HIV Self-Testing in South Africa

The current landscape

Mohammed Majam
08.04.2017
Sunnyside Hotel, Parktown
From 2005 – 2015, there was a sharp increase in HIV-positive diagnoses in Africa. From 2010—2014, > 600 M people received HTS in 122 low- and middle-income countries – nearly half all tests were in Africa.

Source: WHO 2015; WHO 2016
Why are we talking about HIV Self-Testing (HIVST)?

Source: UNAIDS, Gap report 2014
Why are we talking about HIV Self-Testing (HIVST)?

- **100%** PLHIV
- **45%** PLHIV who know their status
- **39%** PLHIV on ART
- **29%** PLHIV virally suppressed

Source: UNAIDS, Gap report 2014
There is a testing gap.

Source: UNAIDS, Gap report 2014
Proposed UNAIDS “90-90-90”

- PLHIV: 100%
- PLHIV who know their status: 90%
- PLHIV on ART: 90%
- PLHIV virally suppressed: 90%

Source: UNAIDS, Ambitious treatment targets, 2014
Global Progress Toward the First 90, 2015

40% of PLHIV still remain undiagnosed worldwide

Source: UNAIDS, 2016 – based on 2015 measure derived from data reported by 87 countries, which accounted for 73% of people living with HIV worldwide; 2015 measure derived from data reported by 86 countries. Worldwide, 22% of all people on antiretroviral therapy were reported to have received a viral load test during the reporting period.
Progress toward the first 90 by region, 2015

- **Asia & the Pacific**: 64% PLHIV diagnosed, 34% Gap to reaching 90-90-90
- **Eastern & southern Africa**: 62% PLHIV diagnosed, 54% Gap to reaching 90-90-90
- **Eastern Europe & central Asia**: 67% PLHIV diagnosed, 45% Gap to reaching 90-90-90
- **Latin America & the Caribbean**: 75% PLHIV on ART, 19% Remaining gap to reach 2030 goal
- **Middle East & North Africa**: 37% PLHIV on ART, 12% PLHIV on ART virally suppressed
- **Western & central Africa**: 36% PLHIV on ART, 12% PLHIV on ART virally suppressed

Source: UNAIDS, 2016
New adult HIV infections globally, 2015

~1.9 M new adult HIV infections in 2015

44% new HIV infections are among key populations and their partners

Source: UNAIDS, Data is for populations 15 years of age and above.
Innovation Needed to Close the Testing Gap

Photo Credit: http://fr.ubergizmo.com/2013/02/15/wifi-gratuit-metro-londonien-fin.html
So what is HIV Self-Testing?

• HIVST is a process by which an individual wanting to know his or her HIV status collects a blood or oral fluid specimen, performs a HIV test, and interprets the results by him or herself.

• HIVST is a “screening test” or Test for Triage

• As a new innovation that has significant potential to extend beyond the limitations of the HIV testing infrastructure and address existing barriers to testing, HIVST could play a substantial role in accelerating progress towards this goal of 90-90-90.
HIVST has been touted as a supplementary strategy to reach key and under-tested populations.

It is a concept that requires optimization for the ‘lay’ person out in the community.
What is HIVST NOT?

• It is not here to replace traditional HTS, and facility based HTS should continue to be the main modality through which the majority of the population learn their status

• It is not a definitive test, but rather the first step towards learning a status. All POSITIVE results must be confirmed using the national algorithm and negatives retested in 3 months. MESSAGING MUST BE CLEAR
Current Wits HSTAR Programme

The HSTAR Programme, currently funded by the BMGF and AIDS Fonds, is evaluating HIV self-testing in the South African market, actively engaging with policy makers and communities, to pave the way for several well-tested products to enter the market, and facilitate the process towards World Health Organisation Pre-Qualification and National Guidance on ST.

The programme will address access, acceptability, product performance, implementation, assessment of social harms and linkage-to-care.

The programme has a multi-phased approach for the performance evaluation of potential devices:

- Phase 1: Usability Assessments of prospective HIV Self-Testing devices including Instruction for Use comprehension and result interpretation.
- Phase 2: Evaluation of prospective HIVST devices in the hands of Trained Users.
- Phase 3: Evaluation of prospective HIVST devices in the hands of untrained users from the general population.
Why WHO Pre-Qualification?

• South Africa does not have a Medical Devices Regulatory Authority, or evaluation framework

• Yogan Pillay DDG Health “NDOH will not allow HIV Self-Tests into Public Health which have not been approved by the WHO PQ process”
Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing
WHO PQ TSS April 2016

7.4.2.1 Part 2-a: Validation of label comprehension for finger stick and OMT job aid and IFU

Study objective
To validate the job aid and IFUs provided for self-testing in either fingerstick whole blood or OMT.

7.4.2.2 Part 2-b: Validation of result interpretation of results from pre-made Y1234-B/O cassettes

Study objective
The study will aimed to evaluate the ability of potential self-testers to interpret the results on non-functional devices pre-prepared with the following results:

7.4.2.3 Part 2-c Validation of device usability by observed self-testing in trained users

Study objective
To evaluate device performance (including collection materials, IFU and job aid, test result and result interpretation) in professional, trained testers conducting observed self-testing.

7.4.3 Part 3: Clinical performance evaluation – self testing

Study objective
The device is intended for self-testing by untrained individuals in resource limited settings. The design input documents require that the devices for OMT and for fingerstick blood, both must meet WHO performance validation criteria, in addition to meeting all the other input requirements.
### Part 3  Qualification of usability (self-testing)

**PURPOSE:** Assessment of product design, instructions for use and usability of RDTs for self-testing by analysis of the following:

- Results of questionnaire to assess whether key messages and instructions from packaging and labelling would be understood and easily followed by untrained intended users (i.e. self-testers).
- Results of interpretation of test-results by untrained users (i.e. self-testers) of simulated RDTs (e.g. pre-made and with contrived results).
- Test results and interpretations when assay is performed by untrained intended users (i.e. self-testers).

- For each of the studies summarized below the study group should comprise untrained subjects whose age, gender, level of education, literacy and additional, supplementary skills can challenge the usability of the IVD in intended users and in unfavourable operational settings (e.g. poor lighting).
- These assessment activities will determine the changes needed to optimize the IVD for use by self-testers. Changes may range from minor (simplification of instructions for use) to major. The impact of any change on safety and performance must be determined.
- Results from any one of the stages summarized below may indicate that assay redesign is necessary. This may in turn result in a need to revalidate the IVD or to perform additional specific performance studies and to update the risk analysis.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Testing requirements</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Qualification of usability (self-testing)</td>
<td></td>
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</tr>
</tbody>
</table>
| 3.1.1 Label comprehension study | Questionnaire-based testing of subjects, representative of end users, to assess ability of intended users to correctly comprehend key messages from packaging and labelling:  
  - Proper self-selection (whether or not users understand if it is appropriate for them to undertake testing).  
  - Understanding key warnings, limitations and/or restrictions.  
  - Proper test procedure.  
  - Test result interpretation.  
  Questionnaire to be administered to at least 200 subjects, representative of end users, in order to demonstrate comprehension of key messages. | 1. Instructions for use and labelling should be clear and easy to understand; use of pictorial instructional material is encouraged. |
| 3.1.2 Results interpretation study | A minimum of 400 subjects to interpret the results of contrived IVDs (e.g. static/pre-made tests) to assess their ability to correctly interpret pre-determined test results. Contrived tests should be made to | 1. The study group may include subject recruited as part of the label comprehension study. |

**References:**
- ISO 18113:2011 (16)
- ISO 15197:2013(en) (17)
- IEC 62366-1:2015 (18)
- MHRA (19)
- FDA (20); example of Summary of Safety and Effectiveness (21)
- EC CTS (2)
- European Directive 98/79/EC (22)
- FDA CLIA Waiver Requirements (23)
- WHO HIV testing
HIV Self-Testing RDT Evaluation

Non Clinical studies

LEVEL 1
Usability Assessment

LEVEL 2
Trained Use Assessment

LEVEL 3:
Intended Use Assessment

LEVEL 4
Expected Use Assessment

X
<table>
<thead>
<tr>
<th>Product performance</th>
<th>Implementation Res</th>
<th>Policy/Advocacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO PQ studies (Gates)</td>
<td>HSTAR004 (Aids Fonds)</td>
<td>WHO GDG</td>
</tr>
<tr>
<td>- HSTAR001</td>
<td>(n = 12000 – commence Q3 ’17)</td>
<td>SA TWG</td>
</tr>
<tr>
<td>• Orasure (n = 250)</td>
<td></td>
<td></td>
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<tr>
<td>• Biosure (n = 250)</td>
<td></td>
<td></td>
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<tr>
<td>• Calypte (n = 200)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Biolytical (n = 200)</td>
<td></td>
<td></td>
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<tr>
<td>• Atomo (n = 200)</td>
<td></td>
<td></td>
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<tr>
<td>HSTAR001A – to follow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- HSTAR003 (n = 900 pp)</td>
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<td></td>
</tr>
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</table>
**Product performance** | **Implementation Res** | **Policy/Advocacy**
--- | --- | ---
WHO PQ studies (Gates) | HSTAR004 (Aids Fonds) | WHO GDG
- HSTAR001 | (n = 12000 – commence Q3 ‘17) | SA TWG
  • Orasure (n = 250)  
  • Biosure (n = 250)  
  • Calypte (n = 200)  
  • Biolytical (n = 200)  
  • Atomo (n = 200)  
HSTAR001A – to follow
- HSTAR003 (n = 900 pp)
Product Pipeline
HSTAR 001 Objectives

The purpose of the Usability Assessment is to document if “lay” people, non-professional and inexperienced in HIV self-testing, can successfully perform the steps to use a HIV Self-Test device, without product familiarization.

- Gain data regarding the usability (IFU comprehension and contrived results interpretation) of the device including any error[s] that may occur including modes of error, critical and non-critical errors, in a simulated “private” setting.

- Stratified for Age, Gender, Education level

Primary Objectives are to document and record:

- Label comprehension (understanding of Instructions for Use, test limitations, test goal, inspection of test components)
- Usability / user interaction with the devices [effectiveness and efficiency] and accuracy of testing process
- Results interpretation (contrived results, no actual diagnosis will be made)
## EXAMPLE Section A: Test Performance

<table>
<thead>
<tr>
<th>Number of participants enrolled (n)</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the participant read/use the IFU?</td>
<td>YES 94%</td>
</tr>
<tr>
<td>2. Did the participant have difficulty removing the test tube from the test pack?</td>
<td>NO 82%</td>
</tr>
<tr>
<td>3. Did the participant the remove the buffer pot and stand in upright in slot?</td>
<td>YES 76%</td>
</tr>
<tr>
<td>4. Did the participant have difficulty lancing their finger?</td>
<td>NO 78%</td>
</tr>
<tr>
<td>5. Did the participant have difficulty forming a blood droplet?</td>
<td>NO 78%</td>
</tr>
<tr>
<td>6. Was the participant able to fill the tube with adequate amount of blood?</td>
<td>YES 78%</td>
</tr>
<tr>
<td>7. Was the participant able to push the test tube right to the bottom of the buffer pot?</td>
<td>YES 68%</td>
</tr>
<tr>
<td>8. Was a control line present?</td>
<td>YES 86%</td>
</tr>
<tr>
<td><strong>AVE</strong></td>
<td>80%</td>
</tr>
</tbody>
</table>

**BLUE: CRITICAL STEPS**

| AVE | 75% |
## Section B: Mock Result Interp

<table>
<thead>
<tr>
<th>Result Category</th>
<th>Correct Count / Total</th>
<th>Percentage</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>23 / 50 – 4/4 Correct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 / 50 – 3/4 Correct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>07 / 50 – 2/4 Correct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01 / 50 – 1/4 Correct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01 / 50 – 0/4 Correct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Result: NEGATIVE</strong></td>
<td>42 / 50</td>
<td>84%</td>
<td>5 read POS, 3 read INVALID</td>
</tr>
<tr>
<td><strong>Result: POSITIVE</strong></td>
<td>44 / 50</td>
<td>88%</td>
<td>3 read NEG, 2 INVALID, 1 did not know</td>
</tr>
<tr>
<td><strong>Result: FEINT POSITIVE</strong></td>
<td>31 / 50</td>
<td>62%</td>
<td>12 read NEG, 7 read INVALID</td>
</tr>
<tr>
<td><strong>Result: INVALID</strong></td>
<td>44 / 50</td>
<td>88%</td>
<td>3 read POS, 2 read NEG, 1 did not know</td>
</tr>
</tbody>
</table>
Recommendations and responses... eg.

a. **Issue: Buffer pot not been placed upright in the slot provided**

The majority of participants, after opening the packaging, do not open the IFU as one would a booklet, but rather as a leaflet. Figure 6 below demonstrates this.

![Figure 6: Opened as leaflet (left) vs. Opened as booklet (right)](image)

As a result, some participants are not locating the slot (red circle) as easily as they would if opened as a booklet (blue circle). Therefore, those participants not locating the slot are standing the buffer-pot on the table, or holding it in their hands. This is not critical; however it does allow the possibility of falling over, spillage and not pushing the tube in correctly.

We recommend that the arrows pointing to the slot be made bolder and more visible however...
HSTAR 001 Results

<table>
<thead>
<tr>
<th></th>
<th>Overall Usability</th>
<th>Critical Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orasure</td>
<td>91%</td>
<td>81%</td>
</tr>
<tr>
<td>Biosure</td>
<td>84%</td>
<td>81%</td>
</tr>
<tr>
<td>Calypte</td>
<td>93%</td>
<td>98%</td>
</tr>
<tr>
<td>Biolytical</td>
<td>97%</td>
<td>96%</td>
</tr>
<tr>
<td>Atomo</td>
<td>90%</td>
<td>85%</td>
</tr>
</tbody>
</table>

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**Graph**

The graph shows the performance of different kits (Orasure, Biosure, Calypte, Biolytical, Atomo) across various categories: Reactive/Pos, Non Reactive/Neg, Low Reactive, Invalid. Each kit is represented across different scenarios (FS1, FS2, FS3, OF1, OF2) with corresponding percentage values.
Other Notable UA in SA pops

Dong et al in KZN, showed 95% usability accuracy in a rural KZN population (35km out of PMB)

Deville et al demonstrated high usability, sensitivity (99%) and specificity (95%) in Moetse region in Groblersdal
Primary Objectives

- The primary objective of this study is to evaluate the ability of untrained users to obtain accurate HIV test results using the XXXXX Rapid HIV Self-Test when compared to professional users and ELISA.

Secondary Objectives

- To evaluate the untrained users’ interaction with the device in terms of effectiveness and efficiency, i.e. successful / unsuccessful completion and difficulty of the critical steps as per the Instructions for Use.
- To assess the ability of the untrained users to correctly comprehend key messaging from device packaging and labelling, including the Instructions for Use.
- Participants will be surveyed for user experience, and satisfaction with the overall process; in addition, users will be asked for comments and recommended improvements for test process.
HSTAR 003 Progress

- Commenced 22 March 2017
- Orasure OF HIVST
- 147 participants completed to date
- Important study for OR PQ submission
Visual Stability Study

• Embedded substudy of 003 where we are looking at the visual stability of the test line on the test kits are D1 – 7, wk 1 – 4, Mo 2 – 6.

• With Liverpool School Tropical Medicine
  • Duncombe, Watson, Taegetmayer
Where are we with HIVST in SA currently?

• Constraints/Barriers to Market Entry
• Target Product Profile
• Product Pipeline
• WHO Pre-Qualification
• Normative Guidance
• Regulatory pathways
• Clinical Research and Implementation Programmes
• SA TWG and Guidelines
Market Entry Barriers for HIVST in SA

<table>
<thead>
<tr>
<th>STRUCTURAL</th>
<th>STRATEGIC</th>
<th>STATUTORY</th>
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</thead>
<tbody>
<tr>
<td>Access to distribution channels</td>
<td>Excess Capacity</td>
<td>Current regulations</td>
</tr>
<tr>
<td>Advertising and Marketing</td>
<td>Experience advantages</td>
<td>SA Policy: Considerations</td>
</tr>
<tr>
<td>Brand Name</td>
<td>Market for product</td>
<td>SA Policy: Formulation</td>
</tr>
<tr>
<td>Capital/Resource requirements</td>
<td>Pricing strategies</td>
<td>SA Policy: Implementation</td>
</tr>
<tr>
<td>Cost of operating in foreign market</td>
<td>Product performance</td>
<td>Regulatory Framework</td>
</tr>
<tr>
<td>Cost of risk and Uncertainty of entry</td>
<td>Research and Development</td>
<td>WHO Pre-Qualification of Devices</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Technology change</td>
<td>WHO Normative Guidance</td>
</tr>
<tr>
<td>Economies of scale</td>
<td></td>
<td></td>
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<tr>
<td>Financial risk</td>
<td></td>
<td></td>
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<tr>
<td>Gaps and Asymmetry of Information</td>
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<tr>
<td>Government regulations</td>
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<tr>
<td>Regulatory processes</td>
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<tr>
<td>Sunk costs</td>
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</table>
Constraints/Barriers to Market Entry

• Barrier 1: Undefined Regulatory landscape†
• Barrier 2: High cost of risk and uncertainty†
• Barrier 3: Lack of demand for quality-assured HIVST translating into concrete purchase orders~
• Barrier 4: Price pressure form donors and governments~
• Barrier 5: Lack of incentives to innovate for further product development~
• Barrier 6: Lack of ownership of and investment in key market functions†~

† Majam (2016), ~ PSI (2016)
Barriers? What barriers?
South African Pharmacy Council ruling

(g) All clients require and deserve the full attention of the person interviewing them. Rushed appointments, abbreviated counselling sessions and inadequate record keeping in no way serves the best interest of the patient.

(h) Pharmacists must not sell HIV tests for patients to perform at home.

(i) It is preferable that the infected person should tell his/her partners and family themselves. A counsellor can be pre-

23 Dec 2016

MINIMUM STANDARD FOR THE SELLING OF HIV SCREENING TEST KITS

1. Purpose

In April 2010, South Africa launched an HIV Counselling and Testing (HCT) campaign that, among other things, sought to increase the number of people who test, know their HIV status and receive treatment. This is in line with the goals laid out in the country’s National Strategic Plan (NSP) for HIV, Sexually Transmitted Infections and Tuberculosis, which aims to significantly reduce the number of new infections and expand access to appropriate treatment, care and support to people diagnosed with HIV.

The minimum standard for the selling of HIV screening test kits aims to provide guidance on how the pertinent issues and concerns relating to HIV home testing should be addressed. These pertinent issues and concerns are the reliability of testing instrument, consent and counselling-related concerns.

2. General Considerations

Pharmacists must only sell HIV test kits for screening which have been approved by WHO or such suitable authority.

3. Pre-test Counselling

Buying a HIV home test kit is deemed to be consenting to testing. Individuals using the tests, however, may not have considered their options and the consequences of the result. Since the person will be performing the test him/herself, access to counselling shall be available to:

(i) prepare the person for the result of the test;
(ii) inform the patient that the self-test should not be taken as a conclusive diagnosis and
(iii) inform the patient that the diagnosis of HIV infection is dependent on a confirmatory test.
On the market
The difference...

**INSTI HIV SELF TEST INSTRUCTIONS**

**Questions?** 1-800-204-6784

**BOTTLE 1**

**BOTTLE 2**

**BOTTLE 3**

**TEST DEVICE POUCH**

**LANCET**

**PREPARATION**

1. Open test device pouch.
2. Place the test device down on a flat surface.
3. Remove cap of Bottle 1. Place on flat surface.

**STEP 1: COLLECT BLOOD**

1. Twist off tip. Throw away tip in waste bin.
2. Rub finger until warm.
3. Place lancet on the side of finger tip.
4. Rub finger to get larger round drop of blood.
5. Let 1 drop fall into Bottle 1.
6. Twist on cap of Bottle 1.

**INTERPRETATION OF RESULTS**

**Negative**

- The control line is visible in the Control (C) region.
- This result indicates that at present in the sample tested there are no HIV-1 and HIV-2 antibodies or that the concentration of HIV antibodies is below the detection limit of the test.
- A negative result at any time does not preclude the possibility of an HIV infection.

**Positive**

- Two colour lines are visible, one in the Control (C) region and one in the Test (T) region.
- The 1 line is a light color. This should be considered a possible positive result and should be followed up with a laboratory test.
- A positive test result indicates the presence of antibodies to HIV in the sample. Any positive results should be followed up with a laboratory test.

**Invalid**

- If there are no visible colour lines, the result is invalid.
- Proper procedures may not have been followed in performing the assay, or the kit may have deteriorated.
- The sample should be re-tested with a new test.

**WARNINGS**

- ALL POSITIVE TESTS MUST BE FOLLOWED UP BY A VISIT TO A HEALTHCARE PRACTITIONER FOR CONFIRMATION.
- TO BE USED IN CONJUNCTION WITH PRE AND POST COUNSELING KEEP OUT OF REACH OF CHILDREN.

- For OTC and professional in vitro diagnostic use only. Do not use after the expiration date. Do not eat, drink or smoke in the area where the specimen is handled. Do not share test if cover is damaged. Handle all specimens as if they are infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Humidity and temperature can adversely affect results.

**STORAGE INSTRUCTIONS**

- Store at room temperature or refrigerated (15°C - 30°C). Keep away from direct sunlight and moisture. Do not freeze the test.

**PRODUCED FOR**

- Cipla South Africa (Pty) Ltd
- 100 Searle and Pintoac Streets.
- Cape Town, 8001
- South Africa
- Tel: 021 4601626
HIVST Target Product Profile (PATH, 2014)

- Unlike HIV RDTs for professional-use, HIV RDTs for self-testing are often employed by lay users who must collect a whole-blood or oral fluid specimen, perform the test, and interpret the results, potentially with little to no assistance.

- This requires that products be designed for ease of use to achieve accuracy, to facilitate interpretation of results, and to support linkage to care.
TPP...cont

• High clinical and analytical sensitivity and specificity
• Low invalid and test failure rates
• Pictorial instructions for use with any text-based instruction translated into local languages
• Low number of test steps which could be achieved through integrated systems to deliver buffer or other such innovations
• Simple to interpret test results which require little instruction
• Reduction in time to result to 5 minutes or less (time from test performance to interpretation)
• Increased stability of test results
ST manufacturers have brought innovation to a stagnant industry

All in one test

Flow through technology
Results in seconds
On-going research into ST

• STAR Project
• Choko et al - Malawi
• Australia, Thailand, Brazil, Kenya programmes
• HSTAR programme (FDA studies, and WHO PQ)
HIV Self-Testing landscape...3

- Company initiated: Research and Development
- Good Candidate Products
- Research
- Research
- Synthesis of SA-based/specific evaluation
- South Africa-based Clinical Evaluation
- South Africa-based Social Evaluation
- WHO Normative Guidance on HIVST
- WHO Pre-Qualification for HIVST devices
- SA Government Policy on HIVST
- SAHPRA Regulatory Framework for IVD’s
- International Harmonization of Medical Devices Regulation
- Potential Market Entry Points

RISK AND UNCERTAINTY OF MARKET ENTRY

HIGH

LOW
South African ST data

- Ndlovu Health (Limpopo)
  - High usability, concordance, Sens and Spec in rural population
- HSTAR (Gauteng)
  - High usability in Oral Fluid and Finger stick products in Inner City Johannesburg
- iTEACH (Gauteng, Mpumalanga, KZN)
  - High concordance, but low LTC in Truck Drivers
- UCT (Western Cape)
  - High acceptability in MSM, and demonstrated utility of online platforms for sale and distribution
- Anova (North West)
  - High acceptability in MSM
Normative Guidance

SUPPLEMENT
GUIDELINES ON
HIV SELF-TESTING AND PARTNER NOTIFICATION
SUPPLEMENT TO CONSOLIDATED GUIDELINES ON HIV TESTING SERVICES
DECEMBER 2016
WHO Guidelines on HIVST

- **5 RCTs** directly comparing HIVST to HIV testing by a provider as of July 2016

- **25 studies** on HIV RDT for self-testing performance as of April 2016
  
  - **125 studies** on acceptability/feasibility (including user values preferences) as of July 2016
  
  - **4 studies** on cost/cost-effectiveness as of July 2016
**HIVST Doubled Uptake & Frequency**

Moderate quality evidence that HIVST doubled overall HIV testing uptake compared to standard HTS

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Risk Ratio</th>
<th>M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gichalgi 2016</td>
<td>3.08</td>
<td>[2.58, 3.69]</td>
</tr>
<tr>
<td>Thirumurthy 2016</td>
<td>1.77</td>
<td>[1.57, 2.00]</td>
</tr>
<tr>
<td>Wang 2016</td>
<td>1.77</td>
<td>[1.57, 2.00]</td>
</tr>
<tr>
<td></td>
<td>2.12</td>
<td>[1.51, 2.98]</td>
</tr>
</tbody>
</table>

**Low quality evidence that HIVST resulted in 2 more tests in a 12-15 month period compared to standard HTS**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Katz 2015</td>
<td>1.70</td>
<td>[0.94, 2.46]</td>
</tr>
<tr>
<td>Jamil 2016</td>
<td>2.30</td>
<td>[2.27, 2.33]</td>
</tr>
<tr>
<td></td>
<td>2.13</td>
<td>[1.59, 2.66]</td>
</tr>
</tbody>
</table>

Effect also shown for increase uptake of couples testing in Gichangni et al & Thirumurthy et al.

Jamil et al also showed HIVST increased the frequency of testing among non-recent testers compared to standard HTS.
No identifiable increased risk of social harm & adverse events

- Studies generally report **HIVST can be empowering**
- **Social harm due to HIVST was not identified in RCTs**
- Reports from other studies were limited and did not suggest HIVST increased risk of harm
- In Malawi, two-years of implementing HIVST found no suicides, no self-harm and no cases of IPV.
  - Reports of coercion identified were mostly among men who also reported that they would recommend HIVST
- In Kenya 4 cases of IPV identified - unclear if due to HIVST. *(41% of participants reported IPV 12 months prior to intervention).*
However, Social Harms remain a concern and will be continually assessed through current and ongoing research

- STAR Phase 1: Over 300,000 tests distributed through various modalities with no incidence of GBV, IPV or Suicide
- Malawi unobserved, unassisted study (n = 14,000), no reports of social harm
- Much of the concern regarding suicide after a positive HIV test comes from speculation and anecdotal reports on the Internet. These remain a concern but no evidence to support the link.
Summary of Values & Preferences

- HIVST is highly acceptable among many different groups and across different settings – but some concern about potential lack of counselling and support, accuracy of test results, and related costs

- Individuals surveyed about HIVST had concerns about possible harm, but most had not self-tested, and concerns were not founded in evidence – despite concern most still found HIVST acceptable

- Many users prefer oral HIVST (e.g. painless) – but many studies did not inform respondents about performance.
  - Some studies show when participants are informed they may actually prefer fingerprick/whole blood-based HIVST.

- Preferences across service delivery approaches vary
  - Key populations, in particular, reported preferences for pharmacies, the Internet, and over-the-counter approaches more appealing because they are more discreet and private
Results of HIV RDTs performed by self-tester were similar to those performed by trained health worker.

Measured using kappa statistic – 16 studies
Generally acceptable levels of sensitivity and specificity were achieved

Sensitivity
as high as 98.8% (95% CI 96.6 – 99.5%)

Specificity
as high as 100% (95% CI 99.9 – 100%)

n = 18 studies
Strong recommendation

**Recommendation**

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

[STRONG RECOMMENDATION, MODERATE QUALITY OF EVIDENCE.]

- **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.
South African Guidance Document

SA TWG:
SAHIVSOC
Wits RHI
NHLS
NICD
MRC
MSF
iTEACH
NDLOVU

... others

South African HIV Self-Testing Policy and Guidance Considerations

A supplement to the National HIV Testing Services Policy 2016
SA Specific Guidance

• Guidance for Implementation
• Guidance to Manufacturers
• Implementation Messaging
• Provision for access to information through various mechanisms in the absence of counselling
• Support systems
  • Websites
  • Apps
  • Helpline
  • Social Media
• Post Marketing Surveillance
HIV Self-Testing landscape...
HIV Self-Testing: A supplementary strategy towards achieving the first 90 in inner city Johannesburg

• This programme addresses the following two interlinked problems:
  • Inadequate HIV testing options, with poor linkage to care
  • Inadequate testing of men, transgender, discordant couples and other key and under-tested populations
  • Using innovative Health Communication Platforms
  • Opportunity to pilot in proposed STAR populations

Distribution of HIV Prevention Packages that include:
  HIV Self-test, Male and Female Condoms, Prevention pamphlets
So who are the under-tested and high risk pop that we want to target:

MEN AGYW

KEY POPS: FSW, MSM, IDU, TRANSG
What would a Distribution Model look like? Men

- Community Based
- Partner Delivery
- Peer referral
- Internet Based
- VMMC
- Sport Events
What would a Distribution Model look like? Adolescent Girls Young Women

AGYW

Community Based

Peer referral

Reproductive Health Centers

Internet Based

Vending Machines

Social clubs
## Where to Begin with HIV Self-Testing

### Know your epidemic & testing gap
- Couples & Partners
- Men
- Key populations
- Young people
- Other
  - At risk populations (SDC, partners of PLHIV, migrants etc.)

### Approaches
- Community-based (outreach, door-to-door)
- Facility-based (PITC, drop-in centres)
- VMMC programmes
- Workplace programmes
- Pharmacies & Kiosks
- Integrated in KP Programmes
- Internet & Apps
- Integrated in RHS & Contraceptive Services
- Vending machines
- Partner-delivered

### Considerations
- Benefits & Risks to Populations
- Support tools
- Linkage
- Increased access
- Increased coverage
Where to Begin with HIV Self-Testing

**Know your epidemic & testing gap**

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Where to Begin with HIV Self-Testing

Know your epidemic & testing gap

Approaches

Couples & Partners
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Men
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Key populations

Young people

Other
At risk populations
(SDC, partners of PLHIV, migrants etc.)

Considerations

Benefits & Risks to Populations
Support tools
Linkage
Increased access
Increased coverage
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- **Integrated in KP Programmes**
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- **Partner-delivered**

### Considerations
- Benefits & Risks to Populations
- Support tools
- Linkage
- Increased access
- Increased coverage
Policy and Advocacy

• South African Guidelines and TWG
  • Final Draft with WHO HIV Dept for review

• WHO TWG

• Engagement with Pharmacy Council and Pharmacy Groups

• TAC

• SANAC

• South African Stakeholder Symposium
WHAT STILL NEEDS TO BE DONE IN THE HIVST WORLD???
QUITE A BIT
HIVST PREP

Acceptability

Willingness to Pay

Usability

DIRECT ACTION

Link to Prevention

Link to Treatment

Triaged out of Health System

DIRECT IMPACT

Health for PLHIV: Reduced Morbidity & Mortality

Reduced HIV Transmission & Infections Averted

Cost and Time Savings (Health System & Users)

ADDITIONAL IMPACT

Social & Economic

Population Productivity & Growth

Social Benefit Social Harm

Health Systems

Efficiency

Expanded Coverage

Equity of Health

DIFFERENT POPULATIONS

DIFFERENT CONTEXTS

DIFFERENT GEOGRAPHIES

Evidence Available
To do list!

• Learn what distribution model works in which populations
• LINKAGE TO CARE!
• How do measure impact of HIVST on National numbers?
• Is this modality cost effective?
• Have we adequately addressed all the concerns of social harm?
STAR Phase 2

- Wits RHI, SFH, PSI and CHAI
- 2.2 million HIVST Kits over 3 years
- Test and research distribution models over the next three years to make both investment and operational implementation recommendations to NDOH
Finally

We don’t have all the answers yet, and we don’t profess a perfect science, but we are moving forward in a responsible and inclusive manner in the hopes of achieving a positive public health impact.
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