



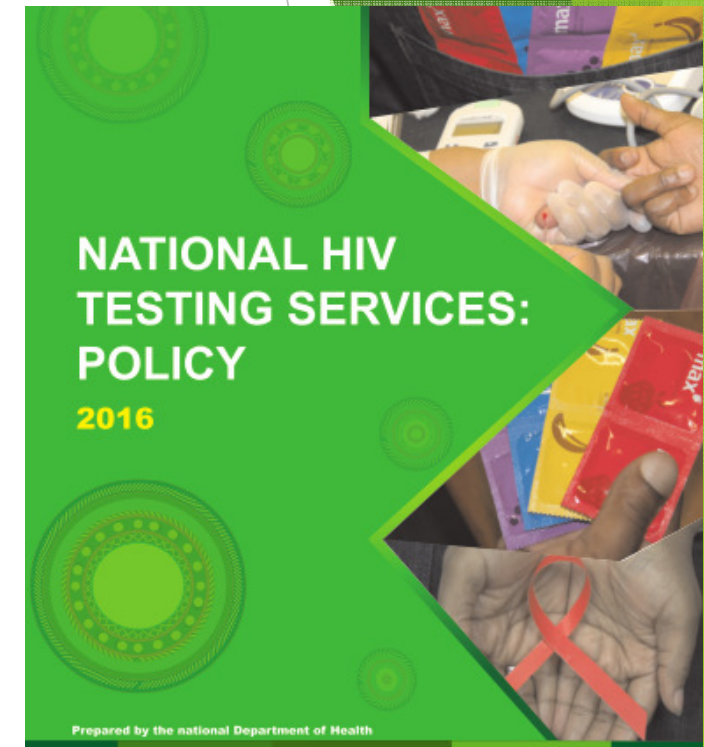
Recommendations for the South African HIV Self-Testing Guidelines

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Supplement to the National HTS Guidelines

- ▶ SA HIV SOC convened a meeting of subject matter experts in Nov 2016 to draft guidelines on HIV Self-Testing that would be proposed to the DOH
- ▶ The TWG consisted of members of the DOH, the WHO regional office, the NHLS, NICD, academic institutes and NGO's
- ▶ The recommended guidelines, once approved by DOH, will serve as a supplement to the National HIV Testing Services Guidelines, until this document is revised to include HIVST as an additional strategy



WHO Guidelines - Dec 2016

- ▶ Launched on 1st December 2016
- ▶ Recommendation:

Recommendation

HIV self-testing should be offered as an additional approach to HIV testing services.

[STRONG RECOMMENDATION, MODERATE QUALITY OF EVIDENCE.]

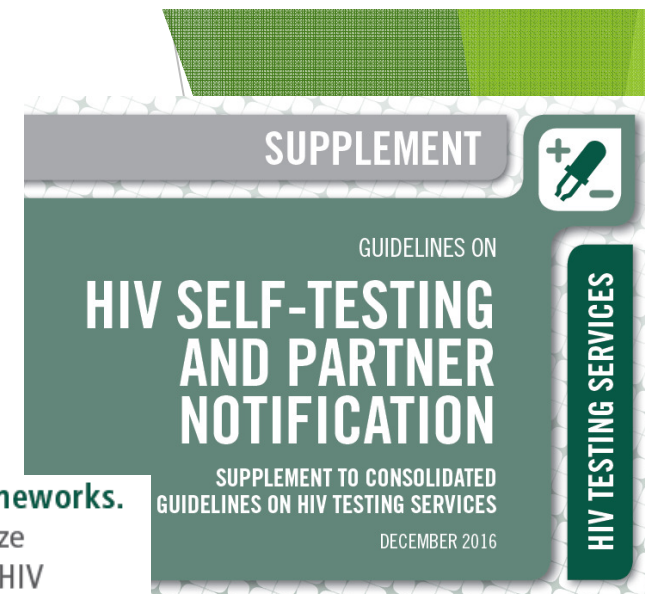
- ▶ Urged member countries to “Adapt, develop and harmonize existing national policies on HIV testing to incorporate HIVST”
 - ▶ Included use of Quality assured products
 - ▶ Consent and rights
 - ▶ Confirmatory algorithms
 - ▶ QA and Post Marketing Surveillance

NEW

- **Policy and regulatory frameworks.**

Adapt, develop and harmonize existing national policies on HIV testing to incorporate HIVST, such as:

- Laws permitting the sale, distribution, advertisement and use of quality-assured RDTs for HIVST;
- Age of consent to self-test;
- Human rights laws, policies and regulations to protect individuals and address misuse of HIVST if and when it occurs;
- National policies on how to confirm an individual’s HIV status following HIVST;
- Quality assurance and post-market surveillance systems for RDTs used for HIVST.



Main Thrusts of the Guidelines

- ▶ **HIVST is not intended to displace the confirmatory facility-based HIV test**, rather HIVST is a complementary approach to existing HIV testing services, with the benefit of reaching previously untested, hard to reach, and test-averse populations.
- ▶ **HIVST is considered a Test for Triage (A0)** since a single Rapid Diagnostic Test cannot is not sufficient to make an HIV-positive diagnosis.
- ▶ **HIVST is not recommended for users with a known HIV status** who are taking antiretroviral drugs, as this may lead to an incorrect self-test result (false non-reactive).
- ▶ **HIVST can be delivered through various approaches in the public and private sectors**, including community-based, facility-based and Internet-based channels. Approaches may also offer the option of using an oral fluid or blood-based HIV RDT for self-testing.

HIV SELF TESTING RAPID DIAGNOSTIC TESTS (RDTs)

- ▶ Evidence has shown that HIVST has high level of test accuracy, in terms of both sensitivity and specificity, when **quality assured products** are used in the hands of untrained users.
- ▶ The technology landscape is driving towards ensuring that HIVST products are **fit for purpose and can demonstrate high accuracy** when compared to use by a trained user.
- ▶ In this regard, a recommendation is made that manufacturers/developers of RDT's aim to conform to the **TARGET PRODUCT PROFILE** for HIVST

Target Product Profile for HIVST

- ▶ Manufacturers/Developers must strive towards producing the ideal devices that are:
 - ▶ High quality manufacturing standards, according to ISO 9001
 - ▶ Acceptable analytical performance in laboratory settings.
 - ▶ High clinical sensitivity and specificity in the hands of untrained users
 - ▶ Pictorial instructions for use with any text-based instruction translated into local languages
 - ▶ Low number of test steps with simple sample transfer
 - ▶ Simple to interpret test results
 - ▶ Fast time to result
 - ▶ Stable test results

Why is this TPP important?

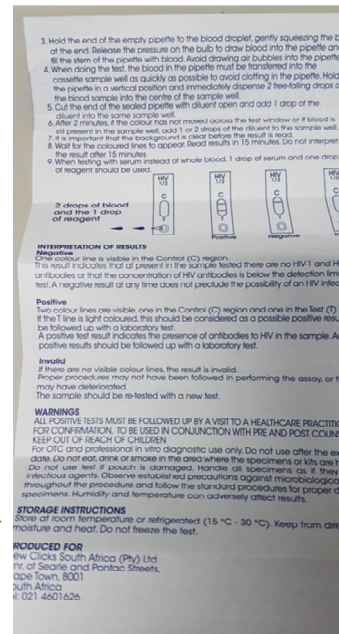
- ▶ An important differentiation must be made between a PROFESSIONAL RDT and HIVST. **THE IFU IS A CRITICAL COMPONENT OF THE HIVST**
- ▶ The HIVST must be geared towards an untrained user, of any level of literacy and education so that the user can complete all the steps for use, and be able to accurately interpret their result



Self Test

VS

Prof Test



Pictorial instructions for use with any text-based instruction translated into local languages

Other features of the TPP...

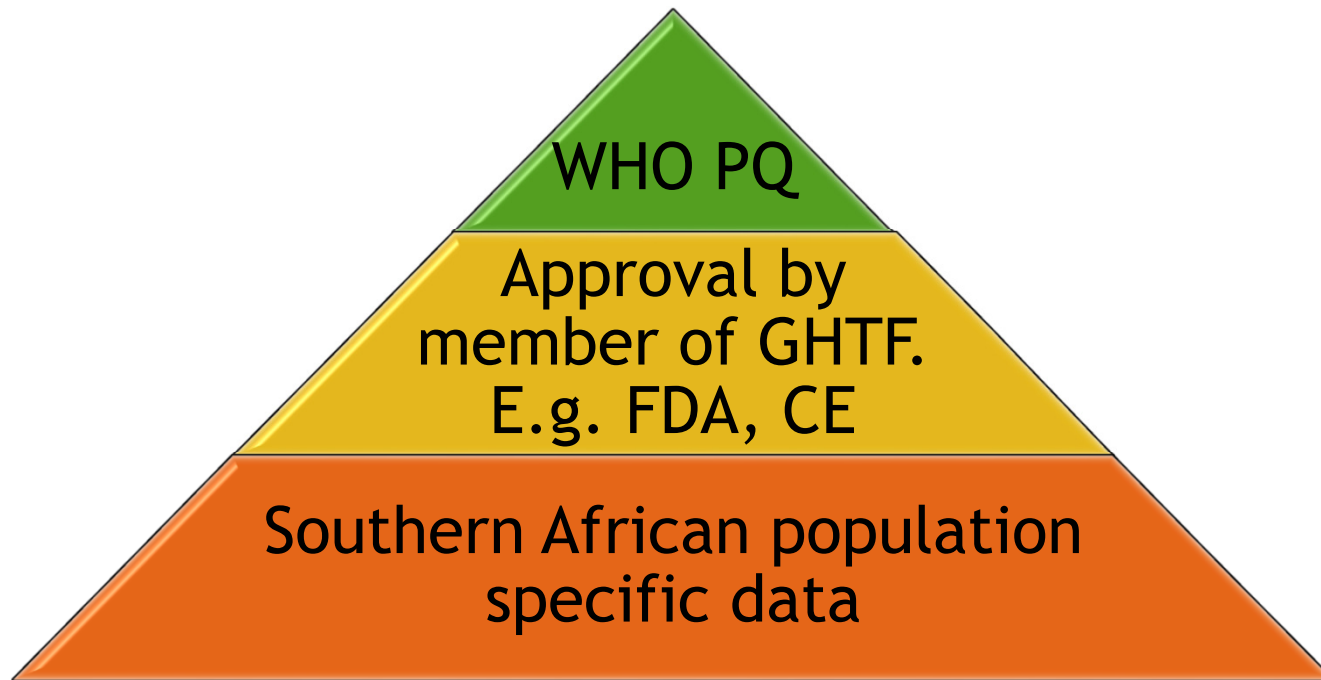


Low number of test steps
with simple sample
transfer



Simple to interpret test results
Fast time to result
Stable test results

Pyramid of requirements



Key points from the Guidelines

- ▶ The need for **appropriate, validated, clear and concise instructions for use**. This is critical in terms of the products usability to ensure that critical errors are minimised and accuracy is maximised.
- ▶ Instructions for use and packaging materials must be **translated and available in local languages**, as well as English
- ▶ **Clear messaging**: Users must understand that a **reactive/positive result must be confirmed** through further testing by a health care worker as well as where to access services
- ▶ **Manufacturers should include a “care card” with the packaging which the user can take to a local clinic as evidence of having self-tested**. Care card information should include the DoH logo, the contact details for the National Aids Helpline, the HIV self-testing website (www.hivselftesting.co.za) and/or the manufacturer’s website that can provide any additional information on linkage to care as needed.

Key points from the Guidelines...cont

- ▶ All products must ensure on the basis of a **conformity assessment certificate issued by a Conformity Assessment Body**, a body corporate or other legal entity, locally or internationally, accredited by SANAS or an international body **recognized by the Medicines Control Council**, according to a standard as determined by the Council
- ▶ **Post Marketing Surveillance and lot number tracking to ensure device failures can be reported**, lot numbers may be recalled and manufacturing quality can be assured. All kits must clearly show the expiry date of the product.
- ▶ All HIVST devices must provide **disposal instructions** and disposal supplies e.g. sealable plastic bags

HIVST IMPLEMENTATION

▶ IMPLEMENTATION CONSIDERATIONS

- ▶ There are several models through which HIVST may be delivered, and will depend on the target population:
 - ▶ These would include Primary Health Care facilities, Hospitals and pharmacies. Less traditional access points could be through internet distribution, workplace programmes, and Vending machines. In terms of community based outreach Self-Testing can be offered as part of a package to clients visiting PrEP facilities, VMMC, Sexual and reproductive health centres, Outreach TB/STI clinics, and campaign multi-diseases.
 - ▶ Secondary distribution includes Peer-to-peer and Couples and partners
- ▶ Within the spectrum of channels for distribution of HIVST, there are also varying levels and type of support that can be offered to self-testers.
- ▶ The following tools can be utilised for assistance or demonstration:
Pictorials, Videos, Hotlines, Apps, Multimedia, SMS

HIVST IMPLEMENTATION... cont

IMPLEMENTATION MESSAGING

- ▶ An HIV self-test is a screening test. An initially reactive/positive self-test result requires further testing and confirmation from a trained tester
- ▶ A non-reactive/negative self-test result does not always indicate that a person is HIV-negative, depending on the test used, window period, and also possible errors in performing the self-test or interpreting results; and, as with all HIV testing, individuals who have had a high risk encounter in the past three-months should be advised to retest.
- ▶ If an individual is on ARV drugs for treatment or PrEP, this may lead to a false non-reactive/negative result, particularly using an oral fluid- based RDT.
- ▶ To minimize social harm, test kits/care cards/packaging must contain the following statements:
 - ▶ This test is private, confidential and voluntary. If you are concerned about the outcome of the result or uncomfortable using the test DO NOT USE IT. Go to a clinic for testing.
 - ▶ If you require assistance telling your partner your result, call the helpline or go to your nearest clinic.
 - ▶ Warning about disinhibition if HIV negative and risk
- ▶ Emphasis must be placed on the correct disposal of used HIV self-tests.

ACKNOWLEDGEMENT

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- ▶ The WHO regional office, and HIV Department (Geneva)
- ▶ Halteres Associates
- ▶ The Bill and Melinda Gates Foundation
- ▶ All Members of the TWG
- ▶ The Medical Research Council (SA)