

Title: Uptake and performance of blood-based self-testing versus oral fluid-based self-testing in Blantyre district, Malawi.

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Abstract (346)

Background: HIV self-testing (HIVST) can use either blood-based (BB) or oral fluid (OF) tests. Previous studies have shown strong preferences for self-testing compared to facility-based services. To date, HIVST has largely used OF self-tests, but with quality-assured BB kits now available, we investigated uptake and performance of OF and BB self-tests in Malawi.

Methods: Individuals (age ≥ 16) with unknown HIV status seeking HIV testing were enrolled from primary care facilities in Blantyre district. Participants were offered HIV testing through provider-delivered testing at a facility or HIVST using OF self-test (OraQuick HIV Self-Test) or BB self-test (INSTI HIV Self-Test). Those opting for HIVST received the kit of their choice and a brief pre-test demonstration (INSTI ~5-8 minutes, OraQuick ~2 mins). Following home HIVST, self-testers returned to report their result and receive confirmatory testing using the national testing algorithm (Determine HIV-1/2, Uni-Gold). Sensitivity and specificity was calculated using the national algorithm as the reference standard.

Results: 713 participants were enrolled in this study. Given the choice, 98.6% (703/713) participants selected HIVST over provider-delivered testing. Of 703 opting for HIVST, 278 (39.5%) chose INSTI, 425 (60.5%) chose OraQuick, and 97.4% returned to report their results. Preference for OraQuick among self-testers was more marked in rural (227/350, 64.9%) than urban (199/353, 56.4%) participants, $p=0.021$.

Among 275 reporting INSTI results, 12 (4.4%) were HIV-positive. INSTI had sensitivity of 100% (95%CI: 75.3-100%) and specificity of 99.6% (95%CI: 97.8-100%), with 15 (5.5%) invalid results. Among 410 reporting OraQuick results 13 (3.2%) were HIV-positive. OraQuick had

sensitivity of 100% (95%CI: 75.3-100%) and specificity of 100% (95%CI: 99.1-100%), with no invalid results.

HIVST sensitivity and specificity did not significantly differ by site, however invalids with INSTI (rural: 9/123, 7.3% vs urban: 6/154, 3.9%) were more common in rural participants.

Conclusion: Offering both BB and OF self-tests resulted in high uptake compared with provider-delivered testing. Both self-tests achieved a high degree of accuracy in the hands of rural and urban users provided with a pre-test demonstration before HIVST at home. More work is needed to reduce the rate of invalid results with BB self-tests.