Optimising instructions for use for an Oral-fluid HIV self-testing through cognitive interviewing in Malawi

"HIV SELF TESTING – GOING TO SCALE" STAR WORKSHOP: 29th March 2017

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Introduction

- HIV self-testing (HIVST) is a promising approach to HIV testing but the ability of laypersons to correctly comprehend instructions, follow the procedure and accurately interpret results is a key concern with HIVST [1].
  - Clients are required to translate abstract information contained in IFUs to concrete actions
- When guided by instructions for use (IFUs) alone, perceptual issues may arise during HIVST process since the design affect cognition and interpretation:
  - In 2007, 85% failed to perform all steps correctly in a blood-based HIVST in Singapore [2]
- Users require appropriate IFUs accompanying HIVST and IFUs with visual images enhance comprehension of the content [3]:
  - In KZN-RSA, a study reported that HIVST was easy to perform and accurate when IFUs were clear [4].
- Clear IFUs are vital in fostering accurate comprehension, correct performance and to minimize the occurrence of user errors [5].

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Objective

- The study to explored aptitude to comprehend and follow new IFUs in order to refine IFUs for HIVST.

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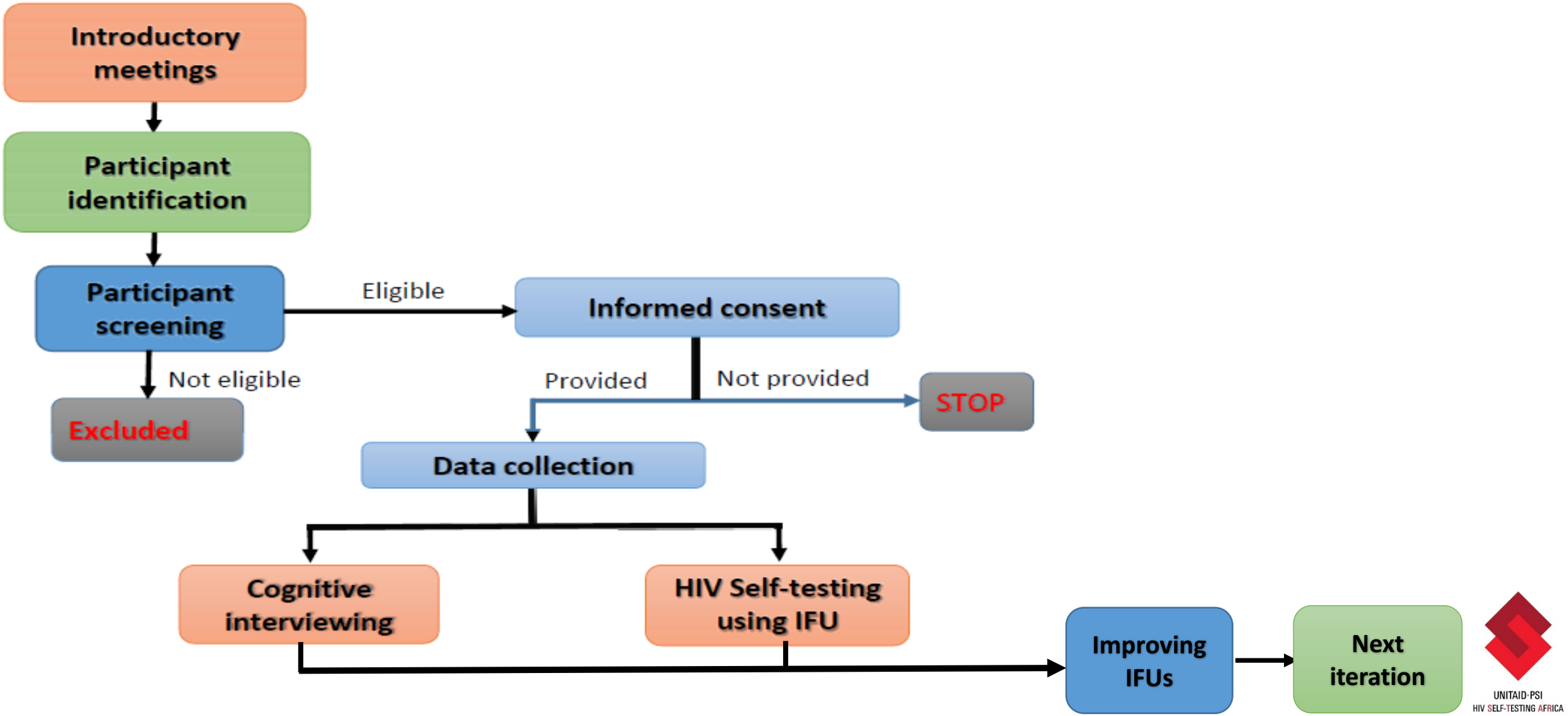
Methods [1]

- The study was part of qualitative formative research of the STAR project in Malawi.
- We recruited 34 clients through convenient sampling from four public health facilities:
  - 2 rural (Mpemba & Madziabango)
  - 2 urban (Limbe & Zingwangwa)
- Convenience sampling was used to identify and recruit clients from HTC clinics for the cognitive interviews:
  - 20 during the first iteration
  - 12 during the second iteration
- All participants were HIVST naïve and were included based on age, usual residence, informed consent and able to read.

Methods [2] – Iterative CI Schema



Results [1]

Iteration 1

8 out of the 20 participants failed to recognise the picture of cutlery.

Caution– Food and Mouth Wash

Iteration 2 – Not revised

1 out of 12 participants felt that the instruction needed more explanation.

"The wording is clear but the picture does not make sense. What does the utensils mean here?" [Male, 20 years, ZNG]

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Results [2]

Iteration 1

10 out of 20 participants did not recognise the warning sign and 2 found the word instruction difficult to understand.

"What happens when one takes medication or brushes their teeth?" [Male, 27 years, ZNG]

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

Iteration 2 – Not revised

4 out of 12 participants felt both the picture and word instruction difficult to understand and needed further explanation.

'One would still test and think that the test-kit has a fault [Male, 25 years, ZNG]'.

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Results [3]

Iteration 1

Iteration 2 - New

YOU WILL NEED A WAY TO TIME THE TEST

Need for a timing device: 6 out of 12 participants incorrectly interpreted this instruction.

DO NOT pour out the liquid

Inaccurate comprehension of instruction - avoiding pouring the liquid from the bottle.

The picture shows that the water from the bottle was spilling" [Female, 22 years, MPB].

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Results [4] – Placing the tube on the stand

Iteration 1

2 out of 20 clients did not understand the word instruction and 15 had difficulties to sliding the tube onto the stand, 2 placed the stand upside down, 2 did not know where to place the tube on the stand and spilled of the fluid.

"I don't understand that the bottle can be in an upright position and not fall, because the stand is tilted" [Male, 27 years, ZNG].

Field observations

Iteration 2 - Revised

Slide the tube into the stand.

11 out of 12 participants understood the instruction and pictures. Participants were able to identify the stand and we observed that performing this instruction was simple.

"Its easy, even though it's a bit hard. It only needs a gentle pressure." [Male, 32 years, MPB].

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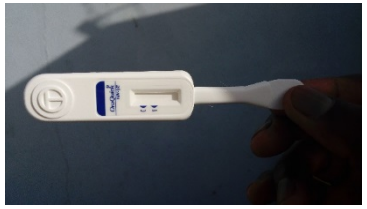
Results [5] – Opening the test device

Iteration 1

Tear open pouch containing the **test device** and remove. **Do not** touch the flat pad with your fingers

6 out of 20 participants had problems with this instruction i.e. Failed to understand the use of preservative, problems with opening the package, understanding of a flat pad and touching the flat pad. Participants found this instruction clustered with many things.

Touching the flat pad



Iteration 2 – Semi-revised

3 out of 12 participants found this instruction still difficult to comprehend because it had many things including 1) opening the pouch, 2) The preservative, 3) Parts of the device and 4) Part not to touch. **Revised** translations somehow improved cognition of this instruction.

"Both sides are flat pads. The instruction should read, Touch the side that is bigger and not on the smaller side" [Female, 44 years, MAB].

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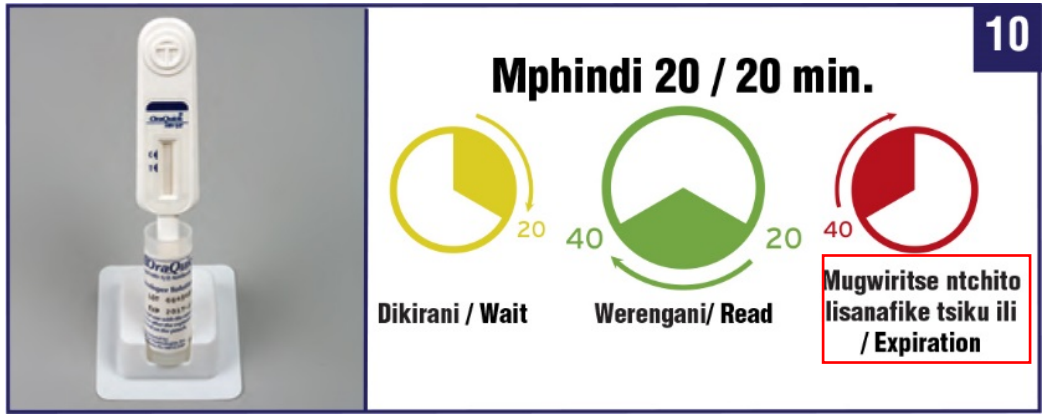
Results [6] – Timing the test

Iteration 1

LEAVE IT THERE for 20 minutes before reading the results. DO NOT read the result after 40 minutes.

7 out of the 20 participants did not understand this instruction because of its wording. Not clear why not to check the results before 20 minutes and after 40 minutes. 9 participants did not to know the time to read the results without having a watch.

Iteration 2 - Revised



Better than initial instruction but 3 out of 12 participants found colour coding difficult to understand and no explanation provided about implications of reading results before and after the recommended time.

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Results [6] – Interpretation of results

HIV POSITIVE RESULT

TWO LINES, even if the line is faint, means you may be HIV positive and you need to seek additional testing.

HIV NEGATIVE RESULT

ONE LINE next to the "C" and NO line next to the "T" your result is HIV NEGATIVE.

INVALID RESULT

No line next to the "C" (even when there is a line next to the "T"), or a red background makes it impossible to read the test, the test is not working and should be repeated.

- In both iterations, **all participants correctly interpreted their test results.**
- Participants had problem in linking the instruction and follow-up action.

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Conclusion

- Amended IFUs at second iteration performed better than initial IFUs at first iteration while instructions that were not improved had similar issues during subsequent iteration.
- Translation was one of the key problems that influenced understanding of the IFUs.
- Pictorial visualization supporting word instructions improved cognition of IFUs but additional supporting IEC materials and demonstrations may be desirable where literacy levels are low.
- New instructions or refined instruction required to be tested.
- Difficulty of universal versus contextually relevant symbols when developing IFUs.

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