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Is manufacturer's Instruction For Use sufficient in a multilingual and low literacy context? The example of HIV self-testing in West Africa

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BACKGROUND

The ATLAS project aims to promote the use of HIV self-testing (HIVST) in Côte d'Ivoire, Mali and Senegal. In order to ensure accurate HIVST use, it was necessary to evaluate if the manufacturer's Instruction For Use (IFU), standardized at the international level, provides complete, accessible and adapted information in the 3 countries' contexts.

MATERIALS & METHODS

In December 2018, cognitive interviews were conducted with 64 participants, mostly Men who have Sex with Men (40,6%) and Female Sex Workers (43,8%) in Côte d'Ivoire, Mali and Senegal.

Characteristics of participants in cognitive interviews

	Côte d'Ivoire	Mali	Sénégal	Total
Number of HIVST distribute	21	20	23	64
First-time testeur	0	3 (15%)	8 (34,8%)	11 (17,2%)
MSM/FSW/PwID/Young	5 / 12 / 0 / 4	11 / 9 / 0 / 0	10 / 7 / 6 / 0	26 / 28 / 6 / 4
Can read	19 (90%)	14 (70%)	7 (31%)	40 (62%)
Number of reactive test	1 (5%)	1 (5%)	3 (13%)	5 (8%)
Number of participants able to interpret their HIVST result correctly without assistance	21 (100%)	19 (95%)	18 (78%)	58 (91%)

Among them, 17,2 % never performed HIV test before and 38% of participants cannot read. They were invited to perform an oral HIVST (OraQuick®) and were requested, at each step of the procedure to share their understanding of the IFU

for HIVST use, of the result interpretation and of related actions to be taken. All participants had in hands the manufacturer's IFU in French, including the free national hotline number. Half of them additionally received manufacturer's demonstration video translated into local languages. Directive interviews guide included 50 questions to collect participants' perception of what was missing or unclear in the supporting tools. The methodology was validated with all national AIDS programmes and ministries of health

RESULTS

Out of 64 HIVST performed, 5 results were positive (7,8%) and confirmed with additional tests. Overall, the IFU was well understood: 58 participants (92%) were able to interpret their HIVST result correctly without assistance. However, some misuses were observed at various stages, particularly for people who cannot read, with some instructions misunderstood or perceived as not adapted. Only participants who can read have access to information as "do not eat" or "do not use the test if you are on ART" as it is not illustrated in the IFU. Most of the participants did not spontaneously identify the promotion of the free hotline number and/or the link to the demonstration video. Some procedure's steps were misinterpreted: 7 participants (11%) did not swab correctly the flat pad along the gum, 3 participants (5%) have read the result at inaccurate time (at 20 seconds, at 5 minutes or after 40 minutes), 13 participants (20%) did not put the stand (for the tube including the liquid) in the right way and 8 other participants struggled to slide tube into the stand. Among 42 participants who can not read and/or who had not seen the video beforehand, 14 of them (33%) had at least one difficulty to interpret the result or to understand what to do after the test/result. On the other hand, the results of the cognitive interviews showed that demonstration video provides a real added value to the user's understanding and accurate HIVST use (31 participants out of 32 found it very easy to understand with 9 of them who felt they do not need the IFU if they previously watched the demonstration video). The video translation into local languages, produced by the ATLAS project, was very much appreciated by the participants.

CONCLUSION

The manufacturer's IFU alone appear not to be sufficient in a multilingual, low-literacy context to ensure accurate HIVST use. Access to additional supporting tools (complementary leaflet, demonstration video or free hotline) is essential in the 3 countries contexts.

figure: manufacturer's IFU presenting the main difficulties encountered by the participants

Only people who can read have access to this information (do not eat, do not take the test if on ARV treatment).

7 people (11%) did not perform a rotational movement (fixed spatula on gum, arrows are not seen), not all of them having had access to the video beforehand.

Of the 42 people who could not read and/or had not previously seen the video, 14 (33%) had at least one difficulty interpreting a result and/or understanding a course of action.

The video asset is not correctly identified.

25 people (39%) do not identify it as a free phone line.

13 people (20%) did not put the support in the right direction and 8 others (13%) had some difficulty inserting the support when it was upright.

14 people (22%) understood the opposite message, i.e. that the liquid had to be poured.

3 people (5%) wanted to interpret the result at inopportune moments (after 20 seconds, after 5 minutes and after 40 minutes).

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