

# Providing user support for HIV self-testing beyond instructions-for-use in Malawi

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## Background

With imminent scale-up of HIV self-testing (HIVST), there is an increasing emphasis on the forms of direct or indirect assistance manufacturers and providers can offer to optimise accuracy of self-testing among low-literacy or rural populations.

## Objectives

1. To assess user understanding of packaged HIVST kits and instructions-for-use (IFU) and methods to optimise comprehension
2. To investigate feasibility, acceptability and accuracy of semi-supervised HIVST

## Methods

OraQuick ADVANCE<sup>®</sup> Rapid HIV-1/2 Antibody Test Kits packaged for HIVST were procured with IFUs in English and ChiChewa. We conducted two studies in Blantyre, Malawi from May to July 2016 under UNITAID/PSI Self-Testing Africa (STAR).

1. **Cognitive interviews (CI)** with literate adults, age  $\geq 16$  years, attending voluntary counselling and testing in rural and urban health facilities (n=20). Respondents were provided the HIVST kits **with no other assistance** and administered a topic guide.
2. **Cross-sectional feasibility study** with members, age  $\geq 16$  years, of randomly selected households and purposively selected peer groups from two rural villages (n=340). Respondents were offered self-testing, standard testing or no testing. **Self-testers received a demonstration** on kit content and usage. HIVST results were compared to a reference standard (2 parallel rapid blood-based tests by trained professionals).

## Results

### 1. Cognitive interviews

All participants completed the self-test and accurately interpreted their results, though there were difficulties affecting timeliness and confidence in validity.

Figure 1. Expected versus observed use of HIVST kits



Table 1. Errors reported from unassisted HIVST

Key findings	Example	Recommendation
<i>Some difficulties with the layout</i>	4 participants did not know where instructions began	Clear labelling of front and back pages
<i>Misinterpretation of universal symbols and illustrations</i>	8 participants did not recognise symbols for cutlery prohibiting eating	Review for familiarity in local context
<i>Organisation of packaging not clear</i>	7 participants did not know how to tear open the package	Ensure packaging includes clear guidance on contents and how to open
<i>Some difficulties understanding purpose and use of equipment</i>	15 participants struggled to slide tube into stand	Include clearer illustrations and purpose of each piece of equipment
<i>Challenges with result interpretation and next steps</i>	15 participants did not understand steps to take after self-test	Clear arrow linking results with next steps

## 2. Feasibility study

Following the CIs, we opted to include a brief explanation and demonstration without any further assistance. Feasibility study participants then self-tested and recorded their own result.

### High acceptability of offer of HIVST

- 85.6% self-tested, 3.8% tested through standard methods, 10.6% declined to test

### High agreement between semi-supervised self-read results and reference standard

Table 2. Cross tabulation of OraQuick and reference results

OraQuick self-test	Positive	Negative	Total
Positive	13	1	14
Negative	1	176	277
Total	14	277	291

### High percentage of participants reporting ease of use and satisfaction

- 99.3% reported the self-test being very or somewhat easy
- 100% would recommend to their friends

## Conclusion

- Literacy may not guarantee ability to follow IFUs in settings where commercial self-assembly products are rarely encountered.
- CIs provide a rapid and convenient way to alert implementers to additional support that may be required.
- Providing a demonstration of use made a substantial difference to the ability of participants to perform the self-test and interpret results, with acceptable accuracy.