NATIONAL HIV SELF SCREENING GUIDELINES

2018

HIV SELF-SCREENING

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ACKNOWLEDGEMENTS

The HIV Self-screening Guidelines, 2018 is the product of strong collaboration amongst the South African Government, international agencies and non-governmental organizations as well as civil society. Wide consultation took place during the development of these guidelines to ensure the success of the rollout and uptake of the guidance included in the document. The national Department of Health extends a special thanks to all the participants for providing support and technical expertise towards the content and finalisation of this document.

FOREWORD

In 2016 South Africa introduced a programme called “Test and Treat All”, which requires all those infected with the Human Immunodeficiency Virus (HIV) to be initiated on antiretroviral therapy (ART), regardless of their CD4 count or World Health Organization (WHO) clinical staging. While there were about 7.1 million people living with HIV (PLHIV) by the end of 2016, only 5.2 million of them were aware of their HIV positive status and 3.7 million had been initiated on ART.

With the current global initiative to accelerate universal access to HIV prevention, treatment, care and support services, HIV testing remains the key entry point in the HIV continuum of care for PLHIV. The National Strategic Plan for HIV, TB and STIs (NSP) 2017-2022 recommends that HIV testing should be focussing on impact and improving “yield”.

The target for the first 90 of the 90 90 90 strategy, which aims to diagnose 90 per cent of PLHIV know their status, is arguably the hardest to achieve, and affects the other two targets. The South African National HIV Testing Services (HTS) Policy (2016) embraces self-testing (referred to as self-screening in this document) as an effort to expand HIV testing, especially for the under-tested and test-averse individuals.

The WHO defines HIV self testing (referred to self-screening in this document) is defined by WHO as a voluntary process in which a person collects his or her own specimen (oral fluid or blood) and then performs a screening test and interprets the result, often in a private setting, either alone or with someone he or she trusts. It should be offered as an additional approach to existing HTS, and not replace it.

The overall goal of HIV self-screening is to improve HIV testing among the historically HIV under-tested, test-averse and hard to reach groups, such as men, adolescent girls and young women (AGYW). It seeks to improve couple testing among pregnant women and lactating mothers and provides an option for regular repeat HIV testing in high risk populations.

The key issues that have to be considered include:

- offering HIV self-screening as an additional approach to, and not replacing,existing HTS.
- use of quality assured products for HIV self-screening
- instructions for self-screening must be appropriate, validated, clear and conciseto minimise errors and maximise the performance
- a reactive (positive) self-screening result always requires further confirmatory testing from a trained tester, who will start from the beginning of a validated national HIV testing algorithm
- a non-reactive (negative) self-screening result is regarded as negative, unless the person has been exposed to HIV in the preceding six weeks, or is at a high ongoing HIV risk
- those on antiretrovirals (ARVs), which include pre-exposure prophylaxis (PrEP) and ART for PLWH. should not do an HIV self-screening test as this may result in a false non-reactive outcome
- anyone uncertain about how to correctly perform the self-screening test, or interpret the result, should be encouraged to use conventional HIV testing

HIV self-screening can be done in two ways:

- directly assisted HIV self-screening, where a trained health worker provides in-person support on how to use the kit and how to interpret results
- unassisted HIV self-screening, where the end-user performs the test using the information package in the kit itself, without any in person assistance.

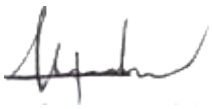
The benefits of self-screening is that it can be done in a private setting and has the ability to reach those that are not able to go to health facilities, busy people can access the test at their convenience and workplaces can ensure employees have ongoing access to HIV testing.

The HIV self-screening test kits can be distributed either through primary distribution, where a self-screening kit is delivered directly to the end-user, or through secondary distribution, where one or more self-screening kits are given to an individual, not for their own use, but to distribute to their sexual partner, family member or anyone in their network.

Various channels can be used to disseminate the self-screening kits. This includes community-based platforms, facilities-based channels, workplace programmes, pharmacy outlets, ies, internet-based sales and vending machines.

Studies have shown that HIV self-screening does not increase HIV risk behaviours such as non-use of condoms or an increase in sexually transmitted infections (STIs) and there is no evidence of any increase in reported social harm compared to standard forms of HIV testing.

It is envisaged that the implementation of HIV self-screening will ensure that no one is left behind and that individuals who have never tested are reached.



MP Matsoso
Director-General
National Department of Health

Date: 20/02/2018

ACRONYMS

AGYW	Adolescent girls and young women
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral (drugs)
CBO	Community-based organisation
DHIS	District Health Information System
DHS	District Health System
EMEA	European Medicines Evaluation Agency
FBO	Faith-based organisation
FDA	United States Food and Drug Administration
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HIVSS	HIV self-screening
HTS	HIV testing services
IQC	Internal quality controls
IVD	In vitro diagnostic (medical devices)
M and E	Monitoring and evaluation
MMC	Medical male circumcision
MSM	Men who have sex with men
NCD	Non-communicable disease
NDOH	National Department of Health
NGO	Non-governmental organisation
NICD	National Institute for Communicable Diseases
NSP	National Strategic Plan for HIV, TB and STIs (2017-2022)
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PLHIV	People living with HIV
PLWH	People living with HIV and AIDS
PMS	Post-market surveillance
PMTCT	Prevention of mother-to-child transmission
PNC	Postnatal care
PrEP	Pre-exposure prophylaxis
QA	Quality assurance
QC	Quality control
QI	Quality improvement
QMS	Quality management system

RDT	Rapid diagnostic tests
SAHPRA	South African Health Products Regulatory Authority
SANAC	South African National AIDS Council
SANAS	South African National Accreditation System
SAPC	South African Pharmacy Council
STI	Sexually transmitted infection
TB	Tuberculosis
VMMC	Voluntary medical male circumcision
WBOT	Ward-based outreach teams
WHO	World Health Organization

DEFINITION OF TERMS

Confirmatory HIV test	An HIV test done by a trained provider using the full national validated testing algorithm - both screening and confirmatory.This is done following a reactive HIV self-screeningtest.
Directly assisted HIV self-screening	Refers to individuals who are self-screening for HIV and receive a direct in-person demonstration from a trained provider or peer before or during HIV self-screening, with instructions on how to complete any step of the self-screening test or how to interpret the self-screening result. This assistance is provided in addition to the manufacturer-supplied instructions for use and other materials found inside HIV self-screening kits.
Harm or social harm	Any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt from one person to another, a person to themselves, or an institution to a person, occurring before, during or after testing for HIV.
HIV self-screen	A process in which a person collects their own specimen (oral fluid or blood) and then performs a screening test and interprets the result, often in a private setting, either alone or with someone they trust.
HIV status	Refers to the final report that is given to the client after a confirmatory test using the full national validated HIV testing algorithm.It is the final interpretation of the client's HIV infection and is based on a collection of self-screening and provider-based testing results generated from one or more assays. HIV status may be reported as HIV-positive, HIV-negative or HIV-unknown.
HIV screen or test result	The result from a single screen or test on a given assay.HIV test results may be reported as reactive, non-reactive or invalid.
Index testing	Afocused approach to HIV testing in which the household, family members, partners (including children) of people diagnosed with HIVare offered HTS (also referred to as index case).
Key populations	Refer to defined groups who, due to higher-risk behaviours, have an increased risk for HIV infection,irrespective of the epidemic type or local context. Examples include men who have sex with men, people who use drugs, sex workersand transgender people.

Non-reactive HIVscreen or test result	A result that does not show a reaction (in the context of HIV it means there is no HIV-1 p24 antigen or HIV-1/2 antibodies).
Pre-screen information	Refers to information on HIV self-screening procedure that should be available to the self-screener prior to doing the test, which should be available in the manufacturer information package or can be provided in person. Various additional tools can assist with pre-screen information, such as brochures, flyers and videos.
Primary distribution of HIV self-screening kits	Delivery of HIV self-screening kits from any distribution point directly to the end-user.
Quality assurance (QA)	A part of quality management focused on providing confidence that quality requirements will be fulfilled.
Quality control (QC)	The set of procedures designed to monitor the testing process to ensure appropriate system performance. It includes testing control materials, charting the results and analysing them to identify source of error, and evaluating and documenting any remedial action taken as a result of this analysis.
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. Systematic and process-oriented efforts are essential to meet quality objectives. Principles of quality management include categories such as documents and records, organisation, personnel, equipment, purchasing and inventory, process control, information management, occurrence management, assessments (external and internal), process improvement, customer services and facilities and safety.
Rapid diagnostic test (RDT)	An in vitro diagnostic medical device of immune-chromatographic or immune-filtration format for the detection of HIV-1/2 antibodies and/or HIV p24-1 antigen in the context of HIV.
Reactive HIV screening or testing result	A result that shows a reaction (in the context of HIV it means there is the presence of HIV-1 p24 antigen or HIV-1/2 antibodies).

Secondary distribution of HIV self-screening kits	When one or more self-screening kits are given to an individual, not for their own use, but to distribute to their sexual partner, family member or anyone in their network.
Sensitivity	The percentage of the results that will be positive when HIV is present (percentage of true positives).
Seroconversion	When an individual's immune system produces sufficient HIV-1/2 antibodies to be detected by a diagnostic test.
Serodiscordant couple	Refers to a couple in which one partner is HIV-positive and the other is HIV-negative.
Specificity	The percentage of the results that will be negative when HIV is not present(true negatives). Denotes the probability that the assay/algorithm will correctly identify specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.
Testing algorithm	The combination and sequence of specific assays used within HIV testing strategies.
Unassisted HIV self-screening	When individuals self-screen for HIV independently, without in-person demonstration,using only manufacturer-provided instructions for use. They may be provided with access to additional support, such as telephone hotlines, brouchers or instructional videos.
Unconfirmed HIV screening results	Refers to a reactive HIV self-screen result.
Window period	The time between HIV infection and the detection of HIV antibodies using an HIV test.

1. INTRODUCTION AND RATIONALE

By the end of 2016, South Africa had an estimated 7.1 million PLWH, with about four (4) million already initiated on ART. Nearly 270 000 people in South Africa were newly infected in 2016, with a prevalence rate of approximately 12.8 per centamong the entire population, or 19.1 per centamong those aged 15 to 49 years, and 30 per centamong pregnant women.

The ambitious 90-90-90 targets set for the year 2020 emphasises knowledge of HIV status as a critical first step to ending AIDS by 2030. If people do not know their HIV status all other steps and targets in the HIV cascade are affected. Gaps in knowledge of HIV status are often largest among young people and men. At the same time adolescent girls and young women are at an unacceptably high risk of HIV infection.

Many men remain untested. Those who are HIV-positive continue to be undiagnosed, delaying linkage to treatment and care. As a result, males have a higher HIV-mortality rate than their female peers. Strategies are needed to increase men's uptake of HIV testing services (HTS)in more accessible settings. Also needed are ways to encourage more testing of male partners in high prevalence settings and testing of male partners of women with HIV in all settings.

Focus for impact is the overall approach for the NSP. It seeks to reduce new HIV infections by more than 60 percent from an estimated 270 000 per annum in 2016 to below 100 000 by 2022, and a reduction in new infections among adolescent girls and young women from an estimated1500 a week to less than 800.

The South African National HIV Testing Services Policy (2016) embraces HIV self-testing (referred to as self-screening in this guideline document to ensure a clear understanding that the full national HIV testing algorithm is required to confirm diagnosis) as an effort to expand HIV testing, especially for under-tested, undiagnosed and test-averse individuals. There is a reported 25% HIV testing gap (PLWH who do not know their status) and offering self-screening as an additional approach to HTS may contribute towards closing this gap, as well as offer a convenient alternative for HIV testing.

In 2016, the WHO released guidelines on HIV self-testing and partner notification which has guided the development of this HIV self-screening (HIVSS) document. The WHO also released specifications guidance for manufacturers wishing to apply for WHO pre-qualification and diagnostic assessment of any HIV self-testing product.

Studies have shown that HIVSS does not increase HIV risk behaviours such as non-use of condoms or an increase in STIs. There is also no evidence of any increase in the reported social harm compared to standard forms of HIV testing.

The HIVSS guidelines should be read in conjunction with the National HIV Testing Services Policy (2016). This document provides guidance on the provision of HIVSS; linkage to services; quality assurance to ensure accurate results; and how to position HIVSS as an additional approach to HTS.

2. GOAL AND OBJECTIVES

The overall goal is to improve HIV testing among the historically HIV under-tested, test-averse and hard to reach groups, such as men and AGYW.

The objectives include to:

- Provide a framework for the implementation of the the HIVSS as an additional HIV testing approach
- Improve couplestesting among pregnant women and lactating mothers, in order to reach untested male partners
- Provide an option for regular repeat HIV testing in key populations, such as sex workers, MSM, transgender people, people who inject drugs and mobile populations (truck drivers, miners, and farm workers)

3. GUIDING PRINCIPLES

3.1 Rights-based approach

HIV self-screening must always be voluntary, and be without any form of coercion. HIV testing and self-screening must always be to benefit the individual screened and improve health outcomes at the population level. A human rights-based approach that prioritises universal health coverage, gender equality and health-related rights such as accessibility, availability, acceptability, appropriateness, and quality of services is essential for the success of HIVSS.

3.2 The 5Cs

The 5Cs are applicable in all forms of HIV testing, including self-screening settings. These are Consent, Confidentiality, Counselling, Correct results and Connection (to post-test services for linkage).

Consent:
The age of consent for HIV self-screening is based on the age of consent for HIV testing (as per the Children's Act, 2005 [Act 38 of 2005]). It is recommended that children and adolescents aged 12 to 18 years should use directly assisted HIV self-screening option. All people who self-screen for HIV, and those who distribute the screening test to their partners, must be informed that it is not mandatory and that it must be provided without coercion. Verbal consent is required for directly assisted HIV self-screening.

Confidentiality:
Since unassisted HIVSS may be conducted in a private setting, it is unlikely that confidentiality can be breached. However, with directly assisted HIVSS, it is important to maintain confidentiality. Disclosure to the partner or significant others should be encouraged and the necessary support provided.

Counselling:
All HIVSS kits will have adequate pre-test and post-test information for the user, which will be provided in the product package insert. Additional support can be provided through flyers, a national AIDS helpline, videos, trained HTS providers, and/or smartphone applications. Counselling will be offered to those who present to a trained HTS provider for confirmatory testing after a reactive self-screening test.

Correct:
To ensure accurate and reliable HIVSS results, The national Department of Health will purchase and distribute HIVSS kits that have been pre-qualified by the WHO. A single reactive self-screen result requires the test result to be confirmed by a trained provider starting with the first test (screening test) within the national testing algorithm. Ongoing risk of HIV and recent exposure should be taken into consideration when interpreting a negative (non-reactive) self-screening result.

Connection:
Linkage to confirmatory testing for those with reactive HIVSS results and linkage to prevention services for those with non-reactive results must be adequately communicated. Confirmatory testing should be accessible in stigma-free settings, and performed by a trained healthcare provider using the full national validated testing algorithm.

4. KEY CONSIDERATIONS FOR HIV SELF-SCREENING (HIVSS)

This section will highlight the most important considerations for the implementation of HIV self-screening:

- Programmes implementing HIV self-screening must use quality-assured products that have been approved for use in South Africa, e.g. a WHO pre-qualified product (see **Table 1**)

- There must be **appropriate, validated, clear and concise instructions for the use** of HIV self-screening kits to minimise errors and maximise the performance. Pictures can support the correct use and interpretation or in-person demonstrations for people with low literacy

- **A reactive (positive) self-screening result** always requires further confirmatory testing from a trained healthcare provider starting from the beginning of a full national validated HIV testing algorithm. Clear messages are essential to ensure self-screeners are aware of what to do after a reactive self-test

- **Those with a non-reactive (negative) self-screening result should** retest after 6 weeks (as indicated on the HIV self-screeninginformation for use (IFU) insert) if they might have been exposed to HIV in the preceding six weeks, or are at high ongoing HIV risk

- **Those on PrEP, PLWH on ARVs and people in HIV-related clinical trials should not do an HIVSS test** as this may result in a false non-reactive outcome

- **If a person is uncertain** about how to correctly perform the self-screening test, or interpret the self-screening result, he or she should be encouraged to access the conventional facility- or community-based HIV testing

5. TARGET AUDIENCE

These HIVSS guidelines are intended to be a reference guide for clinical and non-clinical HTS service providers, which include national, provincial and district health officials, health facility managers and healthcare providers (including healthcare workers, counsellors and community healthcare workers) in private and public health facilities. It must also be used by community-based organisations (CBOs), non-governmental organisations (NGOs), faith-based organisations (FBOs) and any other HTS or HIVSS service providers in the private sector and educational institutions.

6. TARGET POPULATION

The NSP emphasises "high yield" HIV testing and leaving no one behind. HIVSS is not intended to replace current HIV testing modalities, but rather to complement HTS and enable more people to know their HIV status, particularly those that are not reached by existing services. It is important to carefully position this service such that it is highly efficient and effective at reaching the undiagnosed and people with ongoing risk. It should be noted that anyone who requests to self-screen should not be denied the opportunity to do so. However, HIVSS may not be for everyone, and it is important that individuals and communities are aware of how and where to access facility- and community-based testing options.

7. HIV SELF-SCREENING IMPLEMENTATION PROCESS

7.1 Definition

HIV self testing (referred to as self-screening in this document) is defined by WHO as a voluntary process in which a person collects his or her own specimen (oral fluid or blood), performs a screening test, and interprets the result, often in a private setting, either alone or with someone he or she trusts. It should be offered as an additional approach to, and not replace existing HTS.

At a minimum, HIV self-screening should be offered with the following:

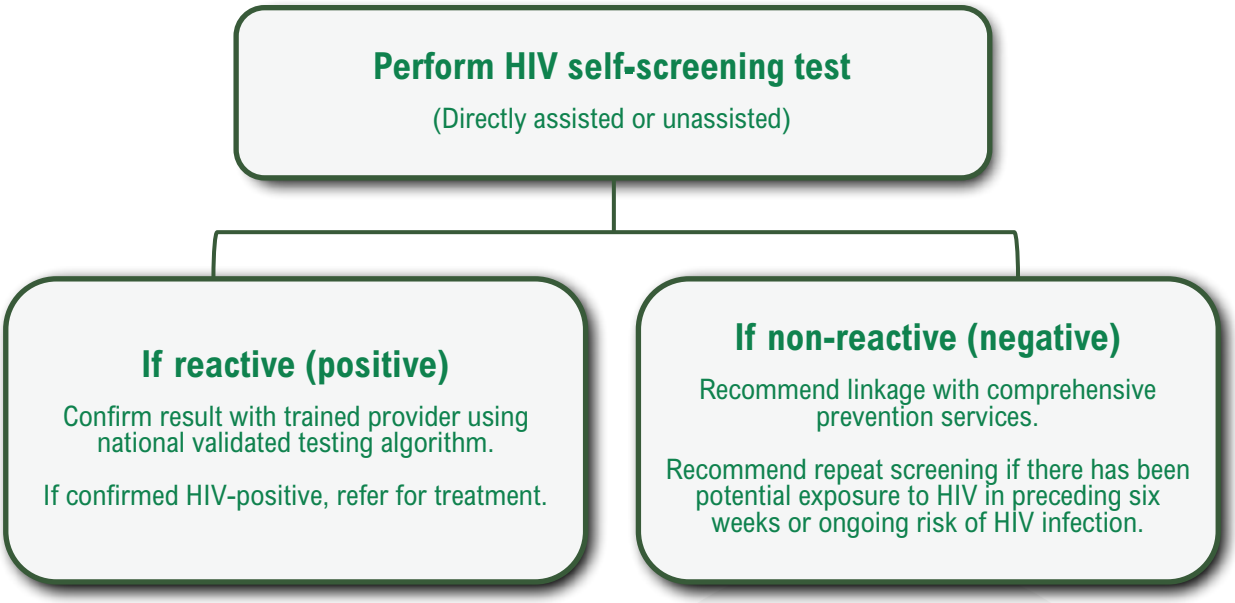
- The application of the 5Cs (see Section 3: Guiding principles)
- Detailed step-by-step instructions (included in the self-screening kit)
- The HIV self-screening kit must meet the specifiedminimum standards
- Referral and linkage to treatment and prevention services
- Support for partner testing and disclosure

7.2 HIV Self-screening Kits

Government will only procure and distribute HIV self-screening kits that are WHO pre-qualified.
All HIV self-screening kits must include procedures for use and safe disposal of the test kit through the general waste system, written in English with translation into at least two local official languages. Package inserts must be simple with clear written instructions plus pictorial diagrams to make it easy for the user to accurately perform the self-screen.

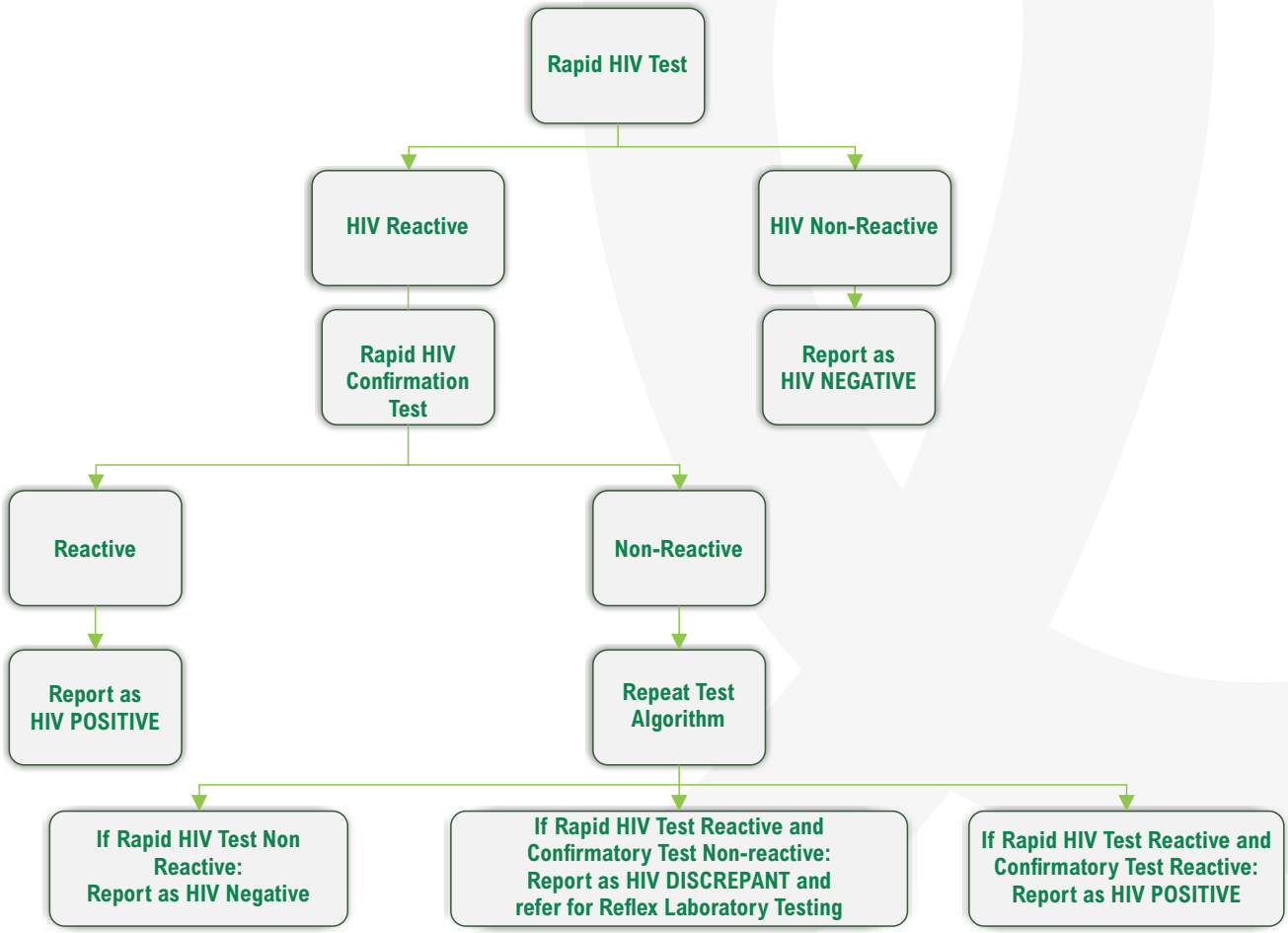
7.3 ALGORITHM FOR HIV SELF-SCEENING

Figure 1: Algorithm for HIV self-screening



Everyone who self-screens reactive (positive) must go for a confirmatory test using the full national validated testing algorithm by a trained healthcare provider at the most convenient service delivery site. It is important that testers confirm this result starting with the first test in the algorithm (**See Figure 2**).

Figure 2: National validated HIV testing algorithm:



9.1 Distribution methods for HIV self-screening kits

HIV self-screening tests can be delivered through primary or secondary distribution methods:

The primary distribution method occurs when a self-screening kit is delivered directly to the end-user.

Secondary distribution occurs when one or more self-screening kits are given to an individual, not for their own use, but to distribute to their sexual partner, family member or anyone in their network.

9.2 Distribution channels for HIV self-screening

Community-based platforms: The distribution of the HIV self-screening kits can be done through community healthcare workers, who can provide both assisted and non-assisted HIVSS options to primary users, through door-to-door delivery or to targeted populations. They can also provide kits to individuals who have tested and are willing to be secondary distributors to their sexual partners. In addition, self-screening kits can be collected from designated community collection points.

Facilities-based channel: HIV self-screening can be used to promote couple or partner testing by offering them to individuals to give to their sexual partners, using the secondary distribution method. Potential settings include patients attending theANC and postnatal care (PNC) clinics, STI clinics, TB, medical male circumcision (MMC) and family planning sites.

HIVSS should not replace the current HIV testing modalities in health facilities, but should be an additional method that seeks to increase the uptake of HIV testing for those that are not easily reached by the traditional method.

Workplace programmes: HIV self-screeningcan be introduced within workplace wellness programmes and can reach men and those at high risk such as miners, truck drivers, and their partners, with a view to facilitating the uptake of HIV prevention. The self-screening kits can be given directly to the end-user through primary distribution, and the individual can be directly assisted or can be unassisted. Workplace programmes can also use secondary distribution by promoting partner delivery of the self-screening kits.

Other outlets: These include pharmacy outlets, internet-based sales and vending machines. Individuals can directly buy or order the self-screening kits.

1.3 Specific considerations for pharmacy distribution of HIV self-screening kits as outlined by the SA Pharmacy Council (SAPC)

Pharmacists must only sell HIV self-screening kits approved by either SAPHRA, the WHO, other regulatory health authorities recognised by SAPHRA (FDA, European Medicines Evaluations Agency (EMEA)) or self-screening kits with CE marking.

Pharmacists and/or pharmacy support personnel must ensure that they have adequate knowledge of the relevant aspects of HIV and HIVSS test kits as well as the ability to demonstrate the use of the test kit to any person as the need arises.

A pharmacist must ensure that the person buying the HIVSS kit has access to the following information:

- IFU leaflet
- Guidance on interpretation of all three possible outcomes of the HIVSS test (Reactive, Non-Reactive, Invalid);
- Information on referral and linkage to care

10. HIV SELF-SCREENING KITS

In addition to instructions for use (IFU), it is recommended that all HIVSS kits distributed be accompanied with client education material such as frequently asked questions or pamphlets.

All distribution points should display illustrations or instructions on HIV self-screeningprocedures should further explanation or testing support be required. Persons dispensing the kits should be in a position to provide all the necessary information on their.

10.1 Requirements for HIV self-screening instructions for use

The manufacturer instructions for usemust have simple and clear instructions on how to perform the self-screen with pictorial diagrams to minimise errors and maximise the performance. The instructions must cover:

- How to handle and store the test kits before usingthe test
- How to interpret the test results
- What to do after reading the results, including information on available post-test services, such as counselling, confirmatory testing and care and treatment
- How to safely dispose of the used test-kit

  The ethical and legal obligations, which includes consent requirements and no coersion.

10.2 Referral and linkage to services

For reactive HIV self-sreening results: Linkage to services (connection) includes linkage to confirmatory HIV testing by a trained healthcare provider in a stigma-free setting.For non-reactive results, clients should be referred and linked to HIV prevention services such as PrEP, VMMC for men, treatment of STIs, provision of condoms and partner testing/notification.

10.2.1 Linkage strategies after HIV self-screening

- Information material, such as manufacturer's instructions for use, brochures and flyers distributed with HIV self-screening kits should have information on linkages for all possible outcomes.
- A telephone hotline that self-screeners can use before, during or after self-screening for psychosocial and/or technical support can help with referral and linkage information.
- Mobile phone text message (SMS) services or a smartphone application can provide information, reminders, videos and messages that encourage linkage following HIVSS
- Proactive, community-based follow-up by peer and/or outreach workers
- Community health workers can provide additional post-screen counselling where appropriate and support with referral to confirmatory testing services
- Couples and partner self-screening can promote linkage and should be encouraged, including partner delivered self-screen kits with information on linkage

Evidence has shown that HIV self-screening has a high level of accuracy for both sensitivity and specificity, when quality-assured products are used in the hands of untrained users (Figueroa, WHO, 2016). All HIVSS kits shall be subject to quality assurance, according to defined national standards and should be monitored and evaluated. In addition, all providers should be trained to provide quality self-screening according to these guidelines.

11.1 Minimum standards for HIV self-screening kits

It is important to note that rapid diagnostic tests (RDTs) that are used for the traditional HTS should not be sold as HIV self-screening kits.

Only HIV self-screening that fulfill the requirements in Table 1 are allowed distribution in South Africa.

- Products should meet all the requirements of the target product profile, as per the WHO guidelines.

- All self-screen kits must undergo in-country laboratory validation to ensure that they meet the minimum quality standards of the national HIV reference laboratory, which is housed at the National Institute for Communicable Diseases (NICD).

- Manufacturers and distributors require verification and certification for HIVSS kits before they are placed on the market. Their certification must be based on a conformity assessment certificate issued by a conformity assessment body, a body corporate or other legal entity, locally or internationally, accredited either by the South African National Accreditation System (SANAS) or an international body recognised by the South African Health Product Regulatory Authority (SAHPRA), according to determined standards, as competent to carry out the assessment.

- Post-market surveillance (PMS)should be done continuously to assess the quality and performance of the self-screen kits in use, in compliance with the set standards. This will include lot-to-lot validation by the reference laboratory for quality and performance before distribution, including new lots of self-screening kits coming into the country. Only those that meet the standards should be distributed.

- PMS will include tracking and investigating user complaints coming through the hotline and internal quality controls (IQCs) by distributors. The reference laboratory will provide distributors with panels for use in checking performance of batches before distribution. This may help detect problems with kits arising from sub-optimal storage e.g. extreme temperature changes or damaged packaging.

Table 1: Minimum requirements for use of HIV self-screening kits

Public health services	Research purposes	Private sector
WHO pre-qualification	WHO pre-qualification or Experts Review Panel for Diagnostics (ERPD) (level 3 minimum)	Approval by a member of the IMDRF (United States Food and Drug Administration (FDA), Conformité Européenne (CE) etc.)
Manufacturer licence in place with SAHPRA		Manufacturer and distributor licence in place with SAHPRA
Distributor licence in place with SAHPRA (for importation)	Distributor licence in place with SAHPRA (for importation)	
National Reference	Kits clearly indicate	Any additional South African
Laboratory Certification	"For research purposes"	Pharmacy Council (SAPC) requirements in place
On national procurement list		

11.1 Ensuring quality of the HIV self-screening process

HIV self-screening kits distribution points must display instructions on the self-screening procedure (e.g. poster, video) or provide brochures which can be distributed with test-kits, illustrating how the self-screening is done. Referral and linkage information must be available to end-users.

All healthcare providers must be aware of the HIVSS option and must know how it is done to be able to provide information and appropriate support to anyone asking during a visit at a health facility.

Effort must be made to make communities aware of the need to confirm any reactive self-screening results through a trained provider. Referral and linkages information should be clearly communicated to communities.

12. COMMUNICATION PLAN

Educating the community and health workers about HIVSS is critical in order to increase its uptake and minimise the risks of misuse. It is also important to communicate to providers that HIV self-screeningcan serve as a tool to create demand for existing services such as VMMC and PrEP. The empowerment of communities will facilitate the correct and accurate use of a service.

The HIV self-screening communication plan is vital in creating awareness and increasing access to HIV self-screening for targeted groups. To ensure that the rollout of HIV self-screeningis effective and efficient, it is important that HIVSS enhances, and does not replace, current HTS efforts, but leads to finding first-time screeners and improving repeat screening in people at high risk of HIV.

HIV self-screening communication to clients and tools developed by implementing partners should all be aligned to national Department of Health materials.

There must be information on the HIVSS available to the general public to raise awareness on the key messages regarding HIV self-screening.

Creating awareness among intended user groups for HIVSS and providing additional support during self-screening can happen at different levels and may involve a variety of communication channels and tools. The various channels that can be used are radio, television, newspapers, billboards, IEC material, different social media, telephone helpline, support groups and face-to-face interactions.

13. MONITORING, EVALUATION AND RESEARCH

The discreet nature of HIVSS translates to challenges associated with collection of information showing programmatic effectiveness and user experience. This section outlines how existing systems will be adapted to monitor programmatic uptake, the correct use of HIVSS kits, and social harm or other adverse events. Additionally, innovative monitoring and evaluation methods will be required in order to show the impact of self-screening on knowledge of HIV status and linkage to services. The monitoring and evaluation of HIVSS programme activities will be conducted through routine reporting and recording as well as through special surveys and research evaluations. Since HIVSS is a component of the HTS, its monitoring and evaluation activities will be integrated into the monitoring and evaluation systems currently in place for the HTS. Measurement of uptake cannot be inextricably linked to usage, as individuals who receive a self-screen kit may not necessarily use it.

Data collection: HTS registers are already collecting information on those who have used HIVSS and documenting the result of the self-screening test. Reports should be sent to the relevant levels as specified in the national HTS guidelines and as per specific programme requirements. The section on comments in the HTS register can be used to record information on method and channel of distribution, so that it is available at a later stage for research purposes. All facilities and community programmes providing HIVSS services will be required to comply with agreed reporting standards and schedules as well as the data flow policy.

Surveys and surveillance systems can be modified to include data on the uptake of HIVSS, the proportion of HIV diagnoses identified through HIVSS, instances of social harm and adverse events. They include:

- Community-based surveillance systems
- Household/population-based surveys
- Health impact assessments and behavioural surveys

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