

# **ANNEX 1: Should trained lay providers perform HIV testing and counselling services using HIV rapid diagnostic tests? : A systematic review**

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## **1.1 Background**

HIV testing services (HTS) are the key entry point into HIV care and treatment services, as well as HIV prevention interventions and approaches. Rapid diagnostic tests (RDTs) now provide HIV results in minutes rather than days. However, in many settings, HTS is not universally available. Task-sharing – or the rational redistribution of tasks from higher-level cadres of health providers to lower-level cadres – might help to expand the availability of HTS services.

WHO has defined a lay health worker (LHW) as “a health worker who performs functions related to health care delivery and is trained in some way in the context of an intervention, but who has not received a formal professional or paraprofessional certificate or tertiary education degree. Other terms for lay health workers include ‘community health workers’ (CHWs) and ‘village health workers’ (VHWs). ‘Trained traditional birth attendants’ (tTBAs) are also regarded as lay health workers” (1). In this review we use the term “lay providers” but also provide the specific terms used in individual studies. We also further specify “trained lay providers” for the PICO question, as these providers have received some form of training in the context of an intervention, but not a formal professional or paraprofessional certificate or degree that is required for licensed and registered trained health professionals.

Lay providers have been used to conduct HTS in a wide range of settings across North America (2), Europe (3, 4), sub-Saharan Africa (5-12), and Asia (13). An analysis of national HIV testing policies across 48 countries showed that lay providers were permitted to perform RDTs in 40% of countries—over 60% in a sub-analysis of 25 policies in Africa—and even greater numbers of countries allowed lay providers to perform pre- and post-test counselling (60% across all countries and 80% in Africa) (14). However, a number of countries still limit these roles to trained health care providers due to concerns about the ability of lay providers to perform RDTs and administer HTS services.

This systematic review is designed to answer the question: Should trained lay providers perform HIV testing and counselling services using HIV rapid diagnostic tests?

## **1.2 Methods**

### **PICO question**

**PICO:** Should trained lay providers perform HIV testing and counselling using HIV rapid diagnostic tests (RDTs)?

**P:** People who receive HTS

**I:** HTS using HIV RDTs performed by trained lay providers

**C:** HTS using HIV RDTs performed by trained health professionals (e.g., nurses or doctors), or no intervention

**O:** Listed below

### **Primary Outcomes**

- (1) Measures of testing quality (quality assurance/quality control) (e.g., lost or damaged/uninterpretable specimens)
- (2) Accurate test results (sensitivity and specificity),
- (3) Adverse events (e.g., coercion, inter-partner violence, psycho-social, self-harm, stigma, discrimination),
- (4) Uptake of HTS

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## Secondary Outcomes

- (4) Rate of CD4 measurement (among all participants found to have HIV, percentage who reached this next stage of triage)
- (5) Linkage to medical visit after diagnosis
- (6) Initiation of ART (among participants eligible per national guidelines)

## Inclusion criteria

To be included in the review, a study had to meet the following criteria:

- Study design that compared people who received HTS using HIV RDTs performed by trained lay providers to people who received HTS performed by trained health professionals (e.g., nurses or doctors), or to no intervention.
- Measured one or more of the primary and secondary outcomes listed above.
- Published in a peer-reviewed journal prior to September 3, 2014.

No restrictions were placed based on location of the intervention. No language restrictions were used on the search.

## Search strategy

The following 10 electronic databases were searched through the search date of September 3, 2014: PubMed, Scopus, CINAHL, LILACS, WHO Global Health Libraries, Ovid Global Health, Sociological Abstracts, PsycINFO, EMBASE, and POPLINE. A set of search terms were adapted for entry into all computer databases, including terms for HIV, cadres of health providers, HIV testing, comparative study designs, and elimination of irrelevant terms. The full search strategy for one database (PubMed) is presented in Appendix 1.5.1.

Secondary reference searching was also conducted on all studies included in the review, as well as on the articles included in seven other related reviews identified through the search process, most focused on lay providers used in HIV care and treatment services (15-21). Finally, selected experts in the field – specifically, members of the WHO guideline development group – were contacted to identify additional articles not found through other search methods.

## Screening abstracts

Titles, abstracts, citation information, and descriptor terms of citations identified through the search strategy were screened independently by two reviewers. Full text articles were obtained for all selected abstracts and both reviewers independently assessed all full-text articles for eligibility to determine final study selection. Differences were resolved through discussion and consensus.

Articles not meeting the inclusion criteria for the review, but presenting potentially interesting or complementary background information – such as review articles – were included in an annotated bibliography.

## Data extraction and management

Data were extracted independently by two reviewers using standardized data extraction forms. Differences in data extraction were resolved through consensus and referral to a senior team member from WHO when necessary. Study authors were contacted when additional information or data were needed.

The following information was gathered from each included study:

- Study identification: Author(s); type of citation; year of publication
- Study description: Study objectives; location; population characteristics; description of the intervention; study design; sample size; follow-up periods and loss to follow-up
- Outcomes: Analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations

For randomized controlled trials, risk of bias was assessed using the Cochrane Collaboration's tool for assessing risk of bias (22). This tool assesses random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias) incomplete outcome data (attrition bias), and selective reporting (reporting bias). Methodological components of the studies were assessed and classified as being at high, low, or uncertain risk of bias.

### **Data analysis**

Data were analyzed according to coding categories and outcomes. If multiple studies reported the same outcome, meta-analysis would have been conducted using random-effects models to combine effect sizes with the programme Comprehensive Meta-Analysis (CMA). However due to the lack of combinable studies, meta-analysis was not possible. Data were summarized in GRADE tables, summary of finding tables, and risk/benefit tables, per the GRADE approach used by WHO.

### **Values and preferences review**

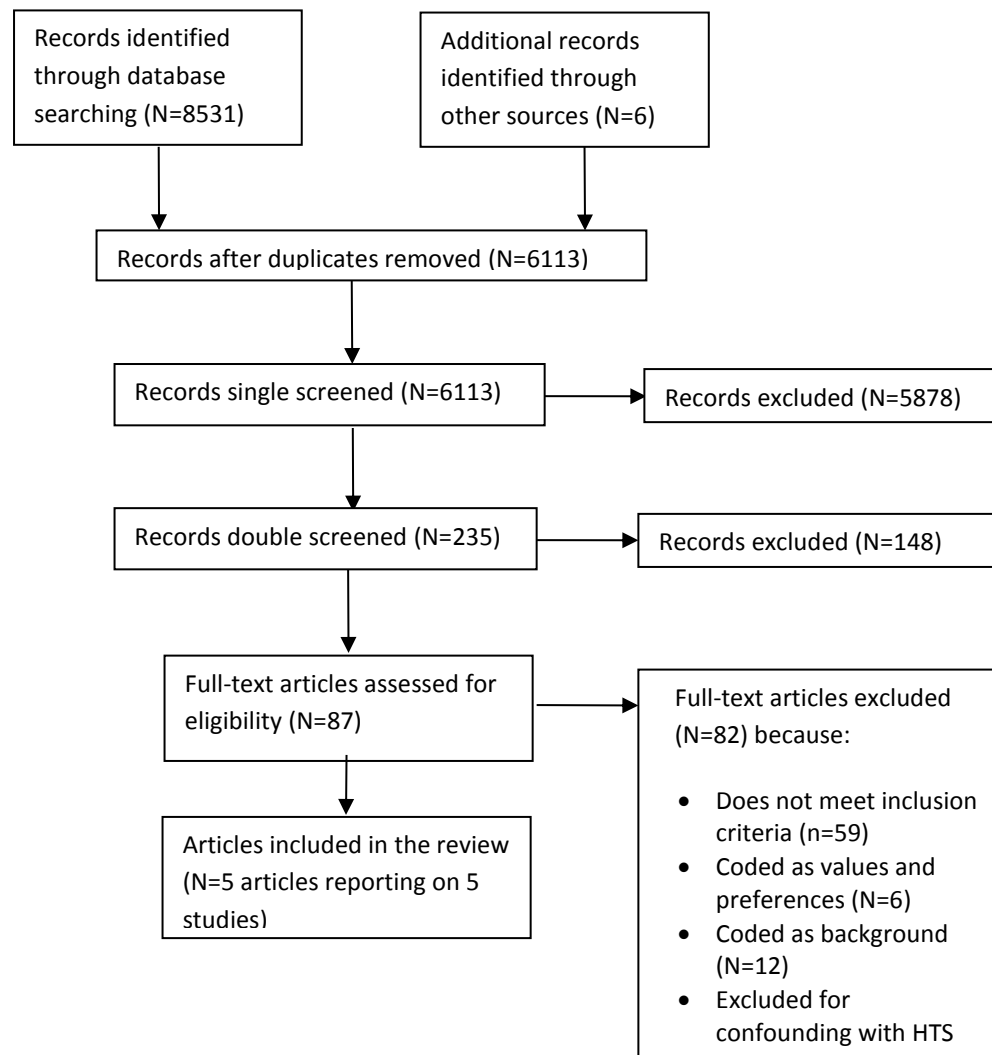
The same search was used to identify studies presenting information on end users' values and preferences related to the PICO. Studies were included in the values and preferences review if they presented primary data examining people's preferences regarding different cadres of health providers and HIV testing. These studies could be qualitative or quantitative in nature, but had to present primary data collection – opinion pieces and review articles were not included. Values and preferences literature were summarized qualitatively and are presented in a separate report.

## **1.3 Results**

### **Search results**

Initial database searching yielded 8531 citations; 6 additional studies were identified through other means, such as searching through the reference lists of relevant articles (Figure 1.1A). Once all duplicates were removed, 6113 unique records were reviewed. Of these, 5878 records were excluded in the initial screening and 148 additional records were excluded in the second phase of screening by two reviewers for not meeting the inclusion criteria. After thoroughly reviewing the remaining 87 articles, 59 were excluded for not meeting the inclusion criteria, 12 were coded as background, and 6 were coded as values and preferences. In the initial round of coding, four studies (reported in 5 articles) were included which were later dropped because the comparisons of lay providers with health care providers were confounded by comparisons of different HTS models or service delivery approaches. These studies examined either (1) home-based HTS using lay providers compared with clinic-based HTS using health workers (5, 6, 8), or (2) provider-initiated testing and counselling (PITC) using health workers compared with client-initiated HTS using lay providers (7, 23). Ultimately, 5 studies reported in 5 articles were deemed eligible for inclusion in the review.

**Figure 1.1A: Disposition of citations during the search and screening process**



### Study characteristics

The 5 studies included in the review were diverse in terms of country, setting, and study design. Two were conducted in Malawi, 1 was conducted in South Africa, 1 was conducted in the United States and 1 was conducted in Cambodia. Given the discrepancies in the study purposes, study designs, and comparisons made, we present results by the following categories: randomized trials, pre/post studies, and quality comparison between lay providers and laboratory staff.

### Study findings

#### 1. Randomized trials (1 study)

In Boston, USA, a randomized trial called the USHER study (Universal Screening for HIV Infection in the Emergency Room) compared two models of HTS provision in an emergency department setting: HTS by lay providers (trained HIV counselors) compared with HTS by regular emergency department healthcare providers (emergency service assistants) (2). In the lay provider arm, all activities were conducted by trained HIV counselors, from test consent to delivery of reactive or nonreactive test results and referral for confirmatory testing. In the healthcare provider arm, emergency service assistants (generally a 2-year college degree) offered and consented participants for HTS, collected the specimen, and developed the test in an on-site laboratory. Non-reactive results were shared with the client by resident

physicians or physician assistants, while clients were told of reactive results by attending physicians who also requested consent for confirmatory testing. All HTS was conducted with the OraQuick® ADVANCE HIV-1/2 (OraSure Technologies, Inc. Bethlehem, PA, USA) HIV rapid diagnostic test using oral fluid. Both lay providers and emergency service assistants received the same 1-day OraQuick® HTS training and successfully completed the accompanying competency test. Lay providers completed the Massachusetts Department of Public Health HIV counsellor certification process; while emergency service assistants also watched a 90 minute training video led by the trial's principal investigator (the training video was optional for other trained healthcare providers responsible for delivery of test results in the lay provider arm of the trial). In the Cochrane risk of bias assessment, this study received a low or uncertain risk of bias across all measures except blinding of participants and personnel; participants, counsellors, and providers were not masked to the assigned study arms (as this would be difficult/impossible given the nature of the comparison), but neither were they incentivized in any way to complete the testing process.

Uptake of HTS among emergency department patients was 57% (1,382/2,446) in the lay provider arm compared with 27% in the healthcare provider arm (643/2,409;  $p < .001$ ). Uptake of HTS was the only PICO outcome measured in this trial.

## **2. Pre/post studies (1 study)**

One study examined HIV testing uptake before and after the use of lay providers for HTS (11). This study was conducted in Thyolo, a rural district of Malawi, and employed a number of different programmatic efforts to enable rapid scale-up of HIV care and treatment services, including task sharing to increase the number of health workers engaged in HIV care, as well as decentralization of care to health centers and community sites, simplification of protocols for testing and treatment; community engagement to increase capacity and support programme sustainability; and health system strengthening. HTS was delegated to health surveillance assistant (HSA) counsellors, who received a 10-week basic training to become HSAs and then an additional 3 weeks of training on HTS to become HTS counselors. Further details on the type of HIV testing were not provided.

After delegating HTS to lay providers (the HSAs in this model), uptake of testing increased from 1300 tests per month in 2003 to 6500 tests per month in 2009. This was the result of an increase from 14 HTS sites at the end of 2003 (with an average of 93 tests per month performed at each site) to 39 sites at the end of 2009 (with an average of 167 tests per site per month). While the study also reported numbers of patients initiated on ART, the additional changes in the health system described above seriously limited the ability to link these outcome changes with the changes in cadres providing HTS.

## **3. Quality comparison between lay providers and laboratory staff (3 studies)**

Three studies conducted quality comparisons between lay providers and laboratory staff.

In Sisonke District, South Africa, the Good Start cluster randomized trial evaluated an integrated, scalable package delivered by community health workers to improve infant feeding and HIV-free infant survival (9). As part of the intervention arm of this trial, home-based HTS was conducted by lay providers. These lay providers completed a 10-day nationally accredited course in HTS, during which they learned how to conduct both of the rapid HIV tests used in the district protocol. They spent a further three months shadowing facility lay counsellors and gaining nurse-supervised testing experience at local health facilities. Additionally, they received one-day training on obtaining and packaging dried blood spot (DBS) samples from laboratory technicians. Testing was conducted using HIV rapid diagnostic tests (SD Bionline (Standard Diagnostics Inc., Kyonggi-do, South Korea) with confirmatory SENSAs (Sensa Tri-line HIV 1/2/0; Hitech Healthcare Ltd, Beijing, China)) on finger prick blood samples. Additional dried blood spot samples from the same finger prick were also taken, and a sample of HIV-negative results (62.5%) and all HIV-positive, indeterminate and discordant-couple results were also sent for laboratory-based enzyme-linked immunosorbent assay (ELISA) testing. Study authors provided further details on the selection of samples sent for laboratory testing. All HIV positive and indeterminate samples were sent for laboratory testing. During the first few months of the study, all HIV-negative samples were sent for laboratory testing, and thereafter a systematic sample of HIV-negative specimens was sent for

laboratory testing. Of 3986 matched samples, lay provider and laboratory results of HTS were concordant in all but 23 cases. Of these, further examination revealed only 2 cases that could be considered “critical errors” where the lay provider found a HIV positive result and the laboratory had a negative result; the rest were cases where at least one result was indeterminate, and most of these were considered cases of the lay provider being extra cautious. Overall, sensitivity was calculated as 98.0% (95% CI: 96.3- 98.9%) and specificity as 99.6% (95% CI: 99.4-99.7%).

In rural Karonga District, Malawi, the Karonga Prevention Study (KPhS) examined the quality of home-based rapid testing on venous whole-blood samples taken by lay providers (10). These lay providers were trained and certified by Ministry of Health staff to perform HIV counselling, whole-blood rapid testing and specimen collection by finger prick, using standard training procedures. HIV testing was conducted using an algorithm of Determine™ HIV-1/2 (Abbott Japan Co Ltd, Tokyo, Japan) with Uni-Gold™ HIV (Trinity Biotech PLC, Bray, Ireland) as the first and second rapid tests, respectively. If the test results were discordant SD Bioline HIV 1/2 3.0 (Standard Diagnostics Inc, Kyonggi-do, Korea) was used as a “tie-breaker”. Of 10819 samples, 2911 were sent to for laboratory quality control or confirmation based on quality control procedures of retesting all positive and every tenth negative specimen. Of these, lay provider and laboratory results were concordant in all but 4 cases, 3 of which were considered most likely the result of “sample peculiarities”. Results showed a sensitivity of 99.6% and specificity of 100.0%.

In Cambodia, a study compared results of rapid HIV testing by lay providers working in a prevention of mother-to-child transmission (PMTCT) site with results from laboratory technicians (13). Lay providers were trained HTS counsellors, who were midwives without any laboratory or phlebotomy experience. They received a half-day training on HTS and how to use Determine™ HIV1/2 (Abbott Japan Co Ltd, Tokyo, Japan) test kits using finger stick whole blood samples. Laboratory technicians routinely did the same test and returned the report of test results to lay providers. A total of 563 samples were tested by both lay providers and laboratory technicians; study authors confirmed that these were all blood samples from pregnant women who wanted to be tested for HIV during the study period. Of these 563 samples, lay provider and laboratory results of HTS were concordant in all but 4 cases. For these 4 cases, the authors report that, “Further investigation confirmed that all the reports by the counsellors were correct, and that human error in writing reports in the laboratory was a cause of these discordant reports” (13).

### Values and preferences

The comprehensive search of the literature identified 6 studies reporting on values and preferences related to lay providers conducting HTS. Of these, four were conducted in sub-Saharan Africa (1 each in Botswana (12), Malawi (24), Zambia (25), Zimbabwe (26)), while two were conducted in the United States (27, 28).

In the United States, two studies were conducted in the context of HTS screening in emergency departments at major urban hospitals. The one randomized controlled trial in the main systematic review of the evidence – the USHER trial from the United States (2) – also published related results from a survey of patient satisfaction with HTS provided through the trial (27). Of 2,025 HTS clients, 1,616 (79.8%) completed the satisfaction survey and most (91.5%) reported being very satisfied with their HTS experience on a 4-point Likert scale. While overall satisfaction was high, results suggested slightly higher satisfaction with lay providers compared with healthcare providers. In multivariate analyses, patients in the healthcare provider arm were more likely to be less than “very satisfied” compared with those in the lay provider (counselor) arm (adjusted odds ratio [aOR]: 1.50; 95% confidence interval [CI]: 1.00 to 2.24). Similarly, less than optimal satisfaction with the time spent on HIV testing was significantly more likely among participants tested by a healthcare provider (13%) than among those tested by a lay provider (8%) (aOR: 1.73; 95% CI: 1.20 to 2.51). The percentages of participants who expressed optimal satisfaction with the tester’s ability to answer questions were comparable: 99.6% for lay providers and 99.5% for healthcare providers.

The second study also examined preferences towards HTS in emergency departments at two urban academic medical institutions in the United States (28). Surveys were completed by 457 patients and 85 emergency department staff and asked about hypothetical preferences, not actual experiences. Both patients and staff preferred to have HIV test results

delivered by a physician compared with lay providers (HIV counselors) or other staff members (nurses, physicians assistants, or social workers); exact statistics were not presented.

Studies from sub-Saharan Africa were more diverse and used both quantitative and qualitative methods. One study from Botswana conducted exit interviews with clients who had received HTS from lay providers (12). Most clients (n=46; 97.9%) reported being satisfied with the HTS services received and the same number (n=46; 97.9%) felt comfortable returning for such services in the future.

The remaining three studies did not examine clients' actual experiences with HTS by lay providers, but provided some insight into characteristics which patients sought in HTS providers. In rural Malawi, a survey of 648 men and 868 women examined preferences for different ways of being notified of HIV test results (24). A large majority of participants who desired to be tested were willing to learn their results from a counselor at the test site and on the same day of the test (>90%). A majority of men (61%) and women (59%) also were open to obtaining their results from an anonymous posting using a patient number, while about half of women (55%) and men (44%) were willing to learn their results from a community counselor at their homes. In Zimbabwe, a qualitative study suggested that clients preferred testing personnel to come from outside the community due to confidentiality concerns (26). Finally, another qualitative study from Zambia, embedded within a larger trial of community-based HTS, found that clients wanted providers they could trust; such trust was based on professional conduct, knowledge, politeness, adeptness in dealing with sensitive issues, and the ability to listen (25).

**Table 1.1A: Risk-benefit table**

Factor	Explanation / Evidence	Judgment
<b>Quality of Evidence</b>	One RCT from a single high-income country, with no major limitations, measuring HTS uptake (plus one before/after study) Three observational studies measuring testing quality (concordance of test results); two measuring sensitivity and specificity	Moderate for the RCT; low for the observational studies
<b>Balance of Benefits vs. Harms</b>	<p><b>HTS uptake</b> In one RCT, uptake among emergency department patients was 57% (1,382/2,446) in the trained lay provider arm compared with 27% in the trained healthcare provider arm (643/2,409; RR: 2.12, 95% CI: 1.96 to 2.28).</p> <p><b>Measures of testing quality</b> In three observational studies, trained lay provider and laboratory staff test results were concordant in 3,963/3,986 cases, 2,907/2,911 cases, and 559/563 cases, respectively.</p> <p><b>Accurate test results</b> In two observational studies comparing trained lay provider and laboratory staff test results, sensitivity was calculated as 98.0% (95% CI: 96.3- 98.9%) and 99.6%, and specificity was calculated as 99.6% (95% CI: 99.4-99.7%) and 100.0%, respectively.</p> <p>No studies reported on the following outcomes: <b>adverse events, rate of CD4 measurement, linkage to medical visit after diagnosis, or initiation of ART.</b></p>	Benefits outweigh harms
<b>Values and Preferences</b>	A systematic review identified six published studies examining values and preferences around lay providers and HTS. These studies generally found support for lay providers conducting HTS, particularly in the strongest study (an RCT) and the other study measuring preferences among people who had actually undergone HTS with a lay provider (rather than hypothetical preference questions).	There is support for lay providers conducting HTS
<b>Resource Use</b>	Trained lay providers generally receive lower salaries than trained health professionals, although full programme costs (including training and supervision), cost-effectiveness and affordability are variable across settings.	Variability in resource use
<b>Feasibility (see Appendix 1.3.2)</b>	Trained lay providers have been used to conduct HTS in a range of clinical and community settings across North America, Europe, sub-Saharan Africa, and Asia. An analysis of national HTS policies from 48 countries showed that in many countries, lay providers are already permitted to perform RDTs (40% overall, and over 64% in a sub-analysis of 25 policies in Africa), and even greater numbers of countries allowed lay providers to perform pre- and post-test counselling (60% across all countries and 80% in Africa). Approximately one-third of policies did not specify the role of lay providers, with only one-third of policies prohibiting lay providers from performing RDTs and less than one-fourth prohibiting them from providing counselling.	Feasible in many settings



**Table 1.2A: GRADE evidence profile**

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**Date:** 2015-03-13

**Question:** Should trained lay providers perform HIV testing and counselling services using HIV rapid diagnostic tests?

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	HTS using RDTs by trained lay providers	HTS using RDTs by trained health professionals, or no intervention	Relative (95% CI)	Absolute		
<b>Uptake of HTS (assessed with: proportion who completed HTS)</b>												
1 <sup>1</sup>	randomized trials <sup>2</sup>	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	single RCT in a high-income country	1382/2446 (56.5%)	643/2409 (26.7%)	Relative Risk: 2.1168 (1.9643 to 2.2811)	298 more per 1000 (from 257 more to 342 more)	□□□□ MODERATE	CRITICAL
<b>Measures of testing quality (assessed with: concordance of HIV test results)</b>												
3 <sup>3</sup>	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	-	-	-	3,963 of 3,986 cases <sup>4</sup>	□□□□ LOW	CRITICAL
									-	2,907 of 2,911 cases <sup>5</sup>		
									-	559 of 563 cases <sup>6</sup>		
<b>Accurate test results (assessed with: sensitivity)</b>												
2 <sup>7</sup>	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	-	-	98.0% (96.3- 98.9%) <sup>8</sup>	-	□□□□ LOW	CRITICAL
									99.6% <sup>9</sup>	-		
<b>Accurate test results (assessed with: specificity)</b>												
2 <sup>7</sup>	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	-	-	99.6% (99.4-99.7%) <sup>8</sup>	-	□□□□ LOW	CRITICAL
									100% <sup>9</sup>	-		
<b>Adverse events - not reported</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Rate of CD4 measurement - not reported</b>												
0	-	-	-	-	-	none	-	-	-	-		IMPORTANT
<b>Linkage to medical visit after diagnosis - not reported</b>												
0	-	-	-	-	-	none	-	-	-	-		IMPORTANT
<b>Initiation of ART - not reported</b>												
0	-	-	-	-	-	none	-	-	-	-		IMPORTANT

<sup>1</sup> Walensky et al., 2011 (29)

<sup>2</sup> In addition to the one RCT by Walensky et al. 2011 (29), one non-randomized study examined HTS uptake before and after the introduction of lay providers in Thyolo District, Malawi (Bemelmans et al., 2010) (30). This study found HTS uptake increased from 1300 tests per month in 2003 to 6500 tests per month in 2009. This was the result of an increase from 14 HTS sites at the end of 2003 (with an average of 93 tests per site per month) to 39 sites at the end of 2009 (with an average of 167 tests per site per month).

<sup>3</sup> Jackson et al., 2013 (31); Molesworth et al., 2010 (10); Kanal et al., 2005 (32).

<sup>4</sup> Jackson et al., 2013 (31): Of 3,986 matched samples, lay provider and laboratory results of HTS were concordant in all but 23 cases. Of these, further examination revealed only 2 cases that could be considered "critical errors" where the lay provider found a positive result and the laboratory had a negative result; the rest were cases where at least one result was indeterminate, and most of these were considered cases of the lay provider being extra cautious.

<sup>5</sup> Molesworth et al., 2010 (10): Of 2911 matched samples, lay provider and laboratory results were concordant in all but 4 cases, 3 of which were considered most likely the result of "sample peculiarities".

<sup>6</sup> Kanal et al., 2005 (32): Of 563 matched samples, lay provider and laboratory results of HTS were concordant in all but 4 cases; of these, "Further investigation confirmed that all the reports by the counsellors [lay providers] were correct, and that human error in writing reports in the laboratory was a cause of these discordant reports".

<sup>7</sup> Jackson et al., 2013 (31); Molesworth et al., 2010 (10).

<sup>8</sup> Jackson et al., 2013 (31).

<sup>9</sup> Molesworth et al., 2010 (10); 95% CI not reported

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## 1.5 Appendix

### 1.5.1 List of search terms

#### Concept 1: HIV/AIDS

"HIV"[mh] OR "HIV"[mesh] OR AIDS[all] OR "HIV-1"[mh] OR "HIV-2"[mh] OR "HIV"[all] OR "HIV-1"[all] OR "HIV-2"[all] OR "Human immunodeficiency viruses"[all] OR "AIDS virus"[all] OR "AIDS viruses"[all] OR "HTLV-III"[all] OR "Human Immunodeficiency Virus"[all] OR "Human Immunodeficiency Viruses"[all] OR "Acquired Immune Deficiency"[all] OR "Acquired Immuno-Deficiency Syndrome"[all] OR "Acquired Immunodeficiency Syndrome"[Mesh] or "Acquired Immunodeficiency Syndrome"[all]

#### Concept 2: Cadres of health care providers

"Health personnel"[mesh] OR "health personnel"[tw] OR "health educators"[mesh] or "health educator"[tw] or "health educators"[tw] OR "nurses"[mesh] or "nurse"[tw] OR "nurses"[tw] OR "physicians"[mesh] OR "physicians, primary care"[mesh] OR "physician"[tw] OR "physicians"[tw] OR "nurses, community health"[mesh] OR "community health nurse"[tw] OR "community health nurses"[tw] OR "community health workers"[mesh] OR "community health worker"[tw] OR "community health workers"[tw] OR "community health aides"[mesh] OR "community health aide"[tw] OR "community health aides"[tw] OR "village health worker"[mesh] OR "village health worker"[tw] OR "village health workers"[tw] OR "barefoot doctor"[mesh] OR "barefoot doctor"[tw] OR "barefoot doctors"[tw] OR "lay provider"[mesh] OR "lay provider"[tw] OR "lay providers"[tw] OR "lay worker"[mesh] OR "lay worker"[tw] OR "primary care physician"[mesh] OR "primary care physician"[tw] OR "primary care physicians"[tw] OR "lay workers"[tw] OR "lay health provider"[mesh] OR "lay health provider"[tw] OR "lay health providers"[tw] OR "lay health worker"[mesh] OR "lay health worker"[tw] OR "community health nurse"[mesh] OR "community health nurse"[tw] OR "community health nurses"[tw] OR "visiting nurse"[mesh] OR "visiting nurses"[tw] OR "visiting nurse"[tw] OR "home nurse"[mesh] OR "home nurse"[tw] OR "home nurses"[tw] OR "health visitor"[mesh] OR "health visitor"[tw] OR "health visitors"[tw] OR "lay health workers"[mesh] OR "lay health workers"[tw] OR "lay health advisor"[mesh] OR "lay health advisor"[tw] OR "lay health advisors"[tw] OR "lay healthcare provider"[mesh] OR "lay healthcare provider"[tw] OR "lay healthcare providers"[tw] OR "lay healthcare worker"[mesh] OR "lay healthcare worker"[tw] OR "lay healthcare workers"[tw] OR "lay health care provider"[mesh] OR "lay health care provider"[tw] OR "lay health care providers"[tw] OR "lay health care worker"[mesh] OR "lay health care worker"[tw] OR "lay health care workers"[tw] OR "lay health advisor"[mesh] OR "lay health advisor"[tw] OR "lay health advisors"[tw] OR "doctor"[mesh] OR "doctor"[tw] OR "doctors"[tw] OR "doctors"[mesh] OR "peer navigator"[mesh] OR "peer navigator"[tw] OR "peer navigators"[tw] OR "CHW"[mesh] OR "CHW"[tw] OR "CHWs"[tw] OR "peer health worker"[mesh] OR "peer health worker"[tw] OR "peer health workers"[tw] OR "peer healthcare worker"[mesh] OR "peer healthcare worker"[tw] OR "peer healthcare workers"[tw] OR "peer health care worker"[mesh] OR "peer health care worker"[tw] OR "peer health care workers"[tw] OR "community health nurse"[mesh] OR "community health nurse"[tw] OR "community health nurses"[tw] OR "healthcare professionals"[mesh] OR "healthcare professionals"[tw] OR "healthcare professional"[tw] OR "healthcare provider"[mesh] OR "healthcare provider"[tw] OR "healthcare providers"[tw] OR "health care professionals"[mesh] OR "health care professionals"[tw] OR "health care professional"[tw] OR "health care provider"[mesh] OR "health care provider"[tw] OR "health care providers"[tw] OR "fieldworker"[mesh] OR "fieldworker"[tw] OR "fieldworkers"[tw] OR "field worker"[mesh] OR "field worker"[tw] OR "field workers"[tw] OR "mobile health units"[Mesh] OR "mobile health unit"[tw] OR "mobile health units"[tw] OR "cadre"[mesh] OR "cadre"[tw] OR "cadres"[tw] OR "task shifting"[mesh] OR "task shifting"[tw] OR "task-shifting"[mesh] OR "task-shifting"[tw]

#### Concept 3: HIV testing

"diagnosis"[mesh] OR "diagnosis"[tw] OR "AIDS serodiagnosis"[mesh] OR "AIDS serodiagnosis"[tw] OR "hiv infections/diagnosis\*"[mesh] OR "HIV antibodies/diagnostic use"[mesh] OR "AIDS serodiagnosis/methods\*"[mesh] OR "AIDS serodiagnosis"[tw] OR "rapid test"[tw] OR "HIV serodiagnosis"[tw] OR "testing"[tw] OR "screening"[tw] OR "hiv test"[tw] OR "hiv tests"[tw] OR "hiv testing"[tw]

#### Concept 4: Comparative studies

"Health Care Quality, Access, and Evaluation"[mesh] OR "feasibility studies"[Mesh] OR "feasibility study"[tw] OR "feasibility studies"[tw] OR "Randomized Controlled Trial"[Publication Type] OR "randomized controlled trial"[tw] OR "randomized controlled trials"[tw] OR "randomized control trial"[tw] OR "randomized control trials"[tw] OR "prospective studies"[mesh] OR "prospective study"[tw] OR "prospective studies"[tw] OR "retrospective studies"[mesh] OR "retrospective study"[tw] OR "retrospective studies"[tw] OR "comparative study"[publication type] OR "comparative study"[tw] OR "comparative studies"[tw] OR "longitudinal studies"[mesh] OR "longitudinal study"[tw] OR "longitudinal studies"[tw] OR "outcome assessment (health care)"[mesh] OR "outcome assessment"[tw] OR "noninferiority"[tw] OR "non-inferiority"[tw] OR "cluster randomized trial"[tw] OR "cluster randomized trials"[tw] OR "task shifting"[tw] OR "interprofessional relations"[mesh] OR "Cluster randomized controlled trial"[tw] OR "cluster randomized controlled trial"[tw] OR "cluster randomized control trial"[tw] OR "cluster randomized controlled trial"[tw]

#### Concept 5: Elimination of irrelevant terms

NOT ("animals"[mh] NOT ("animals"[mh] AND "humans"[mh]))  
NOT "hearing aids"[tw]

### 1.5.2 Cochrane risk of bias assessment for RCTs

Study: Walensky et al., 2011 (29)

Item	Judgment	Support for Judgment
Random sequence generation (selection bias)?	Low risk	"Because it has been shown that HIV test acceptance is affected by sex and age, <sup>18</sup> we randomized USHER study participants into 4 strata (i.e., men <40 years, men ≥40 years, women <40 years, and women >40 years) and performed computer generated block randomisation (with blocks of variable size) within each stratum." (p. 3)
Allocation concealment (selection bias)?	Low/ uncertain risk	Method of concealment is partially described, but exact procedures unclear. "Data center personnel are responsible for providing the research assistant with the computer-generated random assignment schema, with arm assignment within each stratum." (appendix)
Blinding of participants and personnel (performance bias)?	High risk	Participants and personnel were not blinded, and lack of blinding could influence the outcome. "Subjects, counselors, and providers were neither masked to the assigned arms nor incentivised to complete the testing process." (p. 3) However, blinding for this intervention (lay providers vs. health care providers) would be difficult, if not impossible.
Blinding of outcome assessment (detection bias)?	Low risk	Outcome assessment was not blinded, but lack of blinding should not influence the outcome (HTS uptake). Data analysis was blinded. "Data analysis, however, occurred with patients' identification numbers only; investigators were not aware of each patient's assignment." (appendix)
Incomplete outcome data (attrition bias)?	Low risk	No missing data reported (number randomized equal to the number for whom outcomes are reported)
Selective reporting (reporting bias)?	Uncertain risk	Insufficient information to assess high risk or low risk. (Some protocol details available in appendix, but no clear mention of pre-specified outcomes. However, presented outcomes seem likely to be the originally specified outcomes.)
Other bias?	Low risk	The study appears to be free of other sources of bias.