

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

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**Background:** HIV self-testing (HIVST) devices provide a convenient option for home-based testing, but comprehension of standard manufacturer instructions-for-use can be highly variable.

**Methods:** Commercial OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kits packaged for HIVST were procured with pictorial IFUs accompanied by text in both English and ChiChewa. Ease-of-use was assessed through cognitive interview with literate adults (age  $\geq 16$  years) attending HIV testing services in rural and urban Blantyre. Participants were provided with the packaged kits containing IFUs but no other assistance. A standardised questionnaire and observation record was administered during self-testing. Feasibility was then evaluated in two rural villages, with 342 participants from randomly-selected households and community peer groups (age  $\geq 16$  years and not on antiretrovirals). Respondents were offered the options of self-testing, receiving standard HIV testing, or not testing and were administered baseline and exit questionnaires. Respondents opting to self-test received a brief demonstration on kit content and usage. HIVST results were compared to a reference standard (2 parallel rapid blood-based kits by a trained professional).

### Results:

Numerous problems occurred in 20 cognitive interviews, including difficulty in package opening and misinterpretation of translated phrases (“two pouches”; “test stand”) and imagery. Abstract symbolisation (e.g. knife and fork for eating; traffic crosses for ‘do not’) was poorly recognised. Although 18/20 completed HIVST, these difficulties greatly affected timeliness and confidence in validity. In contrast, all 291 feasibility participants (80.0% literate) who opted to self-test completed the test following standardised demonstration. Self-read results agreed with reference for 12/13 HIV-positive participants (sensitivity 92.9%, 95%CI 66.1%-99.8%) and 276/277 HIV-negative participants (specificity 99.60%, 95%CI 98%-100%). Uptake was high, with 85.1% of participants opting to self-test. Respondents also reported high levels of ease and satisfaction, with 100% recommending HIVST to friends and family.

### Conclusions:

In settings where commercially packaged self-assembly products are rarely encountered, literacy may not guarantee ability to follow HIVST IFUs unless accompanied by demonstration of use. Cognitive interviewing provides a rapid and convenient way to alert self-testing implementers of this need in their communities.