Considerations on the accuracy and reliability of HIV self-testing: a literature review

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INTRODUCTION

HIV self-testing (HIVST) provides an opportunity for people to test themselves discreetly and conveniently, but it does not provide an HIV diagnosis. Several countries have already introduced or are considering the introduction of HIVST but there are questions as to how accurate rapid diagnostic tests (RDTs) adapted for self-testing will be, particularly in the hands of untrained users. This review compiles existing evidence and reports on the accuracy of HIV RDTs used for self-testing.

METHODOLOGY

• We systematically searched electronic databases (PubMed, PopLine, EMBASE and BHI/CA/EC/IAS/HPCP conference databases) to identify original studies reporting on the accuracy of HIV RDTs used for self-testing by intended users published between January 1995 to October 2015. References were manually searched and experts were contacted to identify other studies.

• Primary measurements of accuracy included: specificity, sensitivity, and concordance or agreement, in comparison with a reference standard testing strategy. Sensitivity and specificity were recalculated using number of true positive, false positive, false negative and true negative results, as reported by authors. We also extracted the reference standard testing strategy used and assessed its alignment with WHO recommended testing strategies.

• All extracted data was analyzed by type of specimen collection (oral fluid or fingerstick/whole blood), type of approach (supervised or unsupervised) and the HIV prevalence among study participants.

RESULTS

• We included 18 studies; 12 studies used oral fluid-based RDTs, five studies used fingerstick/whole blood-based RDTs and one used both. Most studies (12/18), excluding those among participants with a known HIV positive status (1/18), reported a high proportion of HIV-positivity among study participants (1.6-51%). 13 studies used sensitivity or specificity to measure accuracy; four studies used percentage of agreement and one study used a coefficient for concordance.

• We calculated sensitivity and specificity in 12 studies, it ranged from 68.7% to 98.8% and 94.7% to 100% respectively. 3 studies using fingerstick/whole blood-based RDTs had a better sensitivity compared to 9 studies using oral fluid-based RDTs (96.4%-98.6% vs 66.7%-97.9%), even when support was provided in 1/3 studies using fingerstick/whole blood-based RDTs and in 7/9 studies using oral fluid-based RDTs.

• QUADAS quality critique assessment showed majority of studies were at low risk of bias and applicability. No meta-analyses were performed because of heterogeneity in type of tests, type of approaches and type of reference test used.

• 10 studies reported user error; 1/10 used fingerstick, 8/10 used oral fluid and 1/10 used both. Common errors in test performance and conduct of test were the incorrect or incomplete swap of gums, and the inability or the misuse of the developer fluid: errors in performance were more frequent in the supervised studies.

• Of the 18 studies, 14 used confirmatory testing according to national algorithm, out of this, only five were aligned with WHO recommendations.

LIMITATIONS

• Heterogeneous study methodologies;

• Errors not affecting sensitivity or specificity, such as invalid test results, were not fully analyzed;

• Different reference standard testing strategies, settings and assays were used—few of which aligned with WHO recommendations;

• Few studies used finger-stick/whole blood-based RDTs;

• HIV prevalence could not be assessed in real-world setting, as some studies were among only HIV-positive participants who knew their status.

CONCLUSIONS

• Accuracy of HIV RDTs used for self-testing can be as high as 98.6% sensitivity and 100% specificity, but not always depending on RDT, population and setting.

• Inappropriate products, poor or no instructions for use can result in a poorer accuracy and a high level of user errors reported.

• Particular users, such as known HIV positives on ART and people with low literacy, might need more support and information when self-testing.

Fig. 1. Forest plots of recalculated sensitivity and specificity of HIV RDTs for self-testing

Fig. 2. Number of studies reporting errors in performance