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

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HIV Self Testing Assessments & Research

HIV SELF-SCREENING
1,2,3.SCREEN.KNOW.ACT.

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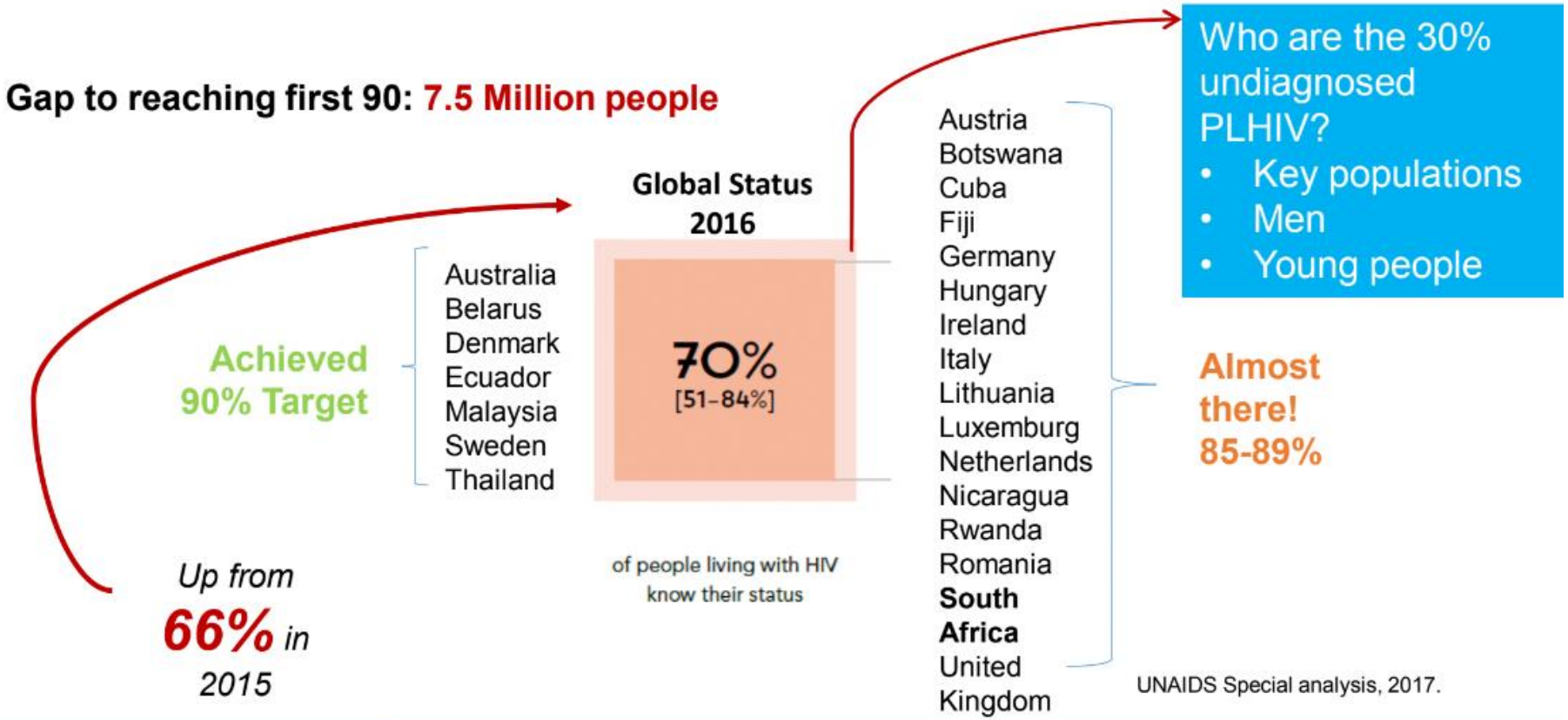
Progress toward 90-90-90 Targets



Slide courtesy: Bekker, IAS March 2018

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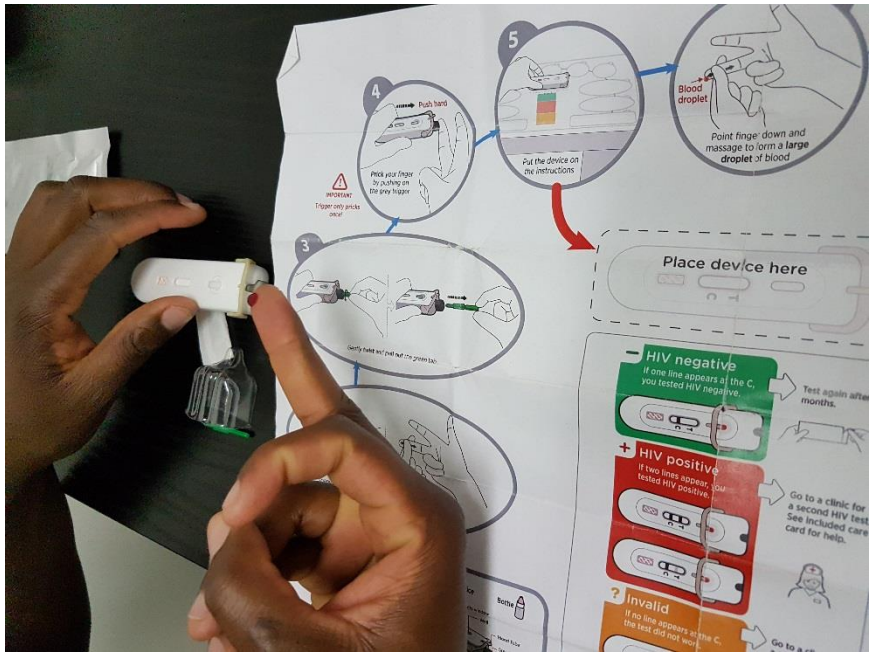
Innovation Needed to Close the Testing Gap

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%)

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Wits RHI HSTAR Programme

HIV Self Testing Assessments & Research

- 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

WHO PREQUALIFICATION TEAM: DIAGNOSTICS

World Health Organization

- TSS updated to include requirements for HIVST in Dec 2016

Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment

- Part 3: Qualification of usability (self-testing) PURPOSE: Assessment of product design, instructions for use and usability of RDTs for self-testing

TSS-1 **Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing**

BILL & MELINDA GATES foundation

Protocols designed to follow the requirements of the TSS

- 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.

WHO PREQUALIFICATION TEAM: DIAGNOSTICS

World Health Organization

Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment

TSS-1 **Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing**

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

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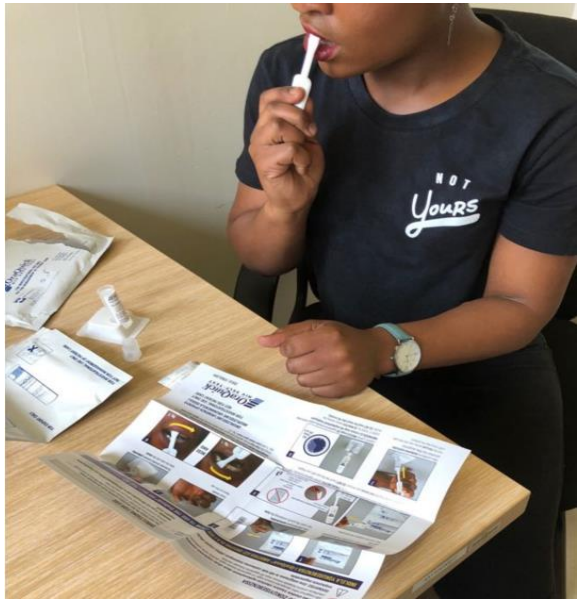
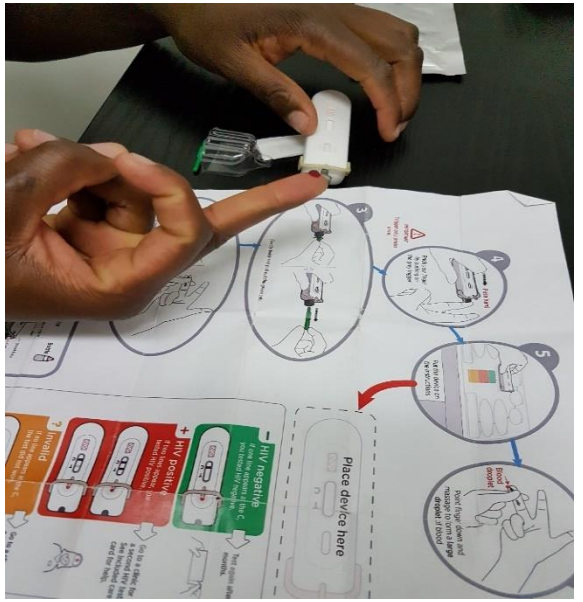
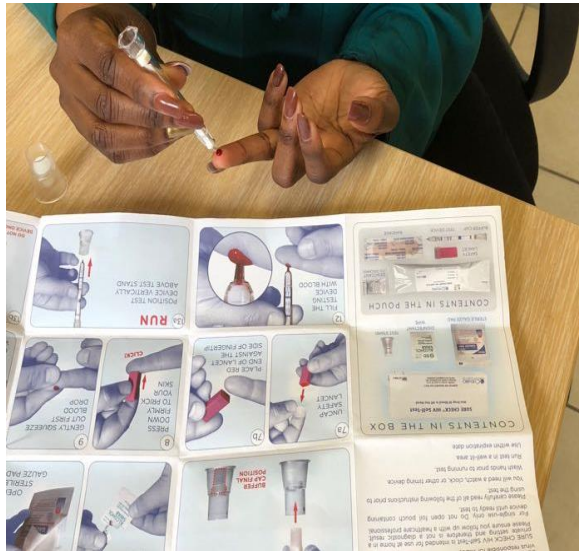
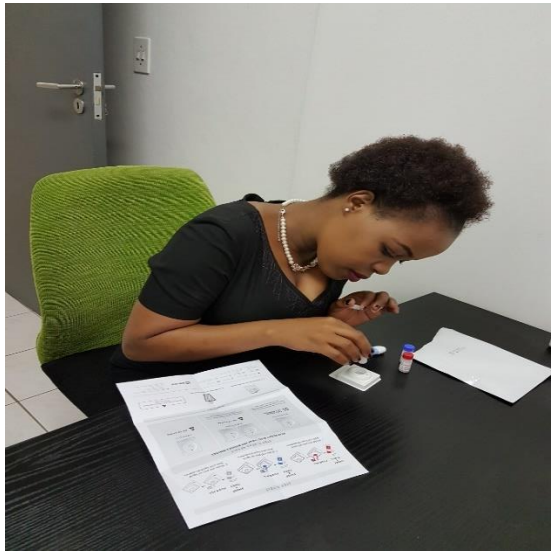




Unassisted test performance





6 products assessed under Usability protocol

OraSure Technologies

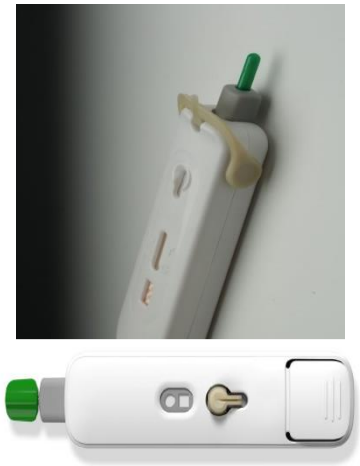
CALYPTE

Oral-based

BioSURE HIV Self Test

bioLytical INSTI

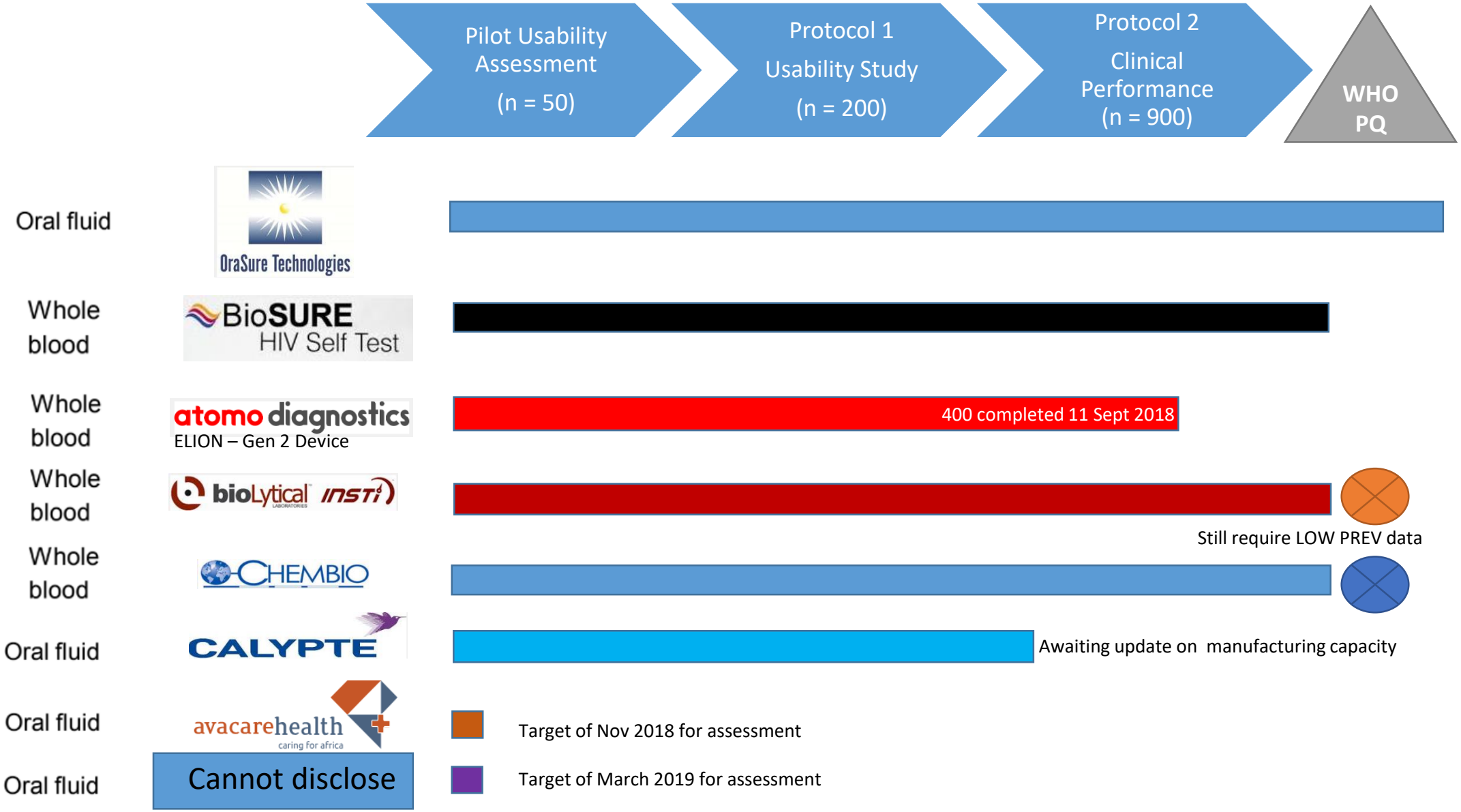
atomo diagnostics



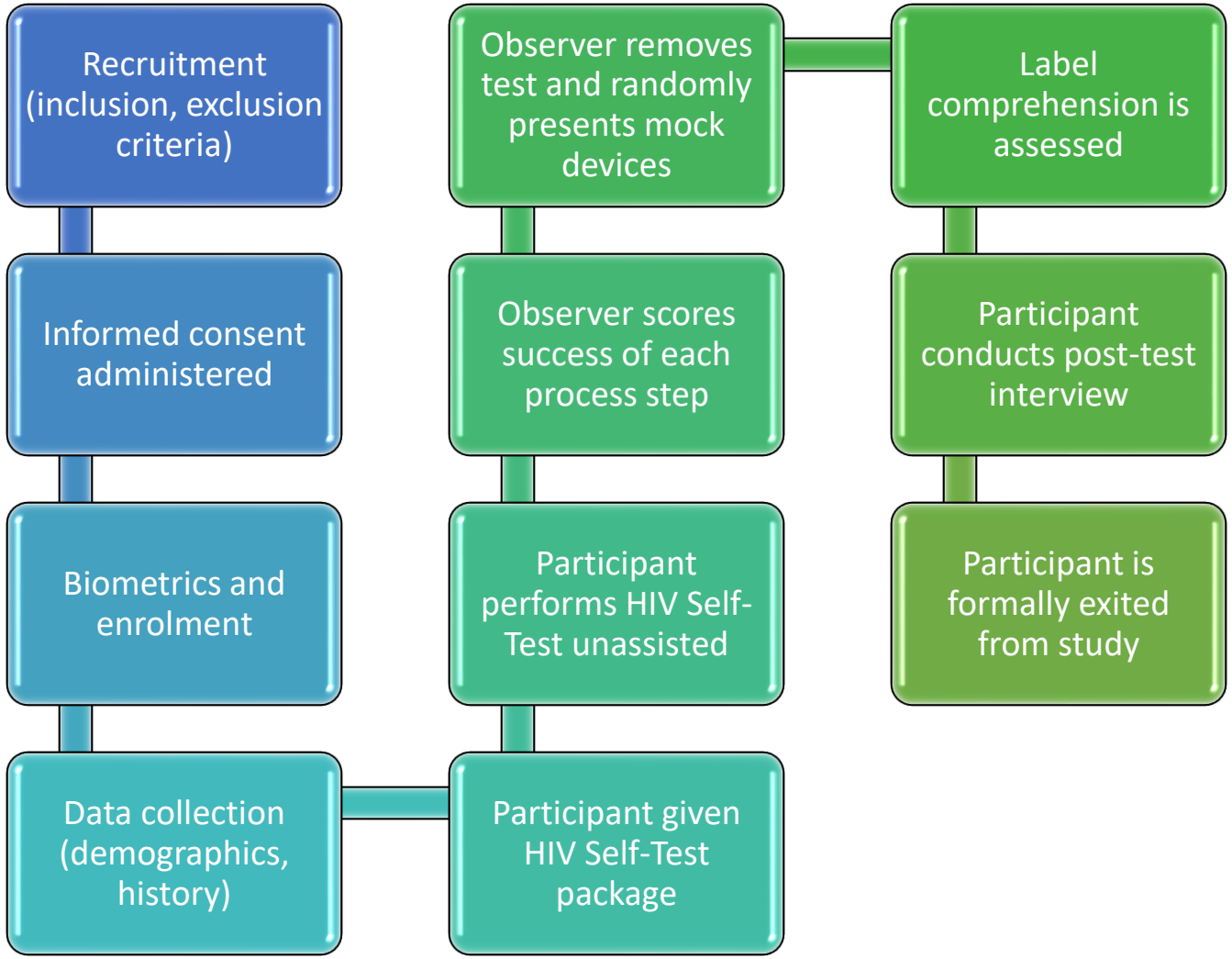
CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

Blood-based

Wits RHI HIVST Evaluations to date



Participant process flow



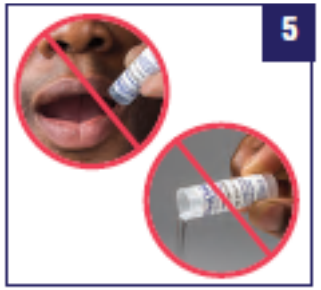
Recruitment strategy:

- 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

Recommendations

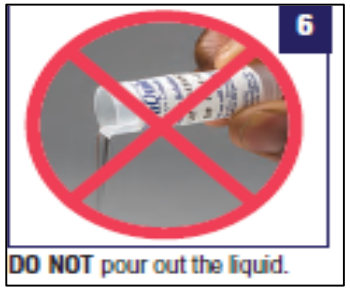
- A significant amount of participants were attempting to pour out the buffer into the stand and were not confident enough to proceed after opening the tube.

Before



DO NOT drink the liquid.
DO NOT pour out the liquid.

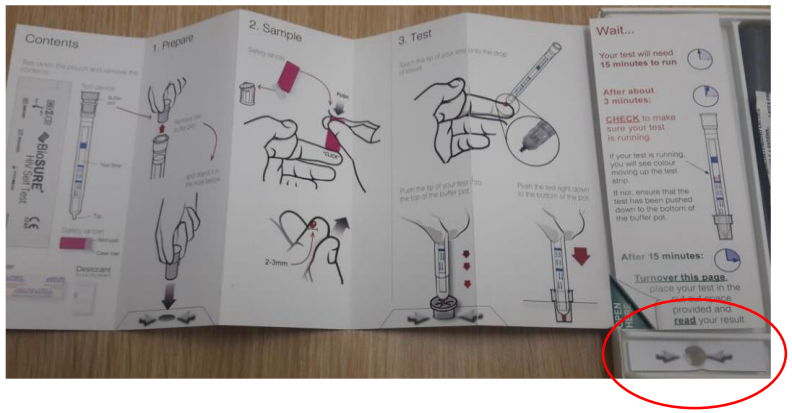
After

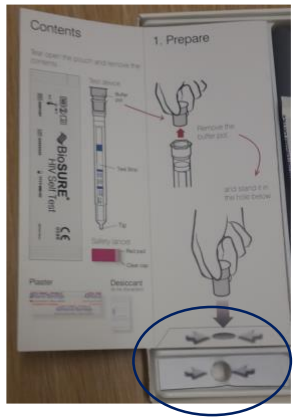


Recommendations continues…

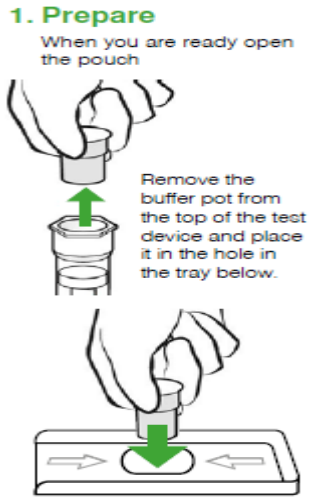
- Buffer pot not being placed upright in the slot provided

Before





After



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

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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?

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Results

USABILITY (n = 900)	Usability Score (%)*
ST 1	96.5
ST 2	95.2
ST 3	96.7
ST 4 (n = 200)	98.5
ST 5	97.5
ST 6	99.1

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

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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.

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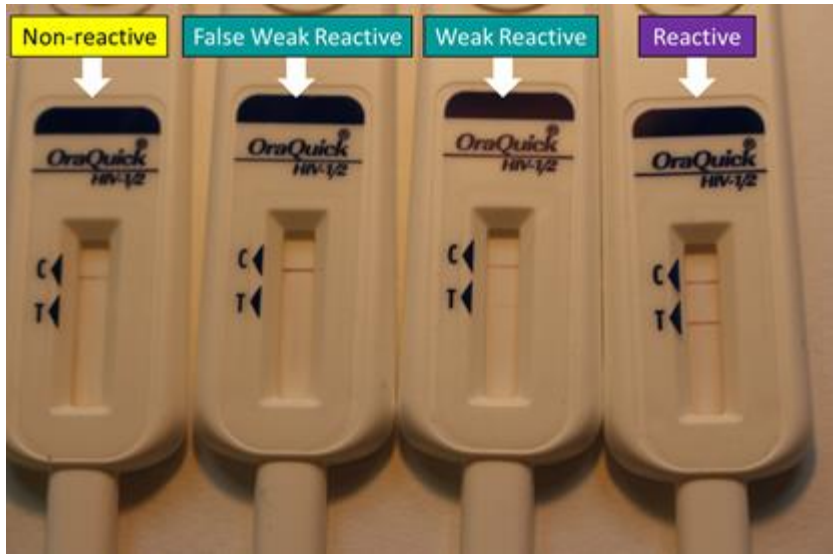
Results...cont

MOCK RESULT INTERPRETATION – Correct read	POSITIVE	NEGATIVE	LOW POSITIVE	INVALID
ST 1	91.0	96.0	49.5	93.0
ST 2	93.0	94.5	74.5	86.5
ST 3	99.0	99.5	94.0	97.0
ST 4	99.0	98.5	70.0	98.0
ST 5	94.0	96.0	63.0	83.0
ST 6	97.5	95.5	86.5	92.0

- 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



Results…cont

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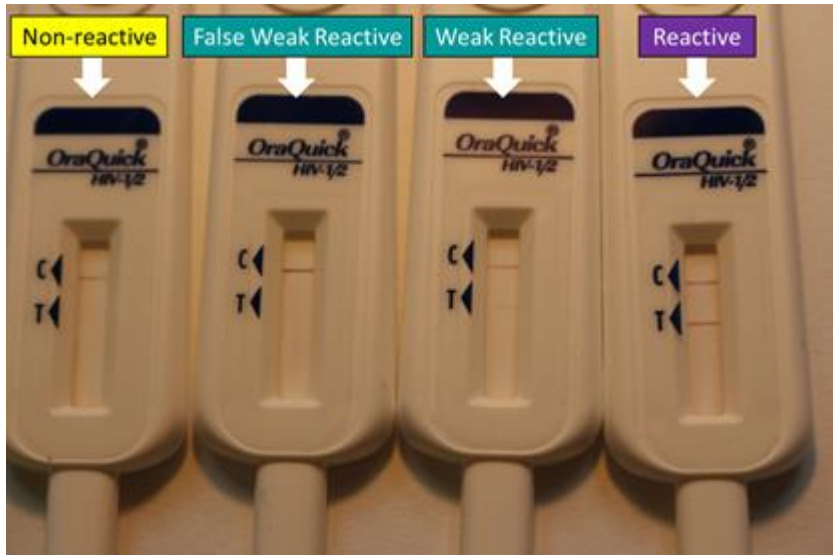

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Findings – Mock result interpretation

- 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:

	FS1	FS2	FS3	OF1	OF2
What should you do if you have a non-reactive/negative result?					
Re-test in 3 months	29.5%	81%	81%	51%	82.5%
Condomize	43.5%	13%	16%	22.5%	17.5%
Other (no answer, partner test, celebrate)	27%	6%	3%	27%	0%
What should you do if you have a reactive/positive result?					
Visit clinic/seek treatment/counselling	94.5%	99%	99.5%	94%	100%
Other (condomize, re-test, stress, acceptance)	5.5%	1%	0.5%	6%	0%

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).

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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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- WHO HIV and PQ teams
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