



UNITAID PSI HIV SELF-TESTING AFRICA



Optimising IFUs for the local context: Lessons learned from Zimbabwe

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Pilot study aimed at determining the acceptability and feasibility of HIV self-testing in Zimbabwe

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THE ACCEPTABILITY AND FEASIBILITY OF HIV SELF-TESTING IN ZIMBABWE

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PROTOCOL VERSION: VERSION 1.6

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STUDY PURPOSE AND BACKGROUND

Access to and demand for HIV testing and counselling (HTC) in Zimbabwe, as elsewhere in Africa, remains inadequate. Over 60% of people living with HIV in resource-poor countries do not know their HIV status.¹⁻³ Delay in diagnosis is a major contributor to high rates of early mortality in African HIV care programs.⁴⁻⁷

Data from Demographic and Health Surveys (DHS) in the general population in Africa show marked inequity in uptake of HIV testing, with males and other key sub-groups such as young people and the poor and/or less educated being least likely to have tested.⁸ Importantly, low uptake of HTC will also limit effective implementation of combination HIV prevention, including male circumcision, and treatment for prevention strategies. In Zimbabwe, provider-delivered HTC (PDHTC) is widely available, yet receiving an AIDS diagnosis within a year of first positive test ("late diagnosis")⁹ remains common, and there are significant demographic disparities in late diagnoses. DHS data from 2010/11 indicate that 39% of males versus 60% of females aged 15 to 49 had ever tested.¹⁰ In addition to males, Zimbabwe has a substantial proportion of other sub-groups (e.g., young people, less educated, those who have never tested) that remain reluctant to attend PDHTC services. Regular repeat testing, essential for those testing negative, is uncommon; 28% of adults, and only 20% of males, reported testing in the previous 12 months.¹⁰ Barriers to testing include concerns about stigma, fear of

Acceptability and Feasibility of HIV Self-testing

Version 1.6 30Mar15
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Study population

- Clients seeking HIV testing in Harare – New Africa House PSI New Start Centre
- Clients seeking testing at PSI outreach HTC sites in Shamva District
- Sex workers attending ‘Sisters Clinic’ in Harare



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Four study aims

- **Aim 1:** Develop instructional materials to support accurate self-testing
- **Aim 2:** Compare the offer of provider delivered testing (PDHTC) vs self-testing
 - % opting for self-testing
 - Rates of linkage to HIV Care and Male circumcision following ST
- **Aim 3:** Qualitative study to explore experiences among self-testers
- **Aim 4:** Similar investigations among sex workers

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Methods used for optimising accuracy



Methods:

- Recruitment by convenience sampling
- Cognitive interviewing

Followed by

- Videoed supervised self-testing

Cognitive interviews

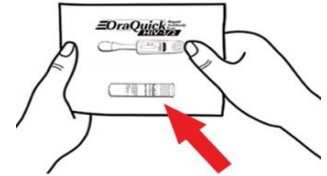
Cognitive interviews

- 8 done in Harare – reviewing first draft of instructions
- 6 in Shamva – reviewing major change of instructions



Insights from cognitive interviews

- Providing spatial instructions alone is inadequate
- Inadequate labelling can cause confusion
- Failure to locate some test kit items
- Unclear translations
- Pictures need to be adjacent to text explanations
- Different interpretations for some symbols



Supervised self-testing

- Conducted among 172 clients in Harare and 131 in Shamva between Aug 2014-Aug 2015
- 86.5% were videoed
- Selected videos were analysed using a checklist
 - All HIV positives
 - Invalid/unsure
 - Discordant with staff read
 - Random selection of HIV negatives



Results from supervised testing in Harare (n=172)

	Participant-read HIVST	Staff-read HIVST	Confirmatory test	
HIV negative	146	150 (146 + 3 unsure + 1 transcription error*)	156 (149 + 7 invalid HIVST)	<ul style="list-style-type: none"> 160/172 = 93% got an accurate HIVST result (in some cases despite failing to follow instructions, as per video recording) 2/172 = 1% got an inaccurate HIVST result* 10/172 = 6% unable to decipher their HIVST result. 7 (4%) of these had performed the test incorrectly, 3 (2%) could not interpret their result
HIV positive	16*	15	16	
HIV unsure	5	0	0	
HIV invalid	5	7	0	

*One was a participant transcription error – she was clear in her post-HIVST interview that she thought she was HIV negative. The second was someone on ART who tested negative via self-test and positive in confirmatory testing

Sensitivity/specificity (n=52)

Sensitivity

- Ignoring known HIV+ person on ART:
 $4/4 = 100\%$
- Including known HIV+ person on ART:
 $4/4+1 = 80\%$

Specificity

- Ignoring unsure/invalid:
 $45/45+1 = 97.8\%$
- Include unsure/invalid as false pos:10
 $48/48+4 = 92.3\%$

The first 29 participants in rural community

- Harare results not replicated
- Among the first 29 participants
 - 31% were unable to determine their results
 - 3% got inaccurate results






Insights from videos

- All participants read instructions
- Participants of lower literacy evidently struggled
- Participants with unsure/invalid/discordant tests typically did not follow instructions
 - Confusion with desiccant
 - Spills because of not using the stand
 - Dipping test device in developer before collecting sample
 - Incorrect sampling
 - Removing test device from developer early
 - Reading results early



Less good accuracy in rural community

- Attributed to lower literacy levels
- Instruction overhaul to make more pictorial and less wordy



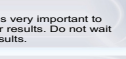
To prepare for the HIV test.

1. Your test kit contains two pouches. Open the bottom pouch which has a picture of the vial (the small bottle with developer solution) by tearing it open at the tear notch. Take out the vial. 
2. Open the lid of the vial by gently rocking the cap back and forth while pulling it off. Slide the open vial into the stand. 
3. Open the top pouch which has a picture of the test device by tearing it open at the tear notch. Take out the test device, taking care not to touch the flat pad. 

CAUTION:
DO NOT DIP the test device into the developer fluid at this stage
To collect the specimen

4. Using the FLAT PAD of the test device, gently swab completely around the outer gums, both upper and lower, one time around each.  

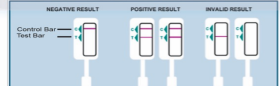
To run and read the test

5. Put the FLAT PAD all the way into the vial of fluid until it touches the bottom. Write down the time and LEAVE IT THERE. 
6. Leave the test to run for 20 minutes. Do not remove the flat pad whilst the test is running. 
7. After 20 minutes pull the test device out of the vial and read your result. 

IMPORTANT: For accurate results, it is very important to wait for 20 minutes before reading your results. Do not wait longer than 40 minutes to read your results.

Interpreting the results:
Two red lines is HIV POSITIVE.
(i) Even a very faint "T" line is positive
One red line maybe HIV- NEGATIVE or invalid
(i) Red "C" line with no "T" is HIV negative
(ii) Red "T" line with no "C" line is invalid
No red lines is invalid
(i) No "C" line and no "T" line is invalid

Continue onto back page...












HOW TO USE THE HIV SELF-TEST KIT

For questions call the following toll-free number: **08000118**



Do not eat or drink for 10 minutes before using the HIV self-test.



TEST TAKES 10 MINUTES - RESULTS READY IN 20 MINUTES



1. Your test kit contains two pouches. 
2. Tear open the pouch containing the vial. 
3. Remove the cap. 
4. Slide the vial into the stand. 
5. Tear open pouch containing the test device and remove. Do not touch the flat pad. 
6. The desiccant is not needed for the test - throw away. 
7. Using the FLAT PAD of the test device, swab completely around the upper and lower gums, one time around each. 
8. Put the FLAT PAD all the way into the vial until it touches the bottom. 
9. LEAVE IT THERE for 20 minutes before reading the results. (Do not read the results after 40 minutes.) 

Turn page over.

INTERPRETING RESULTS

HIV NEGATIVE
A red "C" line ONLY is HIV NEGATIVE.   Seek confirmatory testing in 3 months. Men may seek male circumcision services. Call toll-free **08000118** for more information.

HIV POSITIVE
A red "C" line and red "T" line is HIV POSITIVE. Even a very faint "T" line is positive.   As soon as possible...
or
Visit your nearest New Start Centre or health facility.

INVALID
No "C" line and no "T" line is INVALID.
No "C" line and a red "T" line is also INVALID.   The test did not work properly. Visit your nearest New Start Centre or health facility to test again, or call toll-free **08000118**.

Warning: If you are HIV-positive and on HIV treatment (ARTV) you may get a false negative result.

DISPOSE of test kit
Place the test device in the envelope provided along with the completed questionnaire and return the envelope to the following location:
Throw away remaining contents in the normal trash.

Rural community results after pictorial instructions (n=62)

	Participant -read HIVST	Staff-read HIVST	Confirmatory test	<ul style="list-style-type: none">56/62 = 90% got an accurate HIVST result4/62 = 6% got an inaccurate HIVST result*2/62 = (3%) were unable to decipher their result
HIV negative	55	55 (1 false negative)	59 (54 + 5 invalid HIVST)	
HIV positive	5	2	3	
HIV invalid	2	5	0	

* There was 1 false negative result due to incorrect testing procedures, and 3 false positive results due to incorrect results interpretation.

Sensitivity/specificity (n=62)

Sensitivity

$$2/2+1 = 67\%$$

Specificity

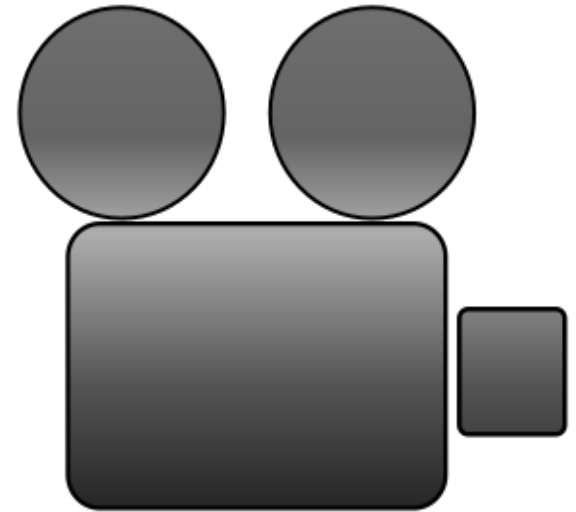
Ignoring unsure/invalid:
 $54/54+3 = 94.7\%$

Include unsure/invalid as false pos:

$$54/54+5 = 91.5\%$$

Less good accuracy in rural community

- Worry about false positive results
- Introduced video instructions
 - Consultation with stakeholders including Ministry of Health
- Feedback from participants indicated that video provides clearer instructions
 - Accuracy improved



Results after introduction of video

	Participant-read HIVST	Staff-read HIVST	Confirmatory test	
HIV negative	34	37 (34+1 false positive+ 2 unsure)	38 (37 + 1 invalid HIVST)	<ul style="list-style-type: none"> 36/40 = 90% got an accurate HIVST result 1/40 = 2.5% got an inaccurate HIVST result
HIV positive	3	2	2	
HIV unsure/invalid	3	1	0	<ul style="list-style-type: none"> 3/40 = 7.5% unable to decipher their HIVST result. 1 of these had invalid results despite following instructions correctly, 2 could not interpret their result.

Sensitivity/specificity (n=40)

Sensitivity

$2/2 = 100\%$

Specificity

Ignoring unsure/invalid:

$34/34+1 = 97.1\%$

Include unsure/invalid as false pos:

■ $34/34+4 = 89.5\%$

Accuracy among female sex workers n=40 – all used video instructions

	Particip ant-read HIVST	Staff-read HIVST	Confirmatory test	
HIV negative	30	31 (30+1 unsure)	31	<ul style="list-style-type: none"> 39/40 = 97.5% got an accurate HIVST result none got an inaccurate HIVST result
HIV positive	9	9	9	<ul style="list-style-type: none"> 1/40 = 2.5% unable to decipher their negative HIVST result.
HIV unsure/invalid	1	0	0	

Sensitivity/specificity (n=40)

Sensitivity

$$9/9 = 100\%$$

Specificity

- Ignoring unsure/invalid:
 $30/30 = 100\%$
- Include unsure/invalid as false pos:
 - $30/31 = 96.8\%$

Summary of lessons

- Need an iterative process to identify problem areas
 - Cognitive interviews
 - Determine accuracy through supervised testing
- It may be more efficient to start with individuals of lowest literacy
- Important to have IFUs which are largely pictorial, with little text
- Instructional video is helpful in improving understanding



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