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TITLE: Introducing HIV self-testing to rural communities in Malawi: cognitive interviewing may alert implementers to the need for additional support beyond that provided by manufacturer's instructions-for-use (IFU)

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ABSTRACT BODY:

Background: Self-testing devices provide a convenient option for home testing, but comprehension of manufacturer's IFUs is likely to be highly variable.

Methods: Commercial OraQuick ADVANCE[®] Rapid HIV-1/2 Antibody Test Kits packaged for self-testing were procured with pictorial IFUs accompanied by text in both English and ChiChewa (Malawian language).

Ease-of-use was assessed by cognitive interview of literate adults (≥ 16 years) attending rural HIV testing services (HTS) in Blantyre. Participants were provided with 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 villages aiming for 250-300 participants from randomly-selected households and community peer groups (age ≥ 16 years, not taking antiretrovirals). Baseline and exit questionnaires were administered. HIVST followed brief demonstration of contents and kit usage. HIVST results were compared to a reference standard (3 rapid kits in parallel; trained professional).

Results: Numerous problems occurred in 20 cognitive interviews, including difficulty opening packaging, and misinterpretation of translated phrases ("two pouches"; "test stand") and imagery. Abstract symbolisation (e.g. knife/fork for eating; traffic signal "do not") was poorly recognised. Although 18/20 completed HIVST, these difficulties greatly affected timeliness and confidence in validity.

In contrast, all 281 feasibility participants (80.0% literate) completed HIVST following standardised demonstration. Self-read results agreed with reference for 11/12 HIV-positive participants (sensitivity 91.70%, 95%CI 61.5%-99.8%) and 268/269 HIV-negative participants (specificity 99.60%, 95%CI 97.9%-100%). 81.0% of randomly selected adults and all peer group members opted to self-test. Perceived ease and satisfaction were high, with 100% recommending HIVST to friends/family.

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