

TITLE

Systematic review on HIV self-testing (HIVST) performance and accuracy of results

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Background: HIVST has potential to increase access to and uptake of HIV testing, particularly among key populations. Many countries have already or plan to introduce HIVST and WHO plans guidance for late-2016. There are, however, concerns about rapid diagnostic tests (RDTs) usability and accuracy when used for HIVST. We will summarize the evidence on HIVST accuracy to inform policy development.

Methods: We searched three databases and five HIV conferences abstracts (January 1995-November 2015) for studies assessing diagnostic accuracy and performance of RDTs used for HIVST. Review was restricted to reports with true/false-positive and true/false-negative, used to calculate sensitivity and specificity. We analyzed data by type of specimen collection (oral-fluid or whole-blood), type of support provided and HIV prevalence among study participants. Study results using the same RDT for HIVST were pooled.

Results: 15 studies were included. Study QUADAS methodological quality was variable and most studies (n=12/15) used oral-fluid RDTs. HIV prevalence was high (median:12.6%). HIVST sensitivity (range:65%-98.8%) and specificity (range:94.7%-100%) were high. Studies using blood RDTs reported higher sensitivity (96.4%-98.8%) compared to those using oral-fluid RDTs (65%-97.9%). Studies reporting low sensitivity were generally among people with known HIV status and/or using ART, and rural populations with lower literacy. Except for Kurth et al(15.1%), studies using blood RDTs (0.86%-5.71%) had a higher proportion of invalids, compared to studies using oral-fluid RDTs (0.06%-3.35%). Pooled estimates for studies using the same test were similar to manufacturer's indications.

Conclusions: Accuracy of RDTs used for HIVST can be high, independent of type of support. Blood RDTs used for HIVST report higher sensitivity, but lead to more invalid results compared with oral-fluid RDTs. Poor sensitivity is related with inappropriate products, poor or no instructions-for-use and the use by people with known HIV status and/or using ART. Policies and regulations should adapt national testing strategies and validate testing algorithms that include HIVST.