HIV Self-Screening Usability and Performance assessments in Johannesburg, South Africa

SA HIV Society Conference 2018: Are you getting the right HIV self-test result?

27 October 2018

Naleni Rhagnath
Progress toward 90-90-90 Targets

Gap to reaching first 90: 7.5 Million people

Achieved 90% Target

- Australia
- Belarus
- Denmark
- Ecuador
- Malaysia
- Sweden
- Thailand

Up from 66% in 2015

Global Status 2016

- Austria
- Botswana
- Cuba
- Fiji
- Germany
- Hungary
- Ireland
- Italy
- Lithuania
- Luxemburg
- Netherlands
- Nicaragua
- Rwanda
- Romania
- South Africa
- United Kingdom

Almost there! 85-89%

Who are the 30% undiagnosed PLHIV?
- Key populations
- Men
- Young people

UNAIDS Special analysis, 2017.

Slide courtesy: Bekker, IAS March 2018

www.iasociety.org
Innovation Needed to Close the Testing Gap
So we started talking about HIV Self-Screening

• 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.

• WHO: HIVST is defined a “screening test” or Test for Triage
Where do we work?

• Inner-City Johannesburg
• 2 Clinics used for the assessments:
  • Yeoville Research Center
  • Hillbrow (Wits RHI Research Center)
• High migrant populations (30 – 40%)
  • Economic migrants and job seekers
• Large student population
  • Adjoining University complex
  • Student residences
• High HIV Prevalence (+15%)
Wits RHI HSTAR Programme

• Kicked off in Dec 2015 with the aim of supporting independent data generation for HIV RDT Manufacturers looking to compile a dossier for HIV Self-Testing for submission to WHO PQ

• TSS updated to include requirements for HIVST in Dec 2016

• Part 3: Qualification of usability (self-testing)
  PURPOSE: Assessment of product design, instructions for use and usability of RDTs for self-testing
Protocols designed to follow the requirements of the TSS

Protocol 1: Usability Assessment

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

- Label comprehension
- Mock Result Interpretation
- Overall usability

NO demonstration provided prior to test use, and manufacturer provided information only (i.e. no additional job aids or IEC materials)

Protocol 2: Clinical Performance Evaluation

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.

- Additionally, assess test usability and successful completion rate
Unassisted test performance
6 products assessed under Usability protocol

Oral-based products:
- OraSure Technologies
- Calypte

Blood-based products:
- BioSURE HIV Self Test
- biolytical INSTI
- atomo diagnostics
- ChemBio
Wits RHI HIVST Evaluations to date

Pilot Usability Assessment (n = 50)

Protocol 1 Usability Study (n = 200)

Protocol 2 Clinical Performance (n = 900)

WHO PQ

Oral fluid

Whole blood

Whole blood

Whole blood

Whole blood

Oral fluid

Oral fluid

Oral fluid

Oral fluid

Cannot disclose

Awaiting update on manufacturing capacity

400 completed 11 Sept 2018

Still require LOW PREV data

Target of Nov 2018 for assessment

Target of March 2019 for assessment

[Image of OraSure Technologies]

[Image of BioSURE HIV Self Test]

[Image of atomo diagnostics ELION – Gen 2 Device]

[Image of bioLytical insti]

[Image of CHEMBIO]

[Image of CALYPT]

[Image of avacarehealth]
Participant process flow

Recruitment strategy:
- General population
- Equal gender representation
- Stratified by age group
- Must be able to read and comprehend the IFU
- Mix of English and Non-English first language
- Varying education levels
  - Primary school
  - Secondary school
  - Tertiary education

Recruitment (inclusion, exclusion criteria)
Informed consent administered
Biometrics and enrolment
Data collection (demographics, history)
Observer removes test and randomly presents mock devices
Observer scores success of each process step
Participant performs HIV Self-Test unassisted
Participant given HIV Self-Test package
Label comprehension is assessed
Participant conducts post-test interview
Participant is formally exited from study
Recommendations

• A significant amount of participants were attempting to pour out the buffer into the stand and were not confident enough to proceed after opening the tube.
Recommendations continues...

• Buffer pot not being placed upright in the slot provided

* This is not critical; however it does allow the possibility of falling over, spillage and not pushing the tube in correctly
Assessment scoring

• The successful completion of process steps was evaluated as a percentage of the overall process, with all critical errors identified which would probably lead to an invalid result.

• For Protocol 2, an additional measure of successful completion rate and clinical performance was added.

• Mock result interpretation was scored as the percentage of correct result interpretations when presented with a contrived result.

• Results of the questionnaire was to assess whether key messages and instructions from packaging and labelling would be understood and easily followed by untrained intended users.
Can untrained users correctly perform HIV self-tests?
## Results

<table>
<thead>
<tr>
<th>USABILITY (n = 900)</th>
<th>Usability Score (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST 1</td>
<td>96.5</td>
</tr>
<tr>
<td>ST 2</td>
<td>95.2</td>
</tr>
<tr>
<td>ST 3</td>
<td>96.7</td>
</tr>
<tr>
<td>ST 4 (n = 200)</td>
<td>98.5</td>
</tr>
<tr>
<td>ST 5</td>
<td>97.5</td>
</tr>
<tr>
<td>ST 6</td>
<td>99.1</td>
</tr>
</tbody>
</table>

*The successful completion of process steps was evaluated as a percentage of the overall process*
Findings

• Critical errors were noted when participants had difficulty obtaining and transferring the specimen

• For the FS devices, the most common sampling errors including:
  • lancing the thumb instead of finger,
  • not acquiring enough of a blood droplet, or
  • not filling the transfer capillary to the fill mark.
  • There were several cases where the lancet was not pressed firmly against the finger, resulting in a too-shallow cut. Notably, many of the “quits” were because of lancet misfire.

• For the OF devices, the most common sampling errors came from placing the sample collector in the mouth instead of moving/swiping, or inserting the wrong end of the collector.
Results...cont

<table>
<thead>
<tr>
<th>MOCK RESULT INTERPRETATION – Correct read</th>
<th>POSITIVE</th>
<th>NEGATIVE</th>
<th>LOW POSITIVE</th>
<th>INVALID</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST 1</td>
<td>91.0</td>
<td>96.0</td>
<td>49.5</td>
<td>93.0</td>
</tr>
<tr>
<td>ST 2</td>
<td>93.0</td>
<td>94.5</td>
<td>74.5</td>
<td>86.5</td>
</tr>
<tr>
<td>ST 3</td>
<td>99.0</td>
<td>99.5</td>
<td>94.0</td>
<td>97.0</td>
</tr>
<tr>
<td>ST 4</td>
<td>99.0</td>
<td>98.5</td>
<td>70.0</td>
<td>98.0</td>
</tr>
<tr>
<td>ST 5</td>
<td>94.0</td>
<td>96.0</td>
<td>63.0</td>
<td>83.0</td>
</tr>
<tr>
<td>ST 6</td>
<td>97.5</td>
<td>95.5</td>
<td>86.5</td>
<td>92.0</td>
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• Each participant was presented with each variant of the possible results in a random manner.

• Participants were asked to provide their interpretation

• The results above present the % of correct reads per mock device
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### Mock Result Interpretation – Correct read

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Findings – Mock result interpretation

• Overall, participants could correctly interpret the non-reactive/negative and reactive/positive results accurately for each of the devices.

• For the weak positive result, some devices were contrived darker and easier to read, others were quite faint – there was no universal standard for intensity of a weak positive. Most of the weak positive errors were called as non-reactive/negative.

• The invalid test result was called correctly in most cases, but for some participants this was a new and confusing concept, and several of the invalid tests were marked as “not sure.”
Results... cont

- Key labelling questions:

<table>
<thead>
<tr>
<th>What should you do if you have a non-reactive/negative result?</th>
<th>FS1</th>
<th>FS2</th>
<th>FS3</th>
<th>OF1</th>
<th>OF2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-test in 3 months</td>
<td>29.5%</td>
<td>81%</td>
<td>81%</td>
<td>51%</td>
<td>82.5%</td>
</tr>
<tr>
<td>Condomize</td>
<td>43.5%</td>
<td>13%</td>
<td>16%</td>
<td>22.5%</td>
<td>17.5%</td>
</tr>
<tr>
<td>Other (no answer, partner test, celebrate)</td>
<td>27%</td>
<td>6%</td>
<td>3%</td>
<td>27%</td>
<td>0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What should you do if you have a reactive/positive result?</th>
<th>FS1</th>
<th>FS2</th>
<th>FS3</th>
<th>OF1</th>
<th>OF2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit clinic/seek treatment/counselling</td>
<td>94.5%</td>
<td>99%</td>
<td>99.5%</td>
<td>94%</td>
<td>100%</td>
</tr>
<tr>
<td>Other (condomize, re-test, stress, acceptance)</td>
<td>5.5%</td>
<td>1%</td>
<td>0.5%</td>
<td>6%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Findings – Label Comprehension

• Most of the IFUs provided simple recommendations for test results with the pictured examples, such as “go to clinic” for a reactive/positive result, and “re-test in 3 months” for a non-reactive/negative result.

• Some IFUs did not include recommendations for the non-reactive/negative test result, and the corresponding study participants had a higher percentage of “other” responses, suggesting the value of a clear IFU recommendation in lieu of a detailed explanation about the window of seroconversion.

• In the “other” category, some participants provided an emotional response: celebrate if good news (negative test result), with stress or acceptance if bad news (positive test result).
Conclusions

• These assessments are a comparison of usability of HIV Self-Tests in the hands of untrained users and not a comparison of the overall clinical sensitivity and specificity.

• Overall, Usability within the study setting was high across all products with no significant difference between blood based and oral tests.

• Usability and successful completion drops off with age and younger age groups (18 – 35) fared better on the assessment. [97% vs 88%]

• There are differences in usability when English is reported as language of choice vs when it is not

• There is an element of community learning that is prevalent as knowledge of HIVST increases. Therefore some participants, although naïve to self-testing enter the programme with some pre-conceived notions
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