

## **HIV self-testing in Zambia: Intended user ability to follow the manufacturer's instructions for use.**

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**Background:** HIV self-testing (HIVST) is a new approach to increase testing uptake. Although evidence demonstrates that supervised users can accurately perform HIVST, the ability of unsupervised users to do so, using manufacturer's instruction for use (IFU) requires further investigation. The Clinical Performance study (CPS) within the PSI/ UNITAID STAR Project provided participants with the OraQuick® HIV rapid self-test (OFT) and IFU, and asked them to perform the test. In the pilot phase of the CPS (June 2016), participants were provided IFU only. Video recording showed low levels of comprehension and poor sensitivity and specificity were obtained. Hence, additional step-by-step demonstrations by health workers were provided before the participant initiated the HIVST. This study investigated intended user ability to understand and follow the IFU.

**Methods:** Cognitive interviews were conducted with 17 purposely selected adults and adolescents to assess understanding of the IFU. Video recordings of 17 participants conducting unsupervised HIVST (76.5% males, 88% rural) were analysed descriptively and scored using a predetermined standardised checklist.

**Results:** Cognitive interviewing revealed that participants struggled to open the test kit easily. The most difficult instructions to understand were those related to the collection of oral fluid by swabbing the gums. Adolescents were more likely to swab accurately and to rely on both images and written instruction compared to adults. Understanding and interpreting images and particular terms (pouch, press firmly e.g.) was perceived challenging.

Video analysis showed that only 8/17 participants read the IFU before the test, despite explicit instructions to do so. There was a significant association ( $p < 0.05$ ) between participants who read the instructions and their ability to correctly collect oral fluid sample. Only 4/17 participants were able to conduct all steps correctly. Women were 2.5 times more likely to perform all steps of the test correctly.

**Conclusion:** The OraQuick® HIV rapid test, though validated under ideal conditions, is shown to be challenging to use under real life conditions even after step-by-step demonstrations. Further improvements of pictorial/written IFU and the way the HIVST kits are designed is required to decrease user errors and to enable people to follow the IFU reliably.