall be no mandatory HIV testing and all testing shall remain voluntary with informed consent, even when the services are initiated by the service provider.

National Health Act 61 of 2003, Section 14

1. All information concerning a client/patient, including information relating to his or her health status, treatment , or stay in a health establishment is confidential.
2. Subject to Section 15, no person may disclose any information contemplated with regards to health status, treatment or stay in a health establishment, unless:
   a. the user consents to that disclosure in writing
   b. a court order or any law requires that disclosure
   c. non-disclosure of the information represents a serious threat to public health.

2.2 Informed consent

Informed consent refers to a person being given relevant and appropriate information about an HIV test, and based on that information, given an opportunity to either accept or refuse to do the HIV test. Informed consent should always be in written form and signed by only the client and the health care provider to avoid unintended disclosure of results.

2.2.1 Requirements of informed consent

The information that clients and patients require in order to give their informed consent may vary based on the service delivery approach and setting, but should generally include information about:

- Benefits and implications of knowing one's status and reasons for recommending HTS.

- Client's right to withdraw consent at any stage of the process.
- Availability of follow-up treatment, care and support, and prevention services.
- Importance of disclosure and partner/family testing and availability of couple HTS.
- HTS process and procedures.

2.2.2 Capacity to consent

Any person aged 12 years and older, and/or with sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of HIV testing, may give consent for HTS in South Africa. The following must be taken into consideration:
Potential clients or patients should:

- understand why they are being tested
- understand and report on the consequences of a negative or positive test result
- report how they are likely to respond to either result.

If the patient/client is assessed as being incapable of giving informed voluntary consent, then proxy consent may be sought. This is consent given by someone else who is acting in the best interests of the patient/client (e.g. a senior clinician in charge of the case). If the patient regains capacity then results must be disclosed. If the patient/client has irreversible neurocognitive impairment, results can be shared with the carer.
HIV testing must always be voluntary and free from coercion. In some cases HIV testing can be prescribed by a court of law. Consent shall be conducted in a language understood by the client, and in child-friendly versions, as applicable. Consent shall be verbal and written.
Informed consent should always be documented in the following settings and populations:

Infants and children: HIV counselling and testing should be offered to the guardians or parents as applicable, and they should provide written informed consent. Where appropriate, children may also provide consent.

Couples: Informed consent should also be given by individuals who are willing to be tested as a couple.

Research settings: Informed consent within clinical trials and other research settings should always be written and documented as stipulated by the national Department of Health's Guidelines for Good Practice in Conduct of Clinical Trials with Human Participants 2006. Illiteracy or inability to write: If the client cannot write, or has a disability that hinders his or her ability to write, the right-hand thumbprint can be used instead of the signature, if the client wishes to take up the HIV test and give signed consent.

Inability to make a decision: According to the National Health Act (Act No. 61 of 2003, Section 7), if a client is unable to give informed consent, for example, in the case of unconsciousness/ incapacitation or cognitive disability, and if the test is clinically indicated, such consent can be given by a person authorised to give such consent, in terms of any law or court order. In the case of adults, the spouse, next-of-kin (parent, grandparent, an adult child or a sibling of the person), clinician or clinical manager, in the specific order listed, can give informed consent. In the case of children, refer to Section 9.1. of this policy.

Any client or patient who does not give consent for HTS should still be provided with the best possible care and should not be denied other health services. Client(s) or patient(s) declining an HIV test should be offered assistance to access HTS in the future, and their decision to decline should be noted in their medical record so that a discussion of HTS can be reinitiated at subsequent visits to the health facility.

2.3 The Children's Act

The Children's Act, No. 38 of 2005, Section 130, stipulates when and how a child may be tested for

HIV. The Act has clearly distinguished HIV testing from other forms of medical treatment and has enforced conditions for HTS among children.

A. **Children may only be tested for HIV in two circumstances:**
- if testing is in their best interest and lawful consent has been given for the test
- if the test is needed to establish the child's HIV status in cases where a health-care worker or another person may have contracted HIV from the child's body fluids.

This provision protects children against discriminatory or arbitrary HIV testing.

B. **Consent for HIV testing for children may be given:**
- **by a c**hild if he or she is older than 12 years
- by a child younger than 12 years if he or she has "sufficient maturity"
- by a parent, caregiver or the provincial head of the Department of Social Development if the child is younger than 12 years and is not sufficiently mature.

This section of the Act ensures that a wide range of people may assist a child by consenting for HIV testing on the child's behalf. It facilitates HTS for orphans and vulnerable children.

C. **Counselling during HIV testing among children:**
- HIV testing must be accompanied by correct pre- and post-test counselling done by an appropriately trained person.

This provision ensures that children and their caregivers make appropriate choices regarding HIV testing.

D. **No person may disclose a child's HIV status without consent.**

Consent for the disclosure of HIV status can be given by the child if he or she is older than 12 years, or is sufficiently mature. If the child does not have the capacity to give consent to the disclosure, consent can be given by a range of people, including a parent or caregiver. This provision aims to ensure that a child's right to confidentiality is protected.

3 CRITICAL ENABLERS

HTS should be made available in all public and private health-care facilities and NGOs that have been approved to offer HTS. Norms and standards, as described below, should be uniformly implemented in facility and community settings.

3.1 Duties and responsibilities

The duties and responsibilities of all health-care personnel should be clearly defined. A primary responsibility of all health-care workers and auxiliary health workers is to counsel people about HIV, so that people can make informed decisions about getting an HIV test. Health-care workers should offer an HIV test to all patients or clients to identify all HIV-positive men, women and their sexual partners, HIV-exposed and -positive infants, children and youth so that they can access HIV care. Practiced within the context of a human and child rights framework, this critical intervention should prolong life and optimise maternal and child survival.

3.2 Challenging discrimination

Discrimination against people with HIV undermines human dignity and hinders an effective response to HIV and AIDS. The National HTS Programme should help reduce discrimination by creating knowledge and competence about HIV in communities.

3.3 Quality of HTS

All HTS (counselling, testing and testing kits) shall be subject to quality assurance, according to defined national standards and should be monitored and evaluated. Counsellors should be trained to provide quality counselling and testing services according to the national policy and guidelines.

3.4 Effective partnerships

All public and private sectors, partners and civil society stakeholders shall collaborate and be involved in the HIV and AIDS response.

3.5 Effective communication

Clear and ongoing communication (with appropriate messages) between government and all civil society stakeholders is necessary for the achievement of the aims of the policy. Effective communication also helps to inform those people who are affected and infected with HIV. Grassroots communication empowers clients by informing them of what they need to do, what services are available and of any new developments in HTS and HIV care and treatment services.

3.6 Strengthening service delivery and integrating services

Strengthening health and social systems within a multisectoral approach is central to effective implementation of the policy and guidelines. Health system strengthening refers to the public and private health sectors, but also to strengthening the organisational capacity of NGOs, FBOs and CBOs. Ensuring integration between services will lead to a stronger health system to respond to the HIV epidemic.

3.7 Using scientific evidence

The interventions outlined in the HTS policy shall, wherever possible, be evidence-based.
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3.8 The South African Government's leadership role

The effective implementation of the National HIV Testing Services: Policy and Guidelines and the attainment of its goals depend on government leadership to provide the necessary resources, develop relevant policies and effectively coordinate the programme and related interventions.

4 SERVICE DELIVERY APPROACHES

4.1 HTS: approaches and settings

HTS can be provided in both facility- and community-based settings. PICT refers to counselling and testing that is routinely offered in a health facility. It includes providing pre-test information and obtaining consent, with the option for individuals to decline testing.

Community-based HTS includes a number of approaches: mobile outreach campaigns, events, workplace testing, home-based testing, testing in educational settings and places of worship. Working in the community increases early diagnosis by reaching first-time testers and people who seldom use clinical services. Men, adolescents and key populations, for example, visit public health facilities less frequently than women and particularly mothers.

A strategic mix of facility- and community-based settings and approaches facilitates the early diagnosis of HIV-positive people. PICT and CICT are two testing models that can be incorporated in both settings. HTS programmes should actively link HIV-positive people to prevention, treatment, care and support services. HIV-negative people should not be lost; risk reduction counselling should be provided, and they should be linked to prevention services. This strategic mix of settings and modalities will maximise yield, efficiency, cost-effectiveness and equity. Equity is important to ensure than that higher risk populations who do are provided with HTS. Finally, the strategic mix should support timely and complete linkage to care.

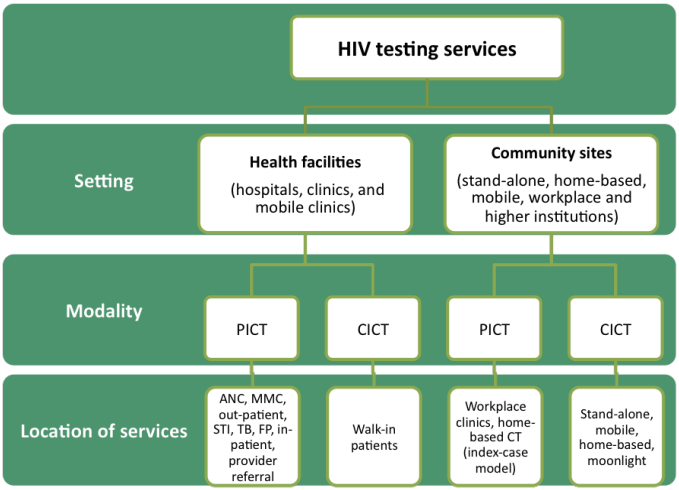


Figure 2: Service delivery platforms

4.2 HTS in health facilities

4.2.1 Provider-initiated counselling and testing (PICT)

Provider-initiated HIV counselling and testing (PICT) is routinely offered by health-care providers to persons attending health-care facilities as a standard component of medical care. PICT should be offered to all persons attending clinical services in both the public and private sector. Health-care providers should recommend HTS to all patients in a health facility, regardless of whether they show signs or symptoms of HIV infection. This allows the health-care provider to make medical decisions that would not be possible without knowledge of the patient's HIV status. Additionally, PICT contributes to increased rates of HIV testing and early identification of HIV-infected persons, who may not otherwise know their HIV status.

PICT models can either be provider-delivered whereby the provider offers and conducts testing or provider-referred whereby the provider recommends testing and refers patient for HIV testing within the facility (i.e. onsite HTS). The patient flow may be adapted to ensure integration of HTS into routine services.

4.2.2 Client-initiated counselling and testing (CICT)

Client-initiated counselling and testing (also referred to as voluntary counselling and testing [VCT]) refers to when HTS is provided within health-care facilities for clients who present specifically for these services. Clients may voluntarily decide to learn their HIV status as an individual, couple or family.

4.3 HTS approaches used in the community setting

The focus of HTS in community-based settings is for properly trained health-care providers to reach out to communities outside of the health facility to increase access to and to normalise HTS for targeted geographic locations and populations. Examples of community-based modalities are described below.

4.3.1 Stand-alone HTS

Stand-alone HTS sites are located within the community, with the sole primary function of providing HTS services to individuals, couples, or families within the community. These are not attached to a health facility.

4.3.2 Home-based HTS

Home-based HIV testing services (HBHTS) is testing offered in clients' homes by a trained health-care worker. It is provided in two ways:

- Door-to door: Refers to an approach to home-based testing that aims for high coverage of services within a specific community or geographic location.
- Index patient model: Refers to HTS providers visiting homes of people diagnosed with HIV or TB and offering testing to their sexual partner/s and other family members, including children.

4.3.3 Mobile and outreach HTS

Mobile and outreach HTS are provided through vans or tents within the community to increase access to hard-to-reach populations such as rural communities, men, mobile populations, or key populations.

4.3.4 HTS in the workplace

HTS may also be offered in schools, higher education institutions and workplaces, including public and private settings.

Many workplaces offer HTS services as part of routine, comprehensive workplace HIV programmes. These services are often extended to immediate family members or dependents of the employee. HTS services may also be introduced into a workplace on an ad hoc basis, for example, during an annual family day event. Workplace HTS may be provided on-site through a workplace clinic or in coordination with a nearby HTS centre. HTS providers may visit the workplace and offer HTS services there, either in an office, a mobile clinic, or in portable tents. Alternatively, a workplace may offer education about HTS and refer employees to a nearby HTS site to receive services. As with any HTS model or approach, workplace HTS providers must adhere to the standard operating procedures (SOPs) of the NDoH as outlined in this document and accompanying resources.

4.3.5 HTS in schools and tertiary institutions

School-based testing provides easy access to HTS for sexually active youth. Testing, however, should only be offered to learners who are at least 12 years old. School-based settings may also be targeted as part of a national HTS campaign.

Higher education-based HTS will be offered continually to all young people attending higher education institutions, as well as to the staff at these institutions. As this is a high risk group, HTS providers should ensure that as many young people as possible are voluntarily tested. These are aligned to the National HTS Programme. Outreach services should also target higher education institutions and all HIV testing conducted in these settings shall be reported to the local health office.

4.4 Self-testing

HIV self-testing (HIVST) is a process in which an individual who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him or herself, often in private. HIVST is a pre-screening test and does not provide a definitive diagnosis. It does not replace the need for the screening and confirmatory HIV test in the validated national testing algorithm. A reactive self-test result must always be followed by additional testing conducted by a trained provider who operates according to the validated national diagnostic testing algorithm.

HIVST provides people an opportunity to test discretely and conveniently and may increase uptake of HIV testing among people not reached by other HIV services. HIVST is currently under policy consideration in South Africa.

Clients participating in clinical vaccine trials should be referred back to their research site for appropriate testing to avoid misdiagnosis.

5 PRE-TEST SERVICES

Several pre-test activities should take place before testing in all settings and to all target populations.

5.1 Demand creation

General promotion and awareness campaigns for HTS must include children and the hard-to-reach populations. The National HTS Programme must focus on promoting HTS to populations where HIV testing rates remain suboptimal. Key populations and adolescents are two hard-to-reach populations in South Africa, and campaigns should be targeted to reach these populations with carefully tailored messages. Existing technological options such as Mom-connect and Be-Wise must be used to encourage individuals to test for HIV.

5.2 Confidentiality

Confidentiality applies to HIV test results, reports of HIV status and to any personal information about an individual. This includes information about sexual behaviour and the use of illegal drugs. HTS providers should be careful not to inadvertently reveal a client's test results or HIV status to others in the waiting room of a public health facility, or any other testing venue. HIV-positive individuals must be counselled in the same room as the other clients. Lack of confidentiality discourages people from using HTS.

5.3 Pre-test information

HIV test results are available within minutes of doing the test and the client also receives post-test counselling on the same day. Intensive and lengthy pre-test counselling is no longer needed and individual risk assessment and counselling during the pre-test information session is no longer recommended. Provision of pre-test information through individual or group information sessions is adequate, although this must be presented in an age-appropriate way.

5.4 Intensified tuberculosis case finding

Tuberculosis (TB) is the most common presenting illness among people living with HIV. Early detection, prompt linkage to TB treatment along with ART can prevent unnecessary deaths. HTS should include screening for TB to improve intensified TB case finding.

5.5 Sexually transmitted infections and non-communicable diseases

Sexually transmitted infections (STIs) and non-communicable diseases (NCDs) such as blood pressure, diabetes, and hypertension contribute to South Africa's quadruple burden of disease. All clients must be screened for STIs and NCDs using existing screening tools. Results must be documented in the relevant register.

HTS must integrate screening for TB symptoms, STIs and NCDs into the pre-test information session at health facilities and in community settings.

Figure 3: HIV/TB screening algorithm to Increase TB case finding in HTS

In public health facilities and other high volume HTS settings, pre-test information and education sessions may be conducted in a group rather than individually. In settings with low HTS volumes individual pre-test counselling sessions may be conducted. Information sessions and print materials should be available in the local language to all clients considering taking the HIV test.

5.6 The pre-test information session

The pre-test information session to an individual or to a group must include clear information on:

- the benefits of HIV testing
- the meaning of an HIV-positive and an HIV-negative diagnosis
- services – including ART provision – that are available should the client test positive
- the potential for incorrect results if a person who is taking ART is tested
- a brief description of prevention options and encouragement of partner testing
- the confidentiality of the test result and any other information shared by the client
- the right to refuse to be tested and that declining testing will not affect the client's access to HIV services or general medical care
- potential risks of testing, particularly in instances where there are legal implications for those who test positive and for those whose sexual or other behaviour is stigmatised.

5.6.1 Pregnant or postpartum women

Pregnant or post-partum women require additional pre-test information including:

- the potential risk of transmitting HIV to the infant
- counselling on infant feeding practices
- how to reduce mother-to-child transmission, including the use of ART to benefit the mother and prevent HIV transmission to the infant
- benefits of early HIV diagnosis for mothers and infants
- benefits of partner testing.

5.6.2 Couple testing

This refers to couples going through the whole HTS process together. When couples test together, the pre-test session must include information on the following:

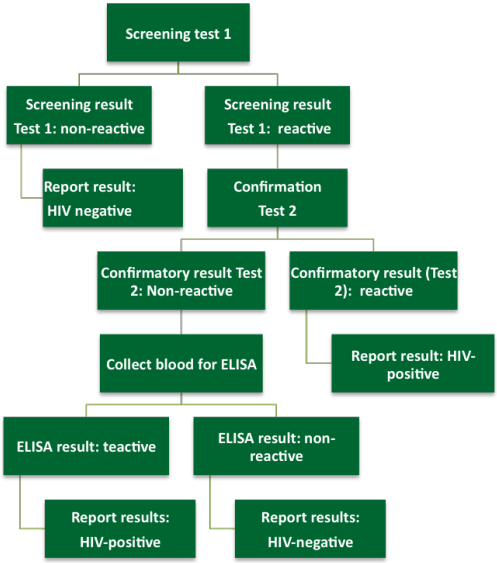
- benefits and encouragement of mutual disclosure of their HIV status
- risk reduction and HIV prevention measures especially in discordant couples

Testing couples may lead to the emergence of sensitive topics, and the counsellor should be aware of this emotional risk. For example, the counsellor should not ask about past sexual behaviour or risks, as this is unnecessary and may create problems for the couple.
Encouraging couples to test together and to mutually disclose their HIV status allows them to make joint, informed decisions about HIV prevention and reproductive issues, such as contraception and conception. There is evidence that couple HIV counselling and testing does increase the uptake of interventions to prevent mother-to-child HIV transmission (PMTCT), to improve infant outcomes, and to improve uptake of and adherence to ART. Ongoing services to sero-discordant couples can prevent HIV transmission to the negative partner.

6 HIV TESTING PROCESS

6.1 HIV testing algorithm

HIV testing in South Africa may be conducted using two HIV testing technologies: a rapid HIV test for children older than 18 months and adults, while PCR should be used for children younger than 18 months.
When implementing HIV rapid testing, a serial testing algorithm should be followed. This means that one rapid test is run as a screening test and if reactive, a different rapid test is then run to confirm the result of the screening test. If the screening test is non-reactive a negative result should be reported but the possibility of recent exposure must be considered. The selection of rapid test kits used in the testing algorithm should be guided by the National Reference Laboratory and approved by the national Department of Health (NDoH).
In case of indeterminate or inconclusive test results, whole blood for an enzyme-linked immunosorbent assay (ELISA) must be collected and the patient/client must be asked to return within seven days for his or her results.



6.2 Managing and documenting HIV results

Key information should be collected for each HTS encounter in all models and settings. This data will allow the health provider to monitor service delivery in a standardised manner and allow for useful analysis of data. Section 11 describes the standard data collection tools that should be used when HTS is provided. Completion of these data collection tools is key to monitoring performance and identifying trends in service delivery.

6.3 Issuing written confirmation of HIV test results

Patients or clients may request written results which can be issued irrespective of their HIV status. All written results should clearly include the patient/client's name, the date of the HIV test, test result, signature, designation of the issuing provider and the facility stamp. Clients/patients who test HIV-negative should be told that written results are a documentation of the results at that specific point in time and are not a substitute for consistent periodic testing.

7 POST-TEST SERVICES

All clients, regardless of the outcome of the HIV test, should be offered and should receive post-test counselling based on their test result. All results must be communicated clearly.

7.1 Post-test services for people testing HIV-negative

Those testing HIV-negative should receive health information about their test results. The health information should include risk reduction counselling and recommendations on uptake of preventive behaviours including consistent condom use. Research has shown that a lengthy post-test counselling session is not needed nor is it beneficial and may not be the best use of limited resources. In sero-discordant relationships, counselling for those who test HIV-negative should include education on methods and behaviours to prevent HIV acquisition, and the provision of male or female condoms, lubricants and guidance on their use.

7.2 Services for people with inconclusive/indeterminate test results

An HIV-inconclusive/indeterminate result means that the first reactive test results were not confirmed by subsequent testing using HIV rapid test (screening test was reactive and confirmatory test was non reactive). Clients with an HIV-inconclusive status should be told that a definitive diagnosis cannot be provided that day and that immediate referral to HIV care or ART initiation is not appropriate. Whole blood should be drawn and sent to the laboratory for ELISA testing as a tie breaker. Clients should be given a clear plan for follow-up testing.
All clients with an HIV-inconclusive result should be encouraged to return within seven days for their ELISA results to confirm their diagnosis.

7.2.1 Re-testing during the window period

The window period should be considered for HIV-negative clients who report recent or ongoing risk of exposure. For most people who test negative additional retesting to rule out window period is not necessary. Re-testing for window period should be done after four weeks from the possible date of exposure.

Table 1: Recommended frequency of testing

Circumstance	When to re-test	Future re-testing
Known positive partner	At four weeks post exposure	Annually with protection
Unknown HIV status of partner	At four weeks post exposure	Annually with protection
Sex worker	At four weeks post exposure	Every three months depending on exposure
MSM and transgender people	At four weeks post exposure	Bi-annual with protection
Post sexual violence and rape	At four weeks and 12 weeks; per relevant guidelines	Annually
Occupational exposure	At four weeks and 12 weeks; per guidelines	Annually
Presenting with clinical conditions(e.g. STI)	At 4 weeks	Annually

Table 2: Testing under different circumstances

Who	When
Pregnant women	At confirmation of pregnancy, and at every visit throughout pregnancy and at labour and delivery
Breastfeeding women (to detect HIV sero-conversion)	Every three months throughout breastfeeding
HIV exposed babies	At birth, at EPI visit according to the relevant guidelines, and at 18 months.
Adolescents and young adults	Every 6-12 months if sexually active or more frequently if the client has a new sexual partner or is having unprotected sexual intercourse
If exposed to HIV (adults)	Immediately, after four weeks for window period, annually
Key populations	At four weeks, every three months

7.3 Services for people testing HIV-positive

People who test HIV-positive should receive health information about their test results. It is essential to ensure that the HIV status test results are correct. All post-test counselling should be client-centred and responsive to and tailored to the unique situation of each individual or couple. Health workers, professional counsellors, social workers and trained lay providers can provide relevant counselling.

The post-test counselling information must include:

- an explanation of the test results and diagnosis
- clear information on ART and its benefits
- where and how to obtain ART
- make an active referral for a specific time and date
- how to prevent transmission of HIV and viral suppression condoms and lubricants and guidance on their use
- how to encourage and offer HIV testing to sexual partners, children and other family members of the client. This can be done individually, through couples testing, index testing or partner notification.

However, the shock of learning one's positive status may make it difficult for the client absorb a lot of information at one time. The counsellor should provide the necessary emotional support by:

- giving the client time to consider the results
- helping the client cope with emotions arising from the diagnosis of HIV infection
- discussing immediate concerns and help the client decide who in her or his social network may be available to provide immediate support
- discussing barriers to linkage to care, same-day enrolment and ART eligibility assessment and arrange for any follow-up of clients
- discussing possible disclosure of the result and the risks and benefits of disclosure
- assessing the risk of intimate partner violence and discussing possible steps to ensure the physical safety of the client, particularly women, who are diagnosed HIV-positive
- assessing the risk of suicide, depression and other mental health consequences of a diagnosis of HIV infection, and providing additional appropriate referrals for prevention, counselling and support
- encouraging and allowing the client to ask additional questions.

7.3.1 HIV disclosure

Deciding about disclosure is a serious issue for a person who has been diagnosed with HIV. Three acceptable types of disclosure are discussed below:

Disclosure to a sexual partner, family member or friend: When people learn their HIV-positive status, they may need time to absorb and accept the diagnosis before they are ready to share it with another person and as such, they do require ongoing counselling for disclosure. Disclosure does benefit sexual partners, but the social context of an individual must be taken into consideration. For example, HTS providers and counsellors should assess the risk of intimate partner violence and make appropriate referrals if necessary.

Disclosure of HIV in children: Disclosure of HIV status in children is not a single event, but rather a process, involving ongoing discussions about the disease as the child matures cognitively, emotionally, and sexually. Whenever possible, disclosure should occur when a child is clinically and emotionally stable and caregiver is ready. Although the process should not be rushed, disclosure should happen before the child enters adolescence. The timing will depend on caregiver's acknowledgment of the disease and readiness to disclose, the child's cognitive skills and emotional maturity, and an ability to maintain confidentiality.

Disclosure among children may be beneficial to the child, as it may:

- provide developmentally appropriate and truthful explanations of the disease and helps the child understand the illness
- validate the child's concerns and clarify misconceptions
- increase the child's willingness to adhere to ART, and consequently improve his or her social functioning and school performance by decreasing stress.

"Shared confidentiality" or disclosure by a health worker to other health workers involved in the client's care is a third type of disclosure. Clients and patients who test positive must be informed that their diagnosis may be shared with other health-care providers to ensure appropriate medical care from the different health-care workers. Such disclosure should respect their basic right to privacy and confidentiality of all medical information.

Disclosure by a health worker to employers, the police or other legal authorities is unlawful and unethical unless the client has given a written consent for his or her HIV status to be disclosed.

8 LINKAGES TO CARE

Linkage or connection to HIV care is defined as a process of actions and activities that support people testing for HIV and people diagnosed with HIV to engage with prevention, treatment and care services as appropriate for their HIV status. For people living with HIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in care or treatment and other health services. It is the responsibility of all HTS providers to ensure that clients and patients are connected to appropriate care. HIV testing alone is of limited value unless it is linked with other services. These services include:

Linkage to appropriate services following a diagnosis is key to the success of the HTS programme.

- treatment, care, support and management of the disease
- sexual and reproductive health (i.e., contraception, PMTCT, cervical cancer screening, anal cancer screening for men, and STI screening)
- testing for partners and families: This includes partner notification and index case testing.
- HIV prevention including dissemination and education on the use of condoms and lubricants, and voluntary medical male circumcision (VMMC)
- other clinical and supportive services.

While it is important to increase the number of clients tested for HIV, a shift is needed in the

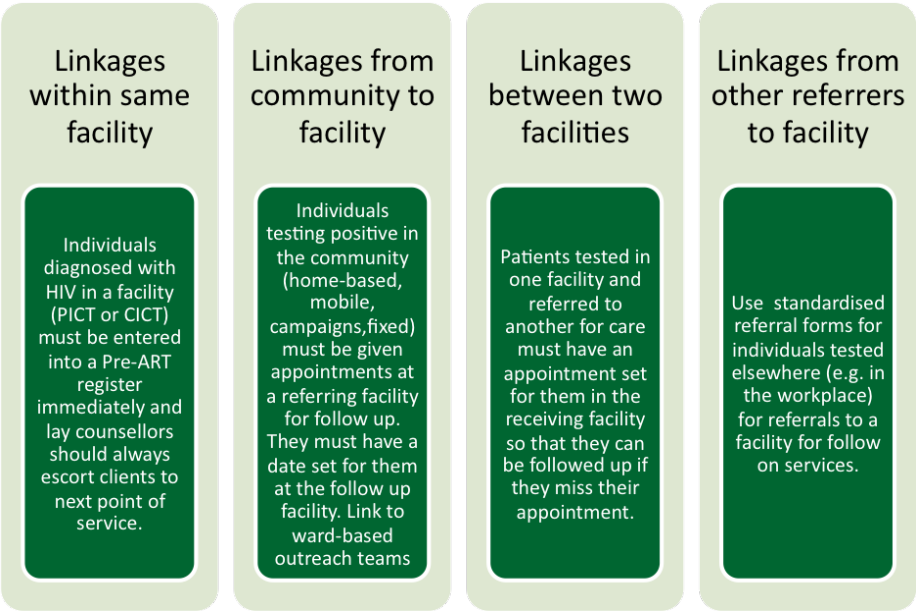


Figure 5: Different linkages related to HTS

National HTS Programme to focus on the outcome achieved through HIV tests. Those who are HIV-negative should be assisted in reducing their risky behaviour and those who are HIV-positive must be successfully linked into the continuum of HIV care.

During HTS	Referral services
☐ TB screening	☐ Family planning
☐ STI screening	☐ For HIV-positive people: IPT; PMTCT, ART
☐ NCD screening	☐ HIV-negative males: MMC
☐ Cervical cancer screening	

Figure 6: List of services available to clients during HTS

9 PRIORITY POPULATIONS

9.1 Infants and children

The HIV-related mortality rate is very high in the first year of life for untreated HIV-infected infants, and it peaks within three to four months of age. With an effective PMTCT programme, the yield of HIV-positive children is likely to shift outside of PMTCT services.

Programmes should prioritise strategies which yield a positivity rate that is higher than the estimated HIV prevalence among children. It is therefore important to integrate HIV testing into other child health programmes and to develop a systematic process to identify and prioritise high-yield testing among infants and children. HTS for children and infants must encompass:

- early infant diagnosis (EID) for all HIV-exposed infants
- testing all infants and children presenting with indicator conditions, such as failure to thrive, oral candidiasis, skin conditions, chronic cough, etc
- offering HTS to all medical admissions to wards
- testing all children receiving TB and malnutrition treatment
- testing all children of adults and siblings who are receiving HIV services
- testing all children accessing services for orphans and vulnerable children (OVC), especially if a parent has died.

9.2 Adolescents and young women

Adolescence is a period of high risk for HIV infection, with adolescent girls generally at higher risk than males in their age group. HIV prevalence in young women aged 20-24 years is three times higher than in men of the same age. In addition, young people who fall into key population groups are at a much higher risk of HIV infection.

Groups of adolescents who need to be considered are:

- adolescents infected vertically, and who have not been diagnosed
- adolescents acquiring HIV horizontally, through early sex
- adolescents from key populations
-

There should be routine testing of adolescents and adequate support for disclosure of HIV status to the adolescents and for support of disclosure to family members or significant others.

9.3 Pregnant women

Providing HTS early in pregnancy enables pregnant women to benefit from all the relevant prevention interventions. For those who test HIV-positive this includes treatment and care, which will reduce the risk of HIV transmission to their infants.

The package of care for pregnant women with HIV should include systematic screening for TB and STIs, and referral and treatment as necessary. The presence of undetected TB among HIV-positive pregnant women doubles the rate of vertical HIV transmission. Pregnant women testing HIV-positive must be linked to ART for PMTCT and HIV services. All pregnant women should retest for HIV at the time of the diagnosis of pregnancy, every three months during pregnancy, at delivery, and every three months during breastfeeding.

9.4 Couples and partners

Testing the partners of people with HIV is an efficient and effective way of identifying additional people with HIV, who also can benefit from treatment. Couples and partner HTS can be conducted in various settings, including ANC and community-based TB services. Those receiving ART services should be encouraged to bring their partners to be tested. Programmes that particularly serve key populations should provide and encourage partner testing

9.5 Men

Fewer men than women report ever testing for HIV and consequently, men are more likely to start ART at later stages of HIV infection and thus experience higher morbidity and mortality after initiating treatment. Greater emphasis on reaching men with HTS is required in many high prevalence settings. Men are less likely than women to use clinical health services, making community-based approaches to reaching men, such as home-based and mobile HTS helpful.

9.6 Key populations

HIV testing services should be routinely offered to all key populations in the community, in closed settings such as correctional facilities, and clinical settings. Community-based HIV testing services for key populations – with linkage to prevention, treatment and care services - is recommended in addition to PICT.

10 QUALITY ASSURANCE AND IMPROVEMENT

Quality assurance (QA) and quality improvement (QI) encompasses the entire process of HTS. Coordination with laboratory services for QA and delivery of accurate HIV test results is a priority and a core component of the 5Cs for HTS.

10.1 Quality assurance for HIV testing

A quality management system (QMS) is a system that directs and controls the programme with regard to quality. QA is the confidence that quality requirements will be fulfilled. Continuous quality improvement (CQI) focuses on increasing the ability to fulfil quality requirements.
There are multiple points along the "diagnostic continuum" that can contribute to incorrect test results including poor quality HIV assay tests, improper storage of test kits, not following SOPs, or poor documentation. Using routine monitoring data to support facility efforts in monitoring, improving and evaluating quality, five key stages of assuring and improving quality are illustrated in Figure 7, should be followed.

Figure 7: Quality assurance cycle

Every effort must be made to ensure that service delivery is of the highest quality. QA for HIV testing refers to those strategies employed by HTS that ensure that the final HIV test results are correct. The availability of rapid HIV diagnostic tests with high performance characteristics alone does not guarantee accurate test results. Errors can occur at multiple points along the "diagnostic continuum". The following elements are key for assuring quality of HIV testing results:

- a National HTS Policy
- pre- and -post-market regulatory controls for in-vitro diagnostics
- validated national testing algorithms (with back-up options)
- QMS for all HIV testing in all settings
- training and supportive supervision for HTS providers
- consistent adequate stock of test kits and consumables
- SOPs for HTS.

Service providers must be trained on how to keep HTS records (e.g. standardised registers), and have an understanding of the importance of proficiency testing (PT) programmes. There must be effective site supervisory visits with informed corrective actions.

10.2 Regulation of HIV diagnostics

The WHO Pre-qualification of in Vitro Diagnostics promotes and facilitates access to safe, appropriate and affordable diagnostics of good quality. WHO reviews the quality, safety and performance of diagnostics that are available in markets in resource-limited settings. South Africa highly recommends the use of WHO prequalified HIV rapid test kits.

10.2.1 Pre- and post-marketing surveillance of diagnostics

Post-marketing surveillance for HIV tests is a critical process for monitoring the quality of test kits that are procured and used within South Africa. Once a product is placed on the market, its quality, safety and performance must be monitored to ensure that it continues to meet the set standards. All rapid test kits utilised in testing sites must be subjected to both pre- and post-market surveillance.

10.3 Quality management system

A QMS can be implemented to varying degrees, but the basic principles still apply to any service providing HIV testing results. Any site conducting HIV testing should implement a QMS that incorporates the 12 elements shown in Figure 8.

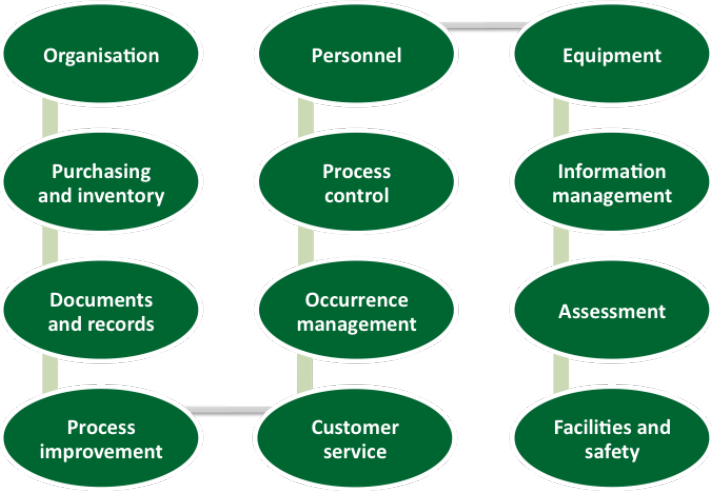


Figure 8: Twelve elements of a Quality Management System

10.4 Quality control (QC)

Quality control refers to processes and activities that ensure that testing procedures are performed correctly, that environmental conditions are suitable and that the assay works as expected. QC will detect, evaluate and correct errors before test results are reported as the HIV status. It is a multi-step process with checkpoints throughout the testing process. QC should be implemented at all HTS sites and records should be kept accordingly.

10.5 External quality assessment and proficiency testing

External quality assessment including proficiency testing (PT) refers to the inter-laboratory comparison to determine if the HIV testing service can provide the correct test status. PT involves testing of unknown samples at regular interval by the testing sites.

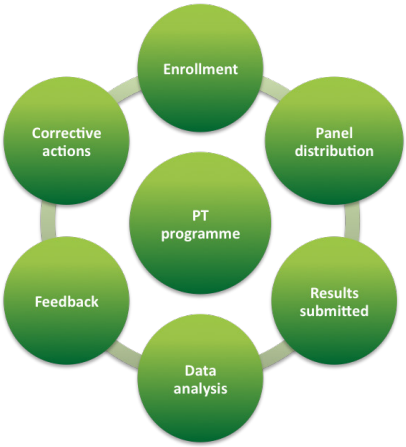


Figure 9: The proficiency testing cycle

10.5.1 Supportive supervision, site assessment and observed practice

Monitoring assessments should be conducted by programme managers or by the referral laboratory supporting the site. Programme managers should support implementers at site level. Any recommended corrective action from a site/supervisory visit should be implemented.

10.6 Quality assurance for HIV counselling

While standard protocols for rapid testing provide the appropriate information for the testing component of HTS, the counselling skills have the greatest impact on the client's HTS experience. It is therefore important to have systems that ensure the quality of counselling. Such approaches are important for ensuring that human rights are respected and the client's needs are met. High quality counselling is defined as non-judgemental, accessible, and client-centred. Counselling should increase the knowledge of HIV prevention, benefits of early treatment for HIV-positive individuals, and help clients to focus on achievable steps to reduce their risk. The following are the national SOPs for QA of counselling that must be followed by all service providers:

- all counsellors must meet the National Minimum Standards for Counselling to ensure that quality counselling is conducted
- QA (i.e. supervision, observations of actual counselling sessions, regular training and feedback to counsellors) of counselling must be performed at least on a quarterly basis. These strategies are important in ensuring that quality counselling and testing is provided.

10.6.1 Mentorship and observations of counselling sessions

Given the burden of the HIV epidemic in South Africa, health-care workers and HTS counsellors may face increased stress and burnout that sometimes compromise the quality of HIV counselling. Counselling support supervision is important for preventing burnout of individual HTS providers and maintaining high level communication between providers and clients or patients.
Quality improvement tools for counselling include:

- counsellor self-assessments
- supervision and mentoring

11 MONITORING AND EVALUATION

11.1 Documenting, monitoring and evaluation

Monitoring and evaluation (M&E) is a necessary component of the implementation and management of the HTS programme, ensuring that the resources going into a programme are utilised, services are accessed, activities occur in an efficient and guided manner, and the expected results are achieved. Routinely monitoring HTS programmes ensures that service quality is improved and the maximum health benefit for the population is obtained.

Monitoring is the routine tracking of service and programme performance using input, process and outcome information that is collected on a regular and ongoing basis. This process makes use of HTS programme tools such as registers, regular reporting systems and templates (e.g., the District Health Information System (DHIS), as well as health facility support visits, client surveys and to some extent, population-based surveys).

Evaluation is the periodic assessment of results that can be attributed to programme activities. It uses advanced data analysis and indicators that are not collected through routine information systems. It also assesses whether the programme is effective in achieving its objectives.

11.1.1 Quality assurance indicators in HTS register

QA indicators in the HTS Register are used for recording the specific results of each individual HIV test kit used, and allows for easier monitoring of the lot number, type, and number of test kits used. They also help HTS providers to address test kit problems, such as expired test kits or inconclusive results. Every HTS provider should complete the HTS Register immediately following the performance of a HIV rapid test with clients or patients. This register should be checked on a quarterly basis by HTS site supervisors.

11.2 Data management

Data management is essential for the effective management and improvement of HTS. Client data should be used to monitor HTS at each site, in each district and region, and at national level. All HTS providers will use a standardised HTS Register as a data collection tool. Data collection will take place at the site or outreach setting where clients/patients are seen (point of service) and data entry will be done at the district level. This will then be collated at the regional level before data analyses, reports and dissemination will be done at the national level.

At each level, the collected data will be analysed and interpreted to help improve the service and for planning and decision-making. Each district and provincial health information office should have a well-defined data management protocol and data flow protocol from different peripheral service points, including those in the private sector, to a central point.
Only health-care workers, HTS counsellors and data capturers/information officers permanently designated to work with health information, at all levels (facility, district, provincial, and national), should have access to data for verification and quality checks (completeness, correctness and accuracy). The confidentiality of clients' records should be maintained at all times.

11.3 Roles and responsibilities for information flow

All required data should flow from the HTS service points to and from the district, provincial and national health offices. Compliance with the data flow policy and the data user agreement must be maintained at each level. All HTS sites, including government and mission hospitals and health centres, NGOs, PLWHA organisations, and private and commercial sites offering HTS must follow these procedures.

Data is collected routinely at the following levels:

Service points: All HTS record-keeping forms and registers will be completed at the service points by the health-care workers and HTS counsellors, consolidated by the facility data capturers and signed off by the facility or programme manager. Periodic reports will be completed at the service points and transmitted to the appropriate health districts.

District office: Data collected from the service points and NGOs or private facilities within districts will be collated, captured on the district health information system (DHIS) database and reported to

the respective provincial office. This will be done monthly by the district health information officers and the district HTS coordinator.

Provincial office: The provincial health information officer and HTS coordinator will compile all district data and report to the national health office.

National office: Final compilation of national HTS service data will occur at the national office. Some indicators will be reported to the South African National AIDS Council (SANAC) M&E unit by the M&E and HTS manager in the HIV & AIDS and STIs cluster, NDOH. The flow of information will also ensure that feedback is provided at each level. The typical information flow of data is illustrated in Figure 10.

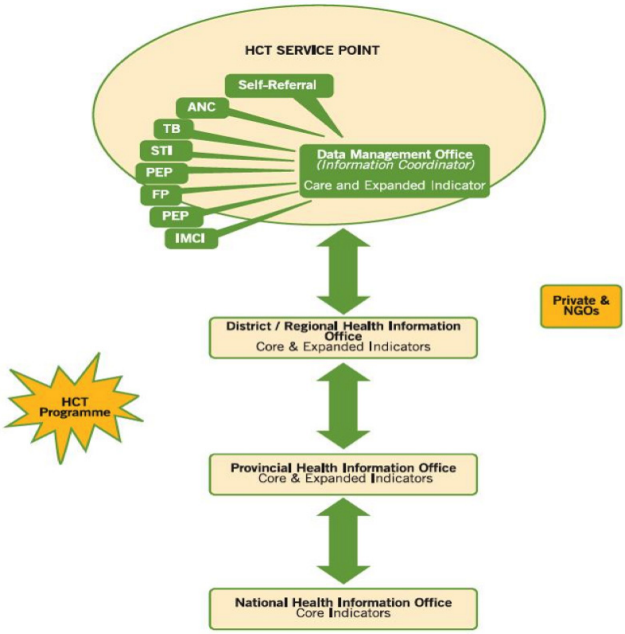


Figure 10: Flow of M&E data

11.4 Monitoring and evaluation framework and objectives

The "input-output-outcome-impact" framework is used in most M&E environments. These stages represent the flow of interventions over time and are intended to capture the relationship starting with input and ending with impact. For an HTS programme to achieve its goals, inputs (policies, budget, staff, HIV test kits), must result in outputs (HIV test kit stocks and supply systems, new or improved HTS services and appropriate ratios of trained staff).

These outputs are often the result of specific processes, such as training sessions for staff and campaigns aimed at promoting the uptake of HIV testing. If these outputs are well designed and reach the target populations, the programme is likely to have positive short-term effects or outcomes, such as an increased number of people from the target population testing for HIV. These positive short-term outcomes should lead to changes in the longer-term impact of HTS programmes, possibly reflected in fewer new cases of HIV infection in a target population.

11.5 HTS programmes: essential and strategic indicators

HTS programmes should continually monitor the minimum set of indicators established by the National HTS Programme. These indicators, which include antenatal care (ANC), TB, opportunistic infections (OI), STI, post-exposure prophylaxis (PEP) in primary health-care clinics and community/home-based HTS programmes should be monitored at every service delivery point offering HTS.

Indicators measuring referral to appropriate services (e.g., TB screening, STI treatment, ART, VMMC) should also be collected. Table 3 shows the set of indicators that are recommended for the purpose of reporting on the implementation of the HTS programme and policy.

Table 3: Recommended HTS indicators

No.	Indicator	Type of indicator	Measurement tool	Frequency of collection	Levels of disaggregation
1.	Number of public health facilities offering HTS	Input	DHIS	Quarterly	Province, district and Facility
2.	Number of non-health facilities providing HTS	Input	Programme monitoring or DHIS	Quarterly	Province and district
3.	Number of campaigns aimed at promoting HTS	Process	Programme monitoring	Quarterly	Province and district
4.	Number of trained lay counsellors on stipend	Process	Programme monitoring or DHIS	Quarterly	Province, District and Facility
5.	Number of clients receiving pre-test counselling	Output	Programme monitoring	Monthly	Province, district, facility, gender and pregnancy status among females
6.	Number of clients tested for HIV	Output	DHIS	Monthly	Province, district, facility, gender and pregnancy status among females
7.	Proportion of HIV-positive clients referred for TB screening	Process	Programme monitoring or DHIS	Monthly	Province, district and facility
8.	Proportion of HIV-negative men referred for MMC	Process	Programme monitoring or DHIS	Monthly	Province, district and facility
9.	Proportion of HIV-positive clients referred for CD4 testing	Process	Programme monitoring or DHIS	Quarterly	Province, district and facility
10.	Number of HIV-positive clients receiving CD4 results	Output	Programme monitoring or DHIS	Monthly	Province, district and facility
11.	Proportion of new TB patients tested for HIV	Output	DHIS	Monthly	Province, district and facility
12.	Proportion of new STI patients tested for HIV	Output	Programme monitoring or DHIS	Monthly	Province and district
13.	Proportion of new pregnant women tested for HIV	Output	DHIS	Monthly	Province, district and facility
14.	Percentage of facilities where the HTS policy guidelines are available	Outcome	Programme monitoring	Quarterly	Province, district and facility
15.	Proportion of individuals who have been tested for HIV in the previous year and have received results	Outcome	Population-based surveys (BSS or DHS)	Periodically	Province, district and facility
16.	Proportion of newly diagnosed HIV-positive people newly enrolled in and receiving care	Process	Programme monitoring	Monthly	Province, district and facility

A data collection tool should be available with a minimum set of data elements, which reflect policy goals and objectives. Indicators should be dynamic and should be revised periodically depending on availability of information and changing circumstances or technologies.

The minimum set of data elements must include the following:

- age
- gender
- location

Indicator relatedness: Programme monitoring activities (in-year monitoring) and periodic outcome and impact activities should be closely linked. Indicators that are logically connected (i.e. inputs, outputs and outcomes) should be used.

Reporting requirements: For reporting, all facilities and community programmes providing HTS services will be required to comply with agreed reporting standards and schedules as well as to comply with the data flow policy outlined in Figure 11.

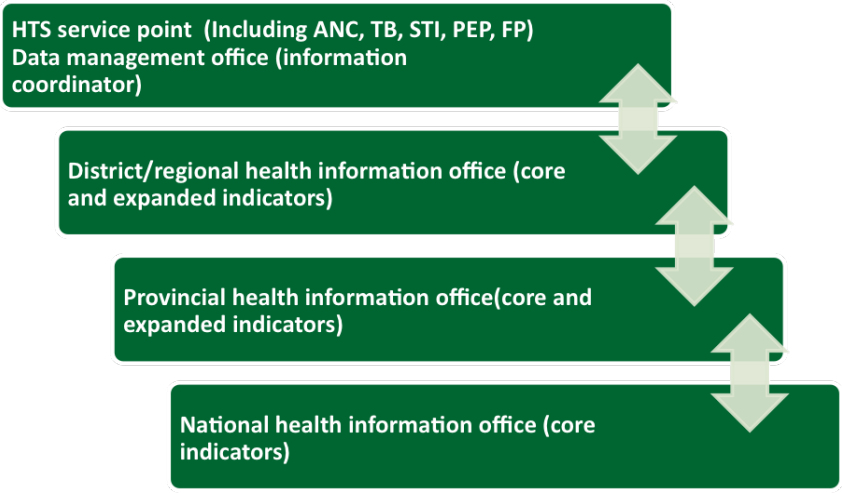


Figure 11: Information flow within the HTS programme

11.6 Data quality assurance

To assure the quality of the data that is reported, the district, regional and national level DHIS officers should select sites to be visited for data verification every quarter. A data verification tool should be developed to assist in this process.

12 SUPPLY CHAIN MANAGEMENT

Procurement processes and procedures should be rigorous enough to minimise stock-outs of rapid test kits and other testing commodities. This is essential for ensuring the quality of HTS.

12.1 Forecasting

Accurate forecasting is necessary to ensure adequate and ongoing supply of HIV test kits and other consumables. Forecasting for HIV rapid test kits should be based on the programme's capacity to provide HIV testing.

The provincial and district authority should ensure proper adherence to inventory management protocols, including maintenance of quality records, timely reporting, accurate forecasting and adequate supply of tests and other essential commodities, in order to prevent the disruption of HTS service provision.

12.2 Procurement of rapid test kits

Rapid HIV test kits procured through the national tender shall be used in the public health sector and in other sectors where testing is undertaken.

12.3 Storage of HIV test supplies

Rapid test kit quality assurance standards must be followed. Refer to the Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach, National Department of Health, 2009.

12.4 Distribution

Distribution of test kits shall follow quality assurance standards.

12.5 Stock-outs

To avoid stock-outs, proper forecasting shall be done.

12.6 Human resources

HTS sites should have adequate human resources including trained professional health workers, HIV and AIDS counsellors or community health workers and other support staff to provide the required services. Service providers should ensure a safe working environment for all health-care staff.

HTS must be carried out by trained health-care providers, community health workers or counsellors, working under the supervision of a suitably trained professional health worker. Counsellor training should be conducted according to the National Minimum Standards for Counselling and Testing. HTS counsellors shall have appropriate training on counselling of children.
A counsellor working in facilities should counsel a minimum of five clients a day, while a minimum of ten clients should be reached per day when doing outreach.

12.7 HTS training requirements

The HTS training curricula must be standardised and aligned to the NDoH's HTS curricula. HTS training shall be made available to all persons providing HTS in health-care facilities, stand-alone, mobile/outreach, home-based, or workplace HTS settings.

12.7.1 Qualifications of HTS providers

HTS providers should at a very minimum, have the following qualifications:

- matric or equivalent
- NDoH-aligned HTS training. HTS training provides skills development on counselling, rapid testing and quality assurance. The rapid test training must include a competency component to ensure providers are proficient at conducting rapid tests.

12.7.2 Certification and recertification

Certification: Persons completing nationally approved HTS curricula will receive competency certificates upon completion of the course by recognised training institutions.
It is the responsibility of health-care workers to register with the Health Professions Council of South Africa and present their HTS training certificates for licensing purposes. Workers who are not engaged in public health care are not required to register with the Council at this time, but should be prepared to do so, as this requirement may change in the future.

Refresher training: Periodic refresher training is necessary to ensure that HTS providers have the most accurate up-to-date information and that they are able to deliver high-quality HTS.
Persons conducting HTS should receive refresher training every 24 months and be recertified as HTS providers. Persons who have not conducted HTS for more than 12 months are required to be recertified before they begin practicing HTS again. Persons who have not provided HTS for more than 24 months are required to be retrained and issued with a new certificate of competency.

13 CONCLUSION

The aim of the National HIV Testing Services: Policy and Guidelines, 2015 is to provide a national framework that will direct the provision of HTS to children, youth and adults in the public and private sectors in South Africa. The main purpose of these policy guidelines is to ensure better quality and greater consistency of the delivery of the many elements of counselling and testing. For these guidelines to take root and to have meaning in the lives of clients who access and ultimately use HTS services, all service providers, programme planners and policy makers must commit and adhere to the spirit and intention underlying these policy guidelines. We need not only collective commitment, but also consistent implementation of the policy if we are to achieve greater quality and improved standardisation of HTS across the country.

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