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Should trained lay providers perform HIV testing? A systematic review to inform World Health Organization guidelines

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ABSTRACT

New strategies for HIV testing services (HTS) are needed to achieve UN 90-90-90 targets, including diagnosis of 90% of people living with HIV. Task-sharing HTS to trained lay providers may alleviate health worker shortages and better reach target groups. We conducted a systematic review of studies evaluating HTS by lay providers using rapid diagnostic tests (RDTs). Peer-reviewed articles were included if they compared HTS using RDTs performed by trained lay providers to HTS by health professionals, or to no intervention. We also reviewed data on end-users' values and preferences around lay providers performing HTS. Searching was conducted through 10 online databases, reviewing reference lists, and contacting experts. Screening and data abstraction were conducted in duplicate using systematic methods. Of 6113 unique citations identified, 5 studies were included in the effectiveness review and 6 in the values and preferences review. One US-based randomized trial found patients' uptake of HTS doubled with lay providers (57% vs. 27%, percent difference: 30, 95% confidence interval: 27-32, $p < 0.001$). In Malawi, a pre/post study showed increases in HTS sites and tests after delegation to lay providers. Studies from Cambodia, Malawi, and South Africa comparing testing quality between lay providers and laboratory staff found little discordance and high sensitivity and specificity ($\geq 98\%$). Values and preferences studies generally found support for lay providers conducting HTS, particularly in non-hypothetical scenarios. Based on evidence supporting using trained lay providers, a WHO expert panel recommended lay providers be allowed to conduct HTS using HIV RDTs. Uptake of this recommendation could expand HIV testing to more people globally.

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HIV testing; HTS; lay providers; task shifting; task sharing



Introduction


The first of the United Nation's 90-90-90 global HIV targets is to diagnose 90% of people with HIV globally (UNAIDS, 2014a). Achieving this goal will require a range of approaches to delivering HIV testing services (HTS) tailored toward different epidemic contexts, groups most at risk for HIV, and people who remain undiagnosed and underserved (WHO, 2015). Rapid diagnostic tests (RDTs) can facilitate this by providing HIV test results in minutes rather than days. However, in many settings, a critical shortage of healthcare providers hampers expansion, and traditional testing approaches may poorly reach key populations and other high-risk groups (UNAIDS, 2014b).

Task-sharing – the rational redistribution of tasks from higher-level health provider cadres to lower-level cadres –

could expand HTS availability by shifting the role of test-provider from doctors or nurses to lay providers. The World Health Organization (WHO) has defined a lay health worker as “any health worker who performs functions related to health-care delivery; was trained in some way in the context of the intervention; but has received no formal professional or paraprofessional certificate or tertiary education degree” (WHO, 2014). WHO recommends that lay health workers can provide a range of clinical services (WHO, 2007, 2013, 2014).

A recent analysis of national policies for HIV testing across 50 countries showed that 42% allowed lay providers to perform testing using RDTs (64% in African countries) and even more allowed lay providers to perform pre- and post-test counseling (56% overall and 80% in Africa) (Flynn et al., 2017). However, several

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countries limit these roles to trained healthcare providers due to concerns about lay providers' ability to perform RDTs (whether fingerstick blood or oral fluid) and administer HIV-testing-related services, including pre- and post-test counseling, linkage to appropriate prevention and clinical care services, and coordination with laboratory services to ensure the delivery of correct test results (WHO, 2015).

In 2015, WHO sought to review the evidence for lay providers conducting HTS to inform WHO guidelines. We conducted a systematic review of the literature to answer the question: Should trained lay providers perform HIV testing using RDTs?

Methods

Search strategy and screening

To be included in the review, a study had to meet the following inclusion criteria: (1) be published in a peer-reviewed journal, (2) employ a comparative study design (either pre/post or multi-arm) where participants receiving RDT-based HTS by trained lay providers (following the WHO definition above) are compared to participants receiving HTS conducted by trained health professionals, or to no intervention, and (3) measure one or more of the following outcomes: (a) Measures of testing quality assurance/control (lost, damaged, uninterpretable specimens); (b) Accurate results (sensitivity, specificity); (c) Adverse events (e.g., coercion, inter-partner violence, self-harm, psychosocial, stigma/discrimination); (d) HTS uptake; (e) CD4 measurement among HIV-infected individuals; (f) Linkage to medical care following HIV diagnosis; (g) Antiretroviral treatment (ART) initiation. No restrictions were based on intervention location or language.

Ten electronic databases were searched through 3 September 2014: PubMed, Scopus, CINAHL, LILACS, WHO Global Health Libraries, Ovid Global Health, Sociological Abstracts, PsycINFO, EMBASE, and POPLINE. Search strategies included terms for HIV, health provider cadres, HIV testing, comparative study designs, and elimination of irrelevant terms. Appendix 1 (see supplementary material) presents the full search strategy for one database (PubMed).

Secondary reference searching was conducted on all included studies and on those included in seven related reviews, mostly focused on lay providers in HIV care and treatment services (Emdin, Chong, & Millson, 2013; Iwu & Holzemer, 2014; Mdege, Chindove, & Ali, 2013; Mwai et al., 2013; Penazzato, Davies, Apollo, Negussie, & Ford, 2014; Rackal et al., 2011; Wong, Luk, & Kidd, 2012). Expert members of the WHO guideline development group identified additional articles.

Titles, abstracts, and citation information were screened independently in duplicate. Full-text articles were assessed independently by two reviewers for final study eligibility. Articles not meeting inclusion criteria but presenting complementary information, such as review articles, were used as background material.

Data analysis

Data were extracted by two reviewers using standardized forms. Differences in data extraction were resolved through discussion and referral to a senior study team member when necessary. The following information was gathered from each included study:

- Study description: Citation information; objectives; location; population characteristics; intervention description; study design; sample size; follow-up periods; loss to follow-up
- Outcomes: Analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations

For randomized controlled trials (RCTs), risk of bias was assessed using the Cochrane Collaboration's tool for assessing risk of bias (Higgins & Green, 2011). For other study designs, rigor was assessed through the Evidence Project's quality assessment tool used in other HTS systematic reviews (Denison, O'Reilly, Schmid, Kennedy, & Sweat, 2008; Fonner, Denison, Kennedy, O'Reilly, & Sweat, 2012; Kennedy et al., 2013).

Data were analyzed according to coding categories and outcomes. Due to the lack of combinable studies, meta-analysis was not possible.

Values and preferences review

The same search was used to identify studies presenting information on end-users' values and preferences. Studies were included 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 excluded.

Results

Search results

Initial database searching yielded 8531 citations, with six identified through other means; 6113 remained after removing duplicates (Figure 1). Initial screening excluded 5878 records and secondary screening 148 for

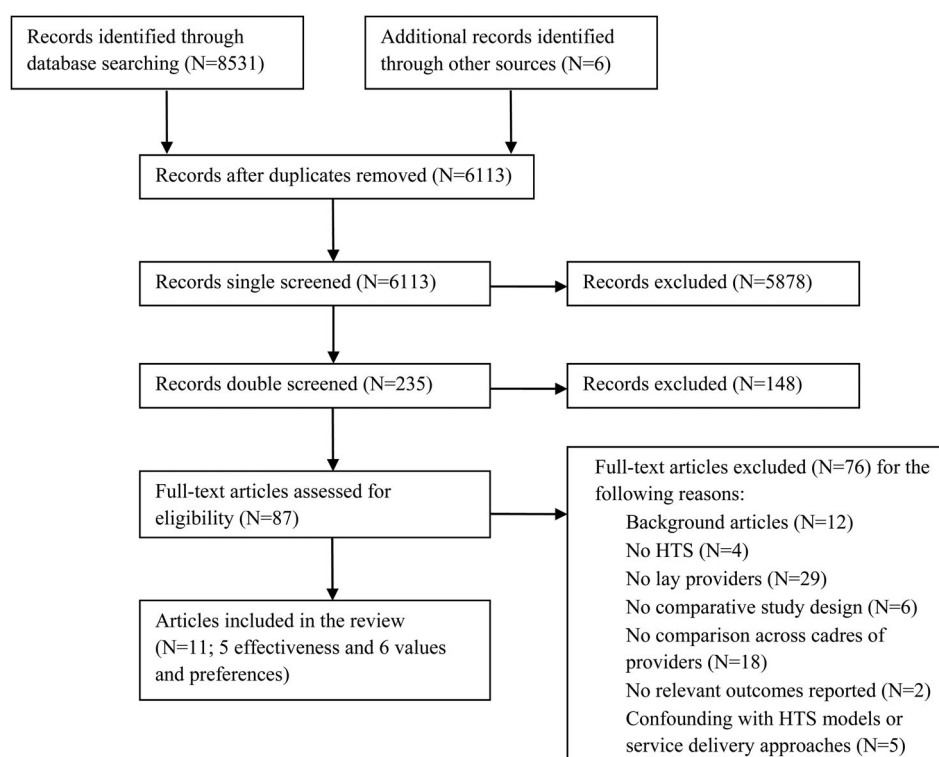


Figure 1. Disposition of citations during the search and screening process.

not meeting the inclusion criteria; the kappa statistic for inter-rater reliability of screening in duplicate was moderately good at 0.571. After thoroughly reviewing and discussing the remaining 87 articles, 76 were excluded, of which 12 were used for background.

Four initially included studies (reported in five articles) were later dropped because comparisons of lay providers with healthcare providers were confounded by comparisons of different HTS models or service delivery approaches. These studies examined either home-based HTS using lay providers compared with clinic-based HTS using health workers (Fylkesnes et al., 2013; Jurgensen, Sandoy, Michelo, & Fylkesnes, 2013; Lugada et al., 2010), or provider-initiated testing using health workers compared with client-initiated testing using lay providers (Leon, Naidoo, Mathews, Lewin, & Lombard, 2010; Seewald et al., 2013).

Ultimately, five studies were included in the effectiveness review (see supplementary material Table 1), and six studies were included in the values and preferences review.

The five studies included in the effectiveness review were diverse in location: two were conducted in Malawi (Bemelmans et al., 2010; Molesworth et al., 2010), one in South Africa (Jackson et al., 2013), one in Cambodia (Kanal et al., 2005), and one in the United States (Walensky, Reichmann, et al., 2011). Of the six studies presenting values and preferences data, four were

conducted in sub-Saharan Africa (one each in Botswana (Ledikwe et al., 2013), Malawi (DeGraft-Johnson, Paz-Soldan, Kasote, & Tsui, 2005), Zambia (Jurgensen, Sandoy, Michelo, Fylkesnes, et al., 2013), and Zimbabwe (Chirawu et al., 2010)), while two were conducted in the United States (Donnell-Fink et al., 2011; Hecht, Smith, Radonich, Kozlovskaya, & Totten, 2011). Table 2 (see supplementary material) presents an assessment of study design and rigor for each included study.

Study findings: effectiveness review

In Boston, USA, an RCT called the USHER study (Universal Screening for HIV Infection in the Emergency Room) compared two HTS provision models in an emergency department setting: HTS by lay providers (trained HIV counselors) compared with HTS by regular emergency department healthcare providers (emergency service assistants, ESAs) (Walensky, Reichmann, et al., 2011). In the lay provider arm, trained HIV counselors performed all services from test consent to test result delivery and referral for confirmatory testing. In the healthcare provider arm, ESAs (generally a two-year college degree) performed the tests but physicians gave results and follow-up. Both lay providers and ESAs received the same one-day training and successfully completed the accompanying competency test. This study was classified as having low or uncertain risk of

bias across all measures except blinding of participants and personnel; while participants, counselors, and providers could not be masked to study arm assignment, neither were they incentivized to complete the testing process. Kappa for inter-rater reliability of risk of bias was good at 0.739. Uptake of HTS among emergency department patients was 57% (1382/2446) in the lay provider arm compared with 27% in the healthcare provider arm (643/2409), a 30% difference (95% CI: 27–32, $p < .001$). The authors suggested that lower testing rates by providers may have been a function of insufficient time in patient encounters and competing demands “in the face of patient acuity and other duties” in a busy emergency department.

One study examined HIV testing uptake before and after the use of lay providers for HTS (Bemelmans et al., 2010). Conducted in rural Thyolo District, Malawi, this study employed various programmatic efforts to enable rapid scale-up of HIV care and treatment services, including task-sharing to increase the number of health workers in HIV care, decentralization of care to health centers and community sites, simplification of testing and treatment protocols, community engagement to increase capacity and support program sustainability, and health system strengthening. HTS was delegated to health surveillance assistant (HSA) counsellors, who received a 10-week basic HSA training and an additional 3-week HTS counselor training. After delegating HTS to lay providers, uptake of testing increased from 1,300 tests per month in 2003 to 6500 tests per month in 2009. HTS increased from 14 sites in 2003 to 39 sites in 2009, growing from an average of 93 to 167 tests per month per site. Likely due in part to this expanded coverage, the proportion of clients testing positive decreased from 36% in 2003 (5612/15,618) to 16% in 2009 (12,364/77,736). 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 HTS-providing cadre changes.

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 infant health package delivered by community health workers (Jackson et al., 2013). As part of the intervention arm, lay providers conducted home-based HTS. These lay providers completed a 10-day nationally accredited HTS course, learning how to use two finger-prick HIV RDTs. They shadowed facility counselors for three months, gained nurse-supervised testing experience at local health facilities, and received one-day training on dried blood spot sample collection from laboratory technicians. Lay provider and laboratory

results from HIV tests were concordant in all but 23 of 3986 matched cases. Further examination revealed only two “critical error” cases where the lay provider found a HIV-positive result and the laboratory had a negative result; the rest had at least one indeterminate result, mostly cases of cautious lay providers waiting for laboratory confirmation. 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 examined the quality of home-based rapid testing (Molesworth et al., 2010). Lay providers were trained and certified by Ministry of Health staff to perform HIV counseling, serial venous whole-blood rapid testing, and finger-prick specimen collection. Of 10,819 samples, 2911 were sent for laboratory quality control or confirmation, retesting every tenth negative and all positive specimens. Lay provider and laboratory results were concordant in all but four cases, considered the result of “sample peculiarities” after several parallel discordant tests. Results showed a sensitivity of 99.6% and specificity of 100.0%, as well as a 99.9% positive predictive value and 99.9% negative predictive value.

In Cambodia, a study compared results of rapid HIV testing by lay providers working in a prevention of mother-to-child transmission site with results from laboratory technicians (Kanal et al., 2005). Lay providers were trained HTS counsellors: 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 desiring HTS during the study period. Lay provider and laboratory results of HTS were concordant in all but four cases, which the authors found were caused by “human error” in laboratory write-ups.

Study findings: values and preferences review

Six studies reported on values and preferences related to lay providers conducting HTS services.

The one RCT identified above (Walensky, Reichmann, et al., 2011) published related results from a patient satisfaction survey (Donnell-Fink et al., 2011). Of 2025 HTS clients, 1616 (79.8%) completed the survey and most (91.5%) reported being very satisfied with their HTS experience. 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 arm (aOR: 1.50; 95% CI: 1.00–2.24). Less than optimal satisfaction with “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: 1.20–2.51). Almost all participants expressed optimal satisfaction with the tester’s ability to answer questions (lay providers: 99.6%, healthcare providers: 99.5%).

A second study examined preferences towards HTS in emergency departments in the United States (Hecht et al., 2011). Surveys, completed by 457 patients and 85 emergency department staff, asked about hypothetical preferences, not actual experiences. Both patients and staff preferred HIV test results delivery by a physician compared with lay providers (HIV counselors) or other staff members (nurses, physician assistants, or social workers); exact statistics were not presented.

Studies from sub-Saharan Africa were more diverse and used both quantitative and qualitative methods. The strongest of these was a study from Botswana, which conducted exit interviews with clients who had received HTS from lay providers (Ledikwe et al., 2013). Most clients ($n = 46$; 97.9%) reported being satisfied with the HTS services received; the same 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 insight into desired HTS provision characteristics. In rural Malawi, a survey of 648 men and 868 women examined preferences for different ways of HIV test result notification (DeGraft-Johnson et al., 2005). Almost all participants who desired testing 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; 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 (Chirawu et al., 2010). Another qualitative study from Zambia, embedded within a larger trial of community-based HTS, found that clients wanted trustworthy providers; trust was based on professional conduct, knowledge, politeness, adeptness in dealing with sensitive issues, and listening ability (Jurgensen, Sandoy, Michelo, Fylkesnes, et al., 2013).

Discussion

The existing literature generally supports using trained lay providers to perform HTS using HIV RDTs. While the evidence base is very limited, findings from one RCT and an observational study suggest that using trained lay providers can increase HIV testing uptake, and findings from three quality comparison studies suggest that lay providers can achieve similar testing quality as trained healthcare providers. Unfortunately, no studies measured adverse events following testing, nor linkage to care. Values and preferences studies, though also limited in number, generally found support for lay providers conducting HTS, particularly in the strongest study designs that examined preferences among people who had actually undergone HTS with a lay provider, rather than hypothetical scenarios.

Based on this evidence, program experience supporting feasibility in many settings (Flynn et al., 2017; WHO, 2015), and cost considerations, the WHO expert panel made the following recommendation (WHO, 2015): *Lay providers who are trained and supervised to use rapid diagnostic tests (RDTs) can independently conduct safe and effective HIV testing services.*

As many countries still require HTS to be performed only by nurses, doctors, or other trained health care professionals, adopting this recommendation could increase availability of HTS services worldwide. Estimates suggest almost 40% of people living with HIV in sub-Saharan Africa are unaware of their status (UNAIDS, 2016); an increase in HTS services globally is thus crucial to help individuals learn their serostatus and engage in appropriate treatment and prevention services. Men, adolescents, and people from key populations are particularly underserved by current HTS approaches, partially because they less frequently attend health facilities (UNAIDS, 2014b). Providing more acceptable community-based HTS options should be prioritized to overcome this disparity.

Using trained lay providers may also enable more cost-effective HIV testing services. Lay providers generally receive lower salaries than trained health professionals, although full program costs (including training and supervision), cost-effectiveness, and affordability vary across settings. The USHER trial embedded a cost-effectiveness study (Walensky, Morris, et al., 2011): estimated HIV screening costs in the healthcare provider and lay provider arms averaged US \$8.10 and \$31.00 per result received. The healthcare provider strategy (compared to no screening) had an incremental cost-effectiveness ratio of \$58,700/quality-adjusted life year (QALY) and the lay provider strategy (compared to the healthcare provider strategy) a ratio of \$64,500/QALY. The authors concluded that provider-based screening was

cheaper on a per-result basis, but fewer overall results were given because providers were already overstretched in terms of time and other clinical activities. As different program factors can dramatically impact cost-effectiveness in different situations, further research on the costs and cost-effectiveness of lay providers in HTS is warranted to provide important information as HIV programs seek increased efficiency.

The limited evidence base identified through this review suggests a need for additional research on the effectiveness and values and preferences around using lay providers for HTS. Future studies could examine the effect of task-shifting HTS services to lay providers on uptake of HTS, linkage to care and ART initiation, adverse events, sexual behavior, HIV serostatus disclosure, and other health and well-being outcomes. Findings from multiple settings could also help elucidate how these issues differ across diverse health systems and HIV epidemics.

Our review had limitations. We only included studies published in peer-reviewed journals, which provided some assurance of study quality given our otherwise broad inclusion criteria, but may have excluded other relevant studies. The limited evidence base did not permit us to judge aspects of the setting, training, or characteristics of lay providers that might yield better outcomes.

Task-shifting to lay providers has been recommended for a range of clinical care services, and the existing evidence supports allowing lay providers to conduct HTS using RDTs. HIV testing is the entry point to HIV care and treatment services and is the critical first step to achieving the UN 90–90–90 targets. Allowing lay providers to conduct HTS will expand the range of options available to countries as they work to meet these goals.

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