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A Review of Self-Testing for HIV: Research and Policy Priorities in a New Era of HIV Prevention

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Inadequate uptake of testing for human immunodeficiency virus (HIV) remains a primary bottleneck toward universal access to treatment and care, and is an obstacle to realizing the potential of new interventions for preventing HIV infection, including treatment for prevention and preexposure prophylaxis. HIV self-testing offers an approach to scaling up testing that could be high impact, low cost, confidential, and empowering for users. Although HIV self-testing was first considered >20 years ago, it has not been widely implemented. We conducted a review of policy and research on HIV self-testing, which indicates that policy is shifting toward a more flexible approach with less emphasis on pretest counseling and that HIV self-testing has been adopted in a number of settings. Empirical research on self-testing is limited, resulting in a lack of an evidence base upon which to base policy recommendations. Relevant research and investment in programs are urgently needed to enable consideration of developing formalized self-testing programs.

Keywords. HIV self-testing; literature review; HIV screening; HIV prevention; policy.

Access to testing for human immunodeficiency virus (HIV) infection is a public health imperative. Effective HIV prevention and care requires knowledge of one's HIV serostatus—defined as having received a positive result or a recent negative result. Yet access to and uptake of HIV testing and counseling (HTC) remain inadequate, and most people, including many at higher risk, do not know their status [1]. Many people living with HIV, including approximately 60% of those living in resource-limited countries, are unaware of their HIV status [1]. This remains a significant bottleneck toward universal access to timely treatment and care; in addition, late testing remains a major contributor to HIV-related mortality in many countries [2, 3]. Inadequate knowledge of

HIV status will also compromise implementation of new prevention strategies including male circumcision, vaginal and rectal microbicides, oral preexposure prophylaxis (PrEP), and earlier/immediate antiretroviral therapy (ART) for prevention. Optimizing HIV prevention, care, and treatment in high-prevalence countries requires regular testing by most adults [4]. This goal is far from being realized under current HTC delivery strategies.

HIV self-testing is defined as any form of HIV testing in which an individual collects his or her own sample; performs a simple, rapid laboratory test; and is, therefore, the first to know the results. Self-testing could add a new approach to support scaling up testing with potential to be high impact, low cost, confidential, and empowering for users. Sales of unregulated test kits and evidence of informal self-testing by health workers indicate a demand for self-testing [5, 6]. However, HIV self-testing, although debated for >20 years, has not been widely endorsed [7].

HTC uptake will remain inadequate in resource-poor settings, particularly among those at high risk, without increasing HTC at the community level. The availability of self-testing approaches could have a significant role in increasing access to testing. The aim of this review was to examine current research and policy priorities around HIV self-testing.

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METHODS

Publications related to self-testing were identified through systematically searching Embase, Medline, Popline, CAB abstracts, and Global Health using the following search terms: (*HIV OR AIDS*) AND (*self-test** OR *home test** OR *home-based test**). Gray literature was identified through a Google search of key terms. References from relevant studies were examined for additional citations, and experts and authors of pertinent studies were contacted for any further references.

English-language references available through 21 May 2012 were included; no additional exclusion criteria were adopted, and all references pertaining to self-testing were retained. Studies were screened in 2 stages. In the first stage, the first reviewer read the titles and abstracts of studies meeting the inclusion criteria. In the second stage, the second reviewer evaluated the screening criteria and reviewed the studies that had been selected, excluding any references not meeting the selection criteria. Disagreements between reviewers were resolved through discussion. One hundred twenty unique citations were identified, and 32 citations representing 24 studies were retained in this review. Heterogeneity of populations, data collection methods, and outcomes precluded meta-analysis of data, and results were analyzed qualitatively and reported in a summary table.

We identified key issues related to self-testing and results of a review of related policy and research. We identified research gaps and discussed applications for HIV self-testing among key populations. We also considered the role of self-testing in supporting increasing coverage of HIV prevention and care.

RESULTS

Arguments for and Against Self-Testing

Policymakers and local health authorities have reservations about self-testing due to potential inaccuracy of results, psychological risks, and difficulty ensuring onward referral for positive individuals [8–11] (Table 1). Proponents cite potential benefits, including increased knowledge of HIV status, facilitation of repeat testing, earlier diagnosis, treatment and care, and destigmatization through normalization of HIV testing [9–12] (Table 1).

Early in the HIV epidemic, arguments against self-testing carried more weight than now. Rapid tests can be highly sensitive and specific [13]. Options such as oral fluid tests can achieve high accuracy, are less technically demanding than blood-based tests, and eliminate sharps and biohazard disposal problems—although a loss in sensitivity as compared to blood-based testing has been documented [14]. As compared to earlier in the epidemic, HIV knowledge is now more widespread, and ART is increasingly available. However, the challenge of linking testing and care remains a significant concern [15].

Table 1. Commonly Expressed Arguments Put Forth by Policymakers and Local Health Systems for and Against HIV Self-Testing

Arguments for:
Potential for a dramatic increase in knowledge of HIV status
Increased confidentiality
Increased convenience
Autonomy and empowerment
Potential to remove the stigma surrounding HIV
Less resource intensive from the healthcare system perspective
Arguments against:
Greater potential for inaccurate results
Psychological danger when decoupling testing and counseling
Greater difficulty ensuring referral to treatment and care
Potential unethical use of HIV self-testing
Self-testing as justification for unprotected sex
Concern for safe disposal of biohazard material

Sources: [8–12].

Abbreviation: HIV, human immunodeficiency virus.

HIV Testing Policy and Practice Environment

International policy no longer emphasizes individualized in-depth pretest counseling, now recognized as a potential barrier to HTC scale-up [16]. HTC policies continue to prioritize confidentiality, informed consent, and availability of counseling [17]. Both individual and public health benefits must be considered; new approaches must be convenient, ensure accurate test results, have good linkages to prevention and care services, and support wide and sustainable coverage, while still maintaining informed consent, voluntarism, and confidentiality. Human-rights dialogue has also changed to emphasize the right to access to HTC and treatment [18]. This shift has expanded the range of HTC models in which self-testing could be an option.

International Policy Concerning Self-Testing for HIV

World Health Organization (WHO) policy emphasizes a public health approach to HTC [17, 19], recognizing the importance of knowledge of status and expansion of access to HTC. There is support for pragmatic approaches to achieving higher coverage, such as routine facility-based provider-initiated testing and counseling (PITC), in which pretest counseling may be minimized. PITC is acceptable and increases access to HTC in many settings [20].

Self-testing was first mentioned by the Joint United Nations Programme on HIV/AIDS/WHO in 2000, where countries were cautioned to “strengthen quality assurance and safeguards on potential abuse before licensing commercial HIV home collection and home self-tests,” and it was recognized that “Home testing and self-testing are likely to be more commonly used. This will provide greater access (to voluntary counselling and testing

[VCT]) for people who are reluctant to attend formal VCT services. However, it is important that adequate information about and provision of follow-up support services are available.” [21]. WHO included the potential benefits and cautions self-testing in its 2012 HTC framework, but did not give specific recommendations for use [22].

National HIV Self-Testing Policies

Recommendations for HTC in the United States, issued by the US Centers for Disease Control and Prevention (CDC) in 2006 [23], aimed to minimize barriers to testing. The guidelines address fear of stigmatization and support the integration of HIV screening into routine healthcare services. Prevention counseling at the time of testing was no longer recommended.

The US Food and Drug Administration (FDA) approved home blood sample collection for HIV testing in 1996 [24]. Sale of the over-the-counter (OTC) OraQuick in-home oral HIV test was approved by the FDA in 2012, after unanimous recommendation from the Blood Products Advisory Committee [25].

Some European countries had permitted sales of OTC tests through pharmacies [26], but later legislation concerning diagnostic devices was standardized to cover most of the European Union, and OTC test sales were halted.

The Kenyan National Guidelines for HTC (2009) [27] validate the use of oral fluid self-test kits and outline standards to support this (Table 2). Kenya is the first African country to develop guidance concerning OTC HIV self-test kits for the general public.

Advocacy for Self-Testing

Many countries have advocated for self-testing. In 2008, the United Kingdom’s National AIDS Trust called for more accessible HIV testing and to permit and regulate self-testing, with assessment of impact on risk-reduction behavior and access to care [28]. The UK government now plans to license home HIV test kits [29]. The *Canadian Medical Association Journal* issued a statement supporting home testing [30]. A joint statement by the Southern African HIV Clinicians Society argued that self-testing presents an opportunity for scale-up of testing and that current legal and policy frameworks be amended to include provisions for self-testing and to remove restrictions on test kit distribution [31].

In a recent article, authors from the CDC highlighted the need for strategies to strengthen implementation of HIV self-testing [32]. The 2012 annual letter of the Bill and Melinda Gates Foundation suggests that widespread HIV testing could be achieved through use of an “inexpensive saliva test that can be used privately” [33].

HIV Self-Testing: A Review of Research Studies

Summary of Studies Included in This Review

The 32 citations identified by the search included 18 peer-reviewed publications, 2 draft manuscripts, 5 reports, 6 abstracts,

Table 2. Excerpt from the National Guidelines for HIV Testing and Counselling in Kenya, 2009

The basic principle of self-testing has been used before for other non-invasive tests, such as in pregnancy tests. Clients can access test kits [for HIV] from pharmacies and other approved suppliers. Self-testing is different from the traditional HTC strategies as the client does not receive basic education, or pre-test counselling. But in order to strengthen support systems for self-testing, there is a need for basic standards. These standards include:
Test kits must be evaluated and approved for use in Kenya;
Test kits must be used before the expiry date;
Storage conditions must be adequate;
Test kits must pass quality control standards in Kenya;
Pharmacists must be trained and approved to dispense, counsel and demonstrate the use of the test kit to clients and patients as the need arises;
Follow-up and referral services, including confirming positive test results, must be accessible for clients.
The vendor should be able to provide the client with step-by-step instructions for
1. How to conduct the test;
2. How to correctly interpret the test results; and
3. Where to access follow-up and support services in the surrounding area.
Persons must also be informed that the results are not confirmed until a second, confirmatory test is conducted. This information should also be made available on a package insert, to be included on all HIV tests sold or distributed in Kenya, along with the minimum standards mentioned above.
Pharmacists and other suppliers of self-test materials should undergo HTC training and be certified by the Ministry of Health. They must provide a private room for clients who may need further information, counselling and social support. Utmost care should be taken to avoid cases of misuse of test kits, as well as to prevent negative social outcomes.

Source: Ministry of Public Health and Sanitation of Kenya [27].

Abbreviations: HIV, human immunodeficiency virus; HTC, HIV testing and counselling.

and data from 1 online media source [7, 26, 34–63]. Citations reported on a number of study populations, study designs, and outcomes. These largely represented exploratory analyses and sample sizes varied widely (range, N = 27 to N = 9169). Six studies addressed health workers [8, 37, 39, 49, 50, 52]. Of the non-health worker studies, 8 surveyed high-risk populations and/or clients of HIV testing facilities to determine acceptability of self-testing, preferred testing methods and reasons for preferences, and/or to identify attributes associated with acceptability of HIV testing [40–42, 44, 45, 54, 55, 57–59, 61–63]. Seven studies evaluated feasibility through participant self-testing, and 4 included confirmation of results (F Spielberg, S Camp, K Tapia, unpublished data) [36, 38, 45, 50, 51, 53, 54, 56, 60, 64]. Two studies considered the acceptability and feasibility of computer-assisted self-testing [35, 47]. We also identified 2 operational evaluations [26, 34]. Table 3 summarizes the research findings.

Table 3. Summary of Research Findings on HIV Self-Testing

Study	Location	Study Design and Population	Interested in Self-Testing	Ever Informally Self-Tested	Confirmation/ Disclosure of Self-Test Results	Accuracy of Self-Test	Additional Comments
(A) Ministry of Health, Kenya, 2006 [39] N = 1897	Kenya	Cross-sectional survey and focus group discussions among doctors, clinical officers, pharmacists, laboratory technologists, and VCT counselors in all 8 provinces of Kenya	73%	FGD indicate many have self-tested.			64% of health workers had ever tested for HIV, but only 43% had tested in the past year and <50% of partners had ever tested.
(B) Corbett, 2007 [8] N = 938	Ethiopia, Kenya, Malawi, Mozambique, Zimbabwe	Situational analysis among a range of disciplines from front-line health providers to support service employees	79%	31%	85% disclosed to at least 1 person, 46% sought confirmatory testing.		70% of health workers had ever tested for HIV. 31% had already self-tested informally.
(C) Kalibala et al, 2011 [37] N = 161	Kenya	Focus group discussions and in-depth interviews among doctors, clinical officers, pharmacists, laboratory technologists, and VCT counselors	FGD indicate many welcomed self-testing.	FGD indicate already common.	FGD indicate disclosure is important.		Many health workers avoid conventional testing services due to fear of stigma, and there would be a great demand for self-testing if made available. Many health workers have already self-tested, but expressed a need for adequate counseling and referral services.
(D) Kruse et al, 2009 [48] N = 483	Zambia	Cross-sectional survey, focus group discussions and in-depth interviews among physicians, clinical officers, nurses, midwives, and pharmacy staff		FGD indicate some have self-tested.			
(E) Skolnik et al, 2001 [44] N = 354	United States	Cross-sectional survey among clients at 2 stationary and 2 mobile public HIV testing facilities; 49% MSM	24% selected as preferred method.				
(F) Phillips et al, 2002, 2002, 2003 [40–42] N = 2964	United States	Cross-sectional state-representative survey	37% would self-test.				

Table 3 continued.

Study	Location	Study Design and Population	Interested in Self-Testing	Ever Informally Self-Tested	Confirmation/ Disclosure of Self-Test Results	Accuracy of Self-Test	Additional Comments
(G) Spielberg et al, 2003 [45] N = 460	United States	Cross-sectional survey among at-risk participants from a needle exchange, 2 bathhouses, and 1 sex venue for MSM, and an STI clinic	20% selected as preferred method.				
(H) Lee et al, 2007 [38] N = 350	Singapore	Cross-sectional survey among known HIV-positive, and high-risk individuals of unknown status clients of 2 HIV testing centers	89% would prefer self-testing, 88% thought self-testing should be made available over-the-counter.			Using Determine finger-prick rapid HIV test there were 56% invalid results.	89% of participants preferred self-testing but thought confidential counseling was necessary.
(I) Spielberg et al, 2003, 2007 [46] N = 240	United States	Evaluation of interest and feasibility in self-testing through 7 waves of self-testing by HIV-positive individuals, with instructions for use modified after feedback form each wave	61% would have preferred to test at home.			Invalid and false-negative results were 9% and 5% with finger-stick and 6% with past-generation oral fluid, respectively.	
(J) Gaydos et al, 2009, 2011 [36, 55] N = 565	United States	Evaluation of acceptability and accuracy of self-testing by patients from 2 urban emergency departments without HIV diagnosis	85% agreed to self-test, of those, 91% agreed to oral self-testing over blood-based.			Self-test results 99.6% concordant with health worker using new-generation oral fluid test.	96% reported oral test "not hard at all to perform correctly," 94% believed results to be "definitely correct," 91% trusted self-test result, 98% would recommend to a friend.
(K) Project Masiluleke, 2009 [43]	South Africa	Pilot research from a nationwide program among the general population from KwaZulu-Natal	Enthusiastic support from both community and healthcare leaders				
(L) Bui et al, 2010 [35] 3 FGD, 27 participants	United States	Computer-assisted counseling and rapid HIV testing among staff from chemical dependency treatment centres	Staff thought their clients would be interested in computer-assisted counseling and in self-testing, and thought self-testing would empower their clients.				

Table 3 continued.

Study	Location	Study Design and Population	Interested in Self-Testing	Ever Informally Self-Tested	Confirmation/ Disclosure of Self-Test Results	Accuracy of Self-Test	Additional Comments
(M) Spielberg, 2010 [47] 8 FGD of 4–8 participants	India	Acceptability and feasibility of computer-assisted HIV self-testing among Internet center staff and potential participants (single women, single men, married women, married men, couples)	Participants asked if they wanted computer counseling and rapid self-testing program in Internet kiosks: on a scale of 1–10, the mean score was 9.8 (mode 10); 86% would rather test themselves than have staff test them.				
(N) MiraTes, 2008 [26] N = 1112	Germany, Netherlands, United Kingdom, Belgium, Austria, Switzerland	Evaluation of motivation for and experience with home testing among a general population of people in Europe, aged 13–76 y (50% reporting unprotected sex and large proportion of MSM)	Only 67% of self-testers reported they would have had an HIV test were a home self-test unavailable.		98% reported they would go to a doctor if they tested positive, 23% conducted the self-test with another person present.		
(O) Van Loon et al, 2007 [34] N = 40	Netherlands	Annual report of Checkpoint HIV testing facility for the general population	40/4400 opted for self-testing, but only 1% knew that self-testing was an option prior to arrival at facilities.		Of 40 clients, 13 returned to facility within 1 mo, 16 returned 1–24 mo later, 10 returned >24 mo after self-test.		
(P) Kalibala et al, 2010 [49]; Kalibala, personal communication, 2011; N = 1454	Kenya	Pilot study of feasibility and acceptability of self-testing among healthcare workers at 7 hospitals	53% accepted self-test kit, most tested within a week.		The majority preferred to confirm results at a VCT center, though some confirmed by self-test.		Self-testing was found to be acceptable and convenient. Few people used the telephone hotline.
(Q) Chavula et al, 2010; Choko et al, 2011; [50, 52] N = 283 including 67 FGD participants	Malawi	Mixed quantitative and qualitative study of supervised self-testing among residents in high-density community residents and peer group members.	92% opted for self-testing over standard HIV testing and counseling, 100% would recommend self-testing, 95% “very likely” to self-test in the future.			99.2% concordant with health worker using new-generation oral fluid test.	96% reported the test was “not hard to do.” Self-testing was considered likely to increase uptake and frequency of HIV testing.

Table 3 continued.

Study	Location	Study Design and Population	Interested in Self-Testing	Ever Informally Self-Tested	Confirmation/ Disclosure of Self-Test Results	Accuracy of Self-Test	Additional Comments
(R) Namakhoma et al, 2010 [51] N = 906	Malawi	Mixed-methods study to explore enablers and barriers to HIV testing among healthcare workers at facilities in 2 districts of Malawi		11%			Most would prefer to test themselves than have a "junior" test them.
(S) Ronda et al, 2009; Ickenroth et al, 2010; Grispin et al, 2011 [57, 58, 62] N = 281	Netherlands	Cross-sectional survey among those who have and have not taken a self-test, to identify determinants of self-testing			19 HIV self-testers had known results: 1 HIV+ sought medical consult; 18 HIV-: 72% no further action, 16% consulted with family/friends, 11% changed lifestyle, 6% sought more information.		HIV self-testing was associated with perceived susceptibility, perceived benefits, self-efficacy, experience of bodily or environmental event(s) that trigger action, belief that individuals or groups support self-testing (subjective norm)
(T) Sharma et al, 2011 [61] N = 6163	United States	Cross-sectional survey among MSM to describe factors associated with willingness to take a free self-test	63% reported being very likely and 20% somewhat likely to self-test.				The hypothetical offer of incentives of \$10, \$20, or \$50 approximately doubled reported willingness to self-test. Black MSM, those having unprotected anal sex in past 12 mo, and those unaware of their HIV status were more likely to be willing to self-test.
(U) Estcourt et al, 2011; Saunders et al, 2012 [54, 60] N = 411	United Kingdom	Cross-sectional survey of men 18–35 y to assess acceptability of self-testing for STI/HIV	91% would be willing to self-test.				Primary care settings (80%), sexual health clinics (67%), and pharmacies (65%) were most acceptable locations for self-test kit pickup.

Table 3 continued.

Study	Location	Study Design and Population	Interested in Self-Testing	Ever Informally Self-Tested	Confirmation/ Disclosure of Self-Test Results	Accuracy of Self-Test	Additional Comments
(V) Katz et al, 2012 [59] N = 133	United States	Qualitative study to describe ease of use and acceptability of oral HIV self-testing among MSM	84% reported availability of self-testing would increase frequency of testing.			Of 69 online surveys completed, 2 reported invalid results and 1 was incorrectly performed.	46% reported they would pay ≤\$20 for self-test, 26% would pay \$20–\$40, 17% would pay ≥\$40. 11% would only use if free. 86% expected to test ≥4 times/year if kits cost \$5 compared to 26% if kits cost \$50.
(W) Carballo-Dieguez et al, 2012 [53] N = 60	United States	Mixed quantitative and qualitative study to determine whether HIV-negative MSM would use self-testing as a harm reduction strategy to screen sexual partners	87% reported they would likely self-test if OTC testing became available, and 80% would likely test a sexual partner at home. 74% chose to take the test in front of an interviewer.			Most participants took the test without mistake. The most common mistake was touching the pad of the testing wand with their fingers.	Reported barriers to testing with a partner included being impractical or killing the mood, and when under the influence of alcohol/drugs; although it was thought some partners might refuse, a violent reaction or unmanageable situation was not anticipated from bringing up self-testing.
(X) Greacen et al, 2012 [56] N = 9169	France	Cross-sectional survey among MSM to assess access and use of unregulated self-test kits available online		30% were aware of online self-test kits. Of those aware and not already HIV-positive, 3.5% had accessed an unregulated kit.	Of 3 men who tested positive by self-test, 2 had sought confirmatory testing and 1 called an HIV hotline.		

Abbreviations: FGD, focus group discussion; HIV, human immunodeficiency virus; MSM, men who have sex with men; OTC, over-the-counter; STI, sexually transmitted infection; VCT, voluntary counseling and testing.

Interest in and Acceptability of Self-Testing

Interest in HIV self-testing was high among all populations surveyed. Among health workers from 5 African countries, 73%–79% reported interest in self-testing (studies A, B, P). Interest was highest among health workers who had never tested for HIV (77% in study A). Respondents felt that self-testing would reduce or eliminate stigma around HIV testing. Self-testing was also viewed a supportive means for family members to test. A large percentage of respondents had already self-tested in the workplace.

In the United States, acceptability ranged from 83% to 89% among respondents at a testing facility (study H), emergency department patients, and among men who have sex with men (MSM; studies T, V, W) with 80% of MSM likely to test with their sexual partner (study W). Among known HIV-positive participants (study I), 61% would have preferred to self-test. In the United Kingdom, 91% of men reported willingness to self-test (study U), in 6 European countries (study N) 67% would not have tested were a home test unavailable, and in the Netherlands more than half of self-testers were first-time testers (study O). Among potential HIV testers in India (study M), 86% preferred self-testing over clinic-based testing. In Malawi (study Q), 92% of community members opted for supervised self-testing over standard voluntary HIV counseling and testing, with 100% indicating they would recommend self-testing to a friend. Reasons for preferring self-testing across studies included privacy, autonomy, confidentiality and anonymity, convenience, and speed.

Accuracy of Self-Testing

Four studies evaluated accuracy of self-testing, of which 2 (studies J, Q) used the current-generation oral fluid tests. They found 99.6% and 99.2% concordance between results of participants and trained healthcare professionals, respectively. The poor performance results for finger-prick testing (studies H, I) were based on earlier versions of rapid tests. Though one (study I) was an older generation CLIA-waived test, the second (study H) required 14 steps. These results may not be applicable to current versions of rapid, whole blood tests which now involve fewer steps. Decreased sensitivity in oral tests compared to blood based tests has been reported [14] but there are limited available data on the performance of whole blood tests in the context of self-testing.

Acceptability and Evidence of Harm

Self-testing de-links testing and counseling, potentially depriving individuals of linkage to a range of critical services. Focus group discussions raised concerns about user error, lack of counseling, and coping capacity for positive results. The minimal data that were available showed little evidence of harm, including expressing regret, feeling unprepared for the results, and anecdotal evidence of fear of self-testing (similar

fears were also expressed with other testing methods). These descriptive studies offer no comparisons with people who tested through standard HTC services.

Self-reported results disclosure and/or confirmatory testing appeared high overall. The majority of health workers reported that their self-test was not their last HIV test, implying that they had sought confirmation. In a general population of self-testing clients (study N), 98% reported they would go to a doctor if they tested positive, and 23% had self-tested with another person present. In study O, 98% of self-testing clients returned for another HIV test. In Malawi (study Q), 95% of self-testers reported they would self-test again. Among Europeans in study N, 62% reported that they would avoid risk following self-testing, 37% reported having always been careful and would continue to do so, and 1% reported they would not avoid risk after self-testing.

DISCUSSION

Summary of Research

This review suggests that self-testing may be an additional way to meet the need for confidential and accessible HIV testing, and may discourage current unregulated self-testing. Current global and national policies on HTC give less emphasis on the need for pretest counseling. Advocacy for self-testing is becoming more common, and some national policies now support regulated self-testing.

Interest and acceptability of self-testing was high in studies reviewed, including among key populations surveyed. Introduction of self-testing programs could, therefore, increase demand for and uptake of HIV testing. The choice of assay will be critical to support accuracy of results. The limited available data suggest that oral fluid testing may have lower sensitivity and specificity than other point-of-care HIV testing, and information about self-testing should therefore emphasize that the self-test result should be considered a screening rather than a definitive test. Self-tests should be confirmed by self-referral to other HTC services. None of the studies reviewed addressed the issue that confirmation of results, according to nationally agreed algorithms, must be ensured. Data are presently insufficient to assess whether self-testing leads to timely linkage to care.

Limitations

Only 24 descriptive studies contained HIV self-testing information, many with small sample sizes. Study populations were heterogeneous, as were study designs, data collection methods, and outcomes, making comparability across studies difficult and generalizability of findings limited. Overall, the studies included in this review were largely exploratory and methodological quality was low. Just 2 studies evaluated the accuracy of self-testing using current oral fluid tests. Only 1 study explored evidence of harm; others examined concerns about implementation

Table 4. Identified Gaps in Research on HIV Self-Testing

	Gaps	Comments	Recommendations
1	Effect of self-testing on levels of uptake of first, repeat, and recent HIV testing	Evidence from studies from many countries that self-testing is highly acceptable. Evidence that there are already high levels of self-testing in African health workers. Unregulated self-test kits are widely available on the Internet, indicating a market for self-testing. Current indications suggest self-testing may be mainly used for the first test, and then by frequent repeaters.	Evaluation of uptake of ever-testing and recent testing should be assessed before implementation of self-testing programs and then monitored at workforce level. Methods to promote regular repeat testing an important issue to be explored in operational research.
2	Secondary beneficial effects of self-testing	Potential for personal empowerment, diminished HIV stigma associated with knowing one's status needs evaluation.	Qualitative research in representative and pilot sites would allow this to be assessed.
3	Secondary harmful effects of self-testing	Potential for greater psychological trauma compared to counselor-provided testing, and greater likelihood of inaccurate results from user error needs evaluation and failure to confirm result.	System for reporting serious adverse outcomes should be considered in representative or pilot sites.
4	Couples testing	There are currently no data on the acceptability and impact of couples self-testing. Ongoing study in Kenyan Health Workers considers this.	Operational research on couples self-testing is need to explore this potential approach.
5	Training, information, and counseling needed to ensure accuracy and minimize potential harm	Defining the essential components and how to provide them in ways that are effective but do not represent a disincentive will be an important part of operationalizing self-testing programs.	In practice will vary according to distribution strategy and population.
6	Quality assurance	Some studies have demonstrated a lower sensitivity with oral HIV testing as compared to blood-based testing. Current approach recommends confirmatory testing, but the acceptability of this and need for confirmation of negative results is not known.	Finger prick-based self-testing may be a consideration for future research. Current recommendations regarding confirmation of results should remain in place. Confirmation for repeat tests with no change in result may be less imperative.
7	Entry into HIV prevention/ care services	Only assessed in participants in the USA Home Access service: qualitative research suggests high ability/willingness to accept results and seek entry into care once positive status is known. Other studies suggest that entry into care is lower with community-based testing as compared to clinic-based testing. Some reasons for this may be compounded with home self-testing.	Self-referral into prevention and/or care services should be promoted, with confirmatory testing at this point. Additional data are required to inform linkage to care, and how best to promote this within the context of self-testing.
8	Cost-effectiveness	Important to determine relative to other options once models are established.	Costs and cost-effectiveness studies are required.
9	Effect of cost on demand	Few data exist to determine acceptable costs for test kits, including for populations at highest risk, and who are unlikely to test through current testing strategies.	The most acceptable price or price range will vary by country and by populations within a given country. Topic for research
10	Marketing and distribution of self-testing	No data on what marketing or distribution strategies will attract populations at highest risk, and those who are unlikely to test through current testing strategies.	Topic for research
11	Systems for monitoring and tracking self-testing	Few data exist on optimal monitoring systems by which we can track who received a test, got results, made the linkage to prevention or care services, etc. Unique challenges for monitoring recruitment and retention at each step in the testing and treatment cascade for those testing without initial contact with a health provider.	The use of mHealth technologies should be explored to track self-testing and linkage to care.

Abbreviation: HIV, human immunodeficiency virus.

of self-testing. All but 2 studies were cross-sectional and do not provide an indication of possible risks or benefits of self-testing in the longer term.

Research Gaps and Recommendations

Although studies indicate interest in self-testing, optimal service delivery strategies have not been documented or

published (Table 4). Data on disclosure, accuracy, confirmation, and risks associated with self-testing are limited, and more information is needed on the training, education, and counseling needed to minimize potential harm. The potential risks of self-testing have not yet been explored in depth. Rates of linkage to a range of prevention, treatment, and care services are unavailable. Information on the potential for secondary benefits of self-testing is unavailable, and the impact of formalized self-testing on informal practices is unclear. There are also insufficient data on how best to market and distribute self-test kits to reach those at highest risk, what effect the cost of self-test kits will have on demand, and how cost-effective self-testing will actually be.

Considerations for Self-Testing Programs and Potential Applications

Healthcare Workers

In generalized epidemics, the provision of formalized self-testing for healthcare workers is potentially appropriate and acceptable. There are already high rates of informal self-testing, as well as familiarity with and access to HIV prevention and care [64]. Obstacles to accessing HIV testing (eg, workplace gossip, stigma, discrimination) should be assessed and addressed, and confidentiality and access to follow-up services ensured. In Kenya, self-testing for healthcare workers is being implemented, with oral test kits available to take home for healthcare workers and their partners.

Couples

Knowledge of partner HIV status is low, and a significant proportion of transmission occurs within stable serodiscordant couples [65]. Couples testing can increase safer sexual behavior and allow timely uptake of and support for ART. Self-testing could provide confidentiality, autonomy, and convenience, and be a potentially suitable model for couples. However the use of self-testing for “serosorting” presents practical and programmatic problems, if the sensitivity of self-testing is suboptimal and because acute infection may not be detected [66]. There are also potential social issues and challenges for clinical follow-up with partner self-testing. Although there are no data regarding coercion, coercive testing by partners is a potential concern, and rigorous monitoring for adverse events is critical if this approach is to be considered.

MSM and Injecting Drug Users

In many countries, HIV transmission remains high among MSM and injecting drug users, and lack of awareness of HIV status is a key factor driving transmission rates [67, 68]. Reluctance to test has been associated with fear of results, and stigma and discrimination often hinder utilization of HIV services [69, 70].

Underserved by many HTC approaches, MSM and injecting drug user populations may benefit from self-testing approaches.

ART for Prevention and Other ART-Based Prevention Strategies

There has been recent debate around “treatment as prevention” [71, 72] and other promising approaches such as microbicides and oral PrEP, all of which require knowledge of HIV status. Successful implementation of these approaches requires near-universal, regular HIV testing. For example, PrEP requires regular (currently monthly) repeat testing, which is often inconvenient [73, 74]. Self-testing options may facilitate this.

CONCLUSIONS, CHALLENGES, CONSTRAINTS, AND THE WAY FORWARD

It is important to scale up HTC to meet global and national prevention and treatment goals, and to support new prevention tools as they become available. Globally, progress has been made toward universal HTC, however many people with HIV remain undiagnosed. There is demand for HIV self-testing and evidence that unregulated self-testing is being practiced. Self-testing could enable people reluctant to test or retest through existing approaches, to learn their status and benefit from treatment and prevention. For effective self-testing, monitoring for quality assurance, confirmation of test results, and appropriate and acceptable links to counseling, care, treatment, and prevention are essential. High uptake will require active promotion and community-level distribution of test kits. Recent global policy has moved toward simplifying HTC, resulting in a more routine approach to testing without requirements for lengthy pretest counseling. As oral fluid HIV tests become more widely available, there is a need to explore self-testing by assessing approaches that provide safe environments that link self-testing to other HIV services and carefully monitoring and evaluating these approaches to provide evidence for larger-scale implementation.

Notes

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