TITLE

Can 'late-read' of self-test devices be used as a quality assurance measure? Results of a pilot HIV self-test project in Zimbabwe

PRESENTER

Yvonne Mavengere

AUTHORS

Y. Mavengere[1], E. Sibanda[1], K. Hatzold[2], F.M. Cowan[1,3], O. Mugurungi[4], S.N. Mavedzenge[5]

INSTITUTIONS

[1]Centre for Sexual Health and HIV/AIDS Research, Harare, Zimbabwe, [2]Population Services International, Harare, Zimbabwe, [3]University College London, Research Department of Infection and Population Health, London, United Kingdom, [4]Ministry of Health and Child Care, Harare, Zimbabwe, [5]RTI International, Women's Global Health Imperative, San Francisco, United States

Background: HIV self-testing (HIVST) may increase testing uptake. Critical to success is HIVST accuracy and quality assurance (QA). We evaluated the potential for "late-read" of self-test devices as a QA measure.

Methods: We conducted supervised self-testing of Oraquick rapid tests, where participants self-tested, and recorded their result, followed by confirmatory testing. Self-test devices were immediately read by study staff. Between 2-6 months after testing, we late read test devices and compared with real-time results to assess late-read validity. We subsequently conducted a HIVST observational study. 695 participants opting to self-test were asked to anonymously return their used test device along with a self-administered questionnaire (SAQ) reporting their test result to a drop-box in their community, and participated in a post-test telephone survey. Test devices were collected weekly, late read, and compared to self-reported results.

Results: 201 supervised self-tests were included in the late-read validation study. 9 (4%) tests had faded test lines at the time of late-read. Results are in Table 1.

	N	Sensitivity	Specificity	Agreement	Kappa statistic
All results	201	100% (80.5%, 100%)	96.6% (92.7%, 98.7%)	93.5%	73.9% (61.2%, 86.6%)
Faint positive dropped	192	100% (78.2%, 100%)	99.4% (96.8%, 100)	96.9%	84.7% (73.0%, 96.3%)

[Table 1: Real time versus late read of supervised self-test results]

In our observational study 541 (78%) self-testers returned their used test devices, 73% returned the SAQ with test result indicated, and 622 (89%) participated in the telephone survey. Late-read HIV prevalence was 13% versus reported HIV prevalence of 8%. 92% of HIV-ve per late-read were reported HIV-ve by SAQ. Accurate reporting of HIV+ve results were less good, with 71% agreement on SAQ, however, telephone survey results were significantly more likely to be HIV+ve than SAQ results (P< 0.01, data not shown).

Conclusions: Supervised self-testing results demonstrated excellent agreement between real-time and late-read, suggesting late-read is a valid QA measure. Observational study participants were largely willing to return used test devices and report their results, necessary steps for QA of HIVST accuracy. Significant differences in reporting HIV+ve results between telephone survey and SAQ plus qualitative data (not presented here) indicating reluctance to disclose HIV status, supports reporting bias. Late-read is a potential strategy for QA of HIVST accuracy, however, measures to address potential reporting bias of results should be considered.