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HIV Self-Testing: a Review of Current Implementation and Fidelity

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Abstract Oral HIV self-testing is an innovative and potentially high-impact means to increase HIV-case identification globally. As a screening test, oral HIV self-testing offers the potential for increased adoption through greater convenience and privacy, and the potential to increase the proportion of the population who test regularly. Research on how best to translate the innovation of oral self-testing to high-risk populations is underway. Currently only one oral HIV self-test kit is FDA-approved (OraQuick In-Home HIV Test) and available for retail sale. In the present report we review recent studies on the dissemination, adoption, and implementation of oral HIV testing. Prior work has focused primarily on adoption, but recent studies have begun to identify methods for improving dissemination and problems associated with self-implementation. At present a major barrier to wider adoption is the relatively high retail cost of the oral HIV test kit. Significant but minor barriers are represented by overly complex instructional materials for some population segments, and dissemination programs of unknown efficacy. Theoretical and practical suggestions for conducting research on dissemination, adoption, and implementation of oral HIV testing are discussed.

Keywords HIV · HIV self-testing · Men who have sex with men (MSM) · African-Americans · Fidelity (performance) · HIV prevention · Science of prevention · HIV diagnosis · Review

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Introduction

The current Centers for Disease Control and Prevention's (CDC) strategy for HIV prevention is called High-Impact HIV Prevention. That approach emphasizes the continuity of care, and is being implemented throughout the USA and its territories [1–3]. The program includes enhanced HIV-testing services targeting high-risk persons, linkage-to-care services, early treatment with antiretroviral therapy, programs to support treatment adherence and retention in care, partner prevention services, and behavioral interventions focused on high-risk persons. HIV testing for high-risk persons represents a critical portal of entry into CDC's high-impact prevention [4], so that HIV-infected individuals can be identified and those HIV-uninfected linked to biomedical and behavioral prevention programs.

Unfortunately, despite improvements in national testing strategies it is estimated that of the 1.2 million persons infected with HIV, at least 168,000 (14 %) of those with HIV infection are unaware of their positive serostatus [5]. Persons infected with HIV who are unaware of their serostatus contribute disproportionally to HIV transmission [6, 7]. A recent meta-analysis conducted in the USA found that persons who are

unaware of their positive HIV serostatus engage in higher sexual-risk behaviors compared to persons infected with HIV who are aware of their HIV serostatus [7].

Facility-based testing for HIV infection is the norm in the USA [8]. National data indicate that approximately 87 % of people were tested for HIV infection at medical facilities, 7 % at community-based organizations, and 6 % at drug treatment centers [8]. However, significant barriers to facility-based HIV testing exist. Those include inconvenience (time, location, and transportation), confidentiality concerns, and fear of social stigmatization [9–14]. Although the CDC supports programs to expand HIV testing to disproportionately affected populations, evidence suggests that these programs may be poorly translated into practice [11]. For example, a recent study found that 48 % of HIV-testing sites ($N = 164$) in New York City could not be reached (i.e., by phone) to obtain information about access; and 23 % of contacted sites offered testing during standard business hours only, limiting access for students and daytime workers [11]. Those data highlight flaws in the expanded HIV-testing efforts that may adversely impact HIV test-seeking by young men who have sex with men (MSM) in particular, the group with the highest rate of new HIV infections. In a recent survey among gay and bisexual MSM, 36 % reported HIV testing greater than 1 year ago, 11 % tested 6–12 months ago, 19 % within the last 6 months, 1 % did not know, 3 % could not remember their last HIV test, and 30 % had never tested for HIV [15]. The 2013 U.S. Preventive Service Task Force has recommended HIV testing every 3–6 months for high-risk populations like young MSM.

The success of CDC's high-impact prevention strategy depends heavily on increasing HIV testing among high-risk individuals like African-American youth and young adults aged 17–24 years. Prior research confirms that large portions of African-Americans in that age group are untested (≈60 %), [16] and the highest rates of undiagnosed HIV infection are among those 17–24 years of age (≈59 %). Among MSM of any age, African-Americans have the highest rate of undiagnosed HIV infection (≈26 %) [17–22]. Failure to get tested and delayed testing following high-risk events create lags in diagnosis and treatment that, in turn, negatively impact early-case findings resulting in high rates of continued HIV transmission and poor clinical outcomes (e.g., [22, 23]). Increasing early and repeat HIV-testing rates among high-risk persons is essential to reducing the time lag between infection and treatment initiation [16].

HIV self-testing approaches are posited to provide an important supplement to facility-based testing, especially in population segments not reached by or accessing current services [24–27]. In October 2012, the Federal Drug Administration (FDA) approved the retail sale of an over-the-counter, self-administered, "at-home" HIV test kit (OraQuick HIV In-Home Test; OraSure Technologies, Bethlehem, PA). OraQuick uses an oral fluid collection technique that is painless and is preferred by many over finger-stick whole blood methods [28]. The OraQuick self-implemented HIV test is composed of three core components: (a) specimen collection and testing, (b) interpretation of results, and (c) use of OraSure's consumer support center for counseling and referrals for confirmatory testing and linkage-to-care in the individual's geographic area. In addition, OraSure seeks to implement self-testing with good fidelity by training consumers appropriately using package instructions and an online video [29]. In brief, OraQuick is a self-implemented testing program that is unique among current HIV-testing and linkage-to-care programs.

Oral fluid self-testing is considered in this review as a screening test, not a replacement for facility-based tests of higher accuracy. Although the sensitivity and specificity of HIV oral self-testing varies across studies and approximates that of the Western blot confirmatory HIV test, oral self-testing has a number of advantages. When the oral self-test is used as screening test for populations that are less likely to use facility-based testing or who do not test frequently enough (3 to 4 times per year), it may help identify more people who would have otherwise gone undiagnosed. On a population level the benefits of a more accessible test with lower sensitivity might outweigh that of a more sensitive test that high-risk populations do not use.

Self-testing offers a viable supplement for addressing the problems of facility-based testing by increasing privacy and convenience thus potentially supporting more frequent repeat testing (28) Repeat testing is more likely to occur (as is partner testing) if there are fewer barriers to testing and the user directly controls the process of testing his or herself (28).

The present review considers oral HIV self-testing in the context of three stages of translation science based on theoretical work. Those three stages include *dissemination*, *adoption*, and *implementation* [29–31]. Dissemination involves the diffusion of an innovation throughout a specific population; in this case, the dissemination of HIV self-testing to high-risk populations. Although some departments of public health in the USA have begun to dispense oral HIV test kits, strategies for optimizing dissemination to high-risk groups at low costs are not well understood or documented. Adoption of an innovation involves factors that affect the degree of uptake by those individuals most in need of the innovation. Although adoption is sometimes considered as a component of either dissemination or implementation, there are substantial reasons for considering it as a separate step in the translation process [31]. With regard to HIV self-testing, there is an abundance of research covering a wide range of populations that indicate oral HIV self-testing is highly preferred over other forms of HIV testing (see section on Adoption). Lastly, public health programs typically require implementation of some set of core components that are essential for efficacious outcomes. With regard to self-testing, the implementer is the user who must

perform a series of steps correctly (core components) in order to obtain accurate results. There are a limited number of studies examining how successful users are in implementing oral HIV self-testing or factors that contribute to successful testing.

Methods

We performed a selective literature review using Pubmed through November 25, 2015. In addition we reviewed recent presentations at HIV/AIDS-related scientific conferences, examined HIVST.org and included personal communication from various HIV-testing organizations and researchers in the field. Our literature search focused on the U.S. and international studies of relevance. Search terms included "HIV self-testing" and/or "dissemination", "preferences", "uptake", "adoption", "implementation", and "fidelity."

Results

Dissemination

Dissemination in the context of oral HIV self-testing is a two-step process. The first step involves the dissemination of oral test kits from the manufacturer to distribution sites such as pharmacies, community-based organizations, commercial venues, and other public venues that are utilized by high-risk populations. The second step involves the dissemination of oral test kits within the context of those venues to individuals. Our discussion will evolve around those two dissemination steps.

Although a number of reports describe instances where departments of public health and various community organizations have formed coalitions to increase the reach of oral HIV test kit dissemination to high-risk populations, these efforts have not been evaluated for impact. For instance, the Virginia Department of Health in collaboration with local clinics has reported implementing self-test kit dissemination through in person distribution. Social media interfaces and peer advocates were utilized to disseminate 257 OraQuick tests to at-risk individuals [32]. No data were provided reporting the percentage of persons who actually utilized a test or the number of new cases of HIV infection identified.

Other large HIV-testing organizations have reported distributing HIV self-test kits. The AIDS Healthcare Foundation distributed 1109 OraQuick tests through a popular gay bath house in Los Angeles and 1,459 kits were given out to community partners (Mark McGrath, personal communication). No data were provided reporting the percentage of persons who utilized a test or the number of new HIV infections identified.

One pilot study by Marlin et al. in young African-American MSM of the use of an OraQuick test voucher redemption strategy through collaboration with three local community-based organizations, student volunteers, and Walgreens pharmacies within the Los Angeles area did report utilization and case-identification outcomes [33]. Six-hundred forty-one OraQuick test kit vouchers were disseminated and 53 kits were redeemed. In a small telephone survey of the participants who used the OraQuick test ($n = 49$), 3 (6.1 %) reported newly testing HIV positive. All reported linkage to care. Two additional participants did not provide information on their test result but both reported follow-up medical care.

A rapid ethnographic study was reported by Catania et al. [34] on pharmacy dissemination in low-income African-American neighborhoods in Chicago. That study found few pharmacies to be openly displaying oral HIV test kits and in some cases offered alternative finger-stick whole blood test kits rather than the oral HIV test kits. Only three of the ten pharmacies studied actually had oral HIV test kits available.

Having sufficient supply of test kits obviously is crucial to dissemination. For example, in New York City, only 27 % of pharmacies surveyed had rapid HIV self-test kits available in stores and only 10 % of pharmacies had kits available for purchase without interaction with a pharmacist or pharmacy assistant [35, 36]. In a recent study of four pharmacy chains in Peru, while all the pharmacy managers confirmed the availability of the HIV self-test, none had the actual OraQuick for sale but were selling the an Orasure oral fluid test marketed for physician-only use in clinical settings [37]. Those data may imply pharmacies in high endemic communities may not have HIV self- test kits readily accessible.

In brief, there is considerable need for research on how to best construct community coalitions and networks that will increase dissemination of HIV self-tests to high-risk populations. The initial effort by the oral HIV test kit manufacturer was directed towards mass dissemination through pharmacies in the USA. A more strategic approach would increase dissemination efforts through pharmacies in geographic areas with large numbers of high-risk persons. Moreover, as discussed in the next section, there is a need to expand beyond pharmacy dissemination to community-based organizations and other venues serving high-risk populations.

Strategies to increase dissemination of HIV test kits directly to high-risk populations have only begun to be studied. Vending machines offer a convenient way of disseminating oral test kits that reduce the social embarrassment of having to ask pharmacists for kits that are typically stored behind counters. A recent study evaluated the feasibility of using an electronic vending machine to disseminate OraQuick test kits. Participants reported that the use of a vending machine was acceptable. Study participants who expressed interest in receiving a free HIV self-test were emailed a code to redeem a self-test kit from the vending machine: 59 codes were emailed

and 12 kits were dispensed. In a small follow-up survey of vending machine users ($n=8$), most reported that using the vending machine was a private experience; all reported certainty in the accuracy of their test result [38].

Another strategy for increasing self-test kit dissemination is to provide a mechanism for reducing the costs of purchasing a kit and allowing for kit purchases to occur under even more private circumstances (e.g., online purchasing). For instance, in another study in Los Angeles in 2014, OraQuick test kits were offered in several different ways to measure the preferences of self-test users: via study staff sending kits through the US mail, via a promotional code for users to obtain a free mailed test kit using Walgreens.com, via voucher redemption for in-store pharmacy collection, and via vending machines. In the first phase among 334 self-test requestors, 67 % requested test kits from study staff via the US mail, 30 % requested by voucher, and 3 % requested by a vending machine. In the second phase of 333 self-test requesters, 58 % requested test kits from study staff by US mail, 17 % by promotional code using Walgreens.com, 17 % by voucher and 8 % by vending machine. Of the 159 survey respondents who used the test, 6 (3.8 %) reported newly testing HIV-positive and all reported linkage to medical care [39].

In another study in Seattle, 230 MSM were randomized to two different HIV testing strategies: access to HIV self-test kits via the mail or standard of care through existing facility-based testing services over 15 months. Men in the self-test group had an average of 5.3 tests over the follow-up period versus only 3.6 in the standard of care arm ($P<0.001$) [40]. In Kenya, in an effort to increase HIV testing uptake, women seeking antenatal or post-partum services were given an oral HIV test kit and two extra kits to disseminate within their social networks. Sex workers who utilized the drop-in clinic were given an oral HIV test kit and four extra kits to disseminate within their social networks. Most HIV test kits were given to partners and clients. It was reported that 5 % of test disseminated by pregnant women had a positive reading and 15 % positivity in test disseminated by sex workers [41].

In sum, some small pilot studies suggest that creative dissemination strategies may significantly boost the dissemination of oral test kits to high-risk populations if those strategies can themselves be disseminated on a large scale basis. An additional area of study should be focused on methods of increasing the adoption of dissemination strategies by organizations that intersect with high-risk populations.

Adoption

Adoption of an innovation is heavily influenced by the user's perceptions of the costs and benefits of the innovation, personal need, and the degree of convenience in accessing the innovation [31] One of the benefits of oral HIV self-testing is that it is relatively painless compared to HIV testing using a finger-stick whole blood or venipuncture specimens, and therefore is highly preferred by users over these other methods of testing [28, 34]. Multiple international studies have found HIV oral self-testing to be an acceptable form of HIV testing among high-risk populations such as MSM and sex workers [28, 42]. Wood et al. reported two systematic literature reviews including 11 international studies and found overall 70 % of study participants found HIV oral self-testing to be acceptable. The highest acceptability of home HIV oral self-testing was in Malawi (92 %) with minimal performance supervision [42]. In another systematic review, that assessed the acceptability of supervised and unsupervised HIV oral self-testing among 21 studies, acceptability ranged from 74–96 % [28] In San Francisco among 50 HIV negative transgender women who were given access to oral HIV test kits, 44 utilized the kit at least once and 94 % reported ease of use [43]. Benefits of oral HIV self-testing include increased confidentiality, privacy, and reduced social stigmatization related to public or medical testing facilities [44–46].

As currently priced in the United States and most places where the oral HIV self-test may be available globally, oral HIV self-test kits pose a significant economic cost to the consumer. Considering that a large portion of the high-risk population in the USA and other countries are of low socioeconomic status, that economic barrier to adoption is critical. The retail cost of the OraQuick test ranges from $40–46 in leading US pharmacies [47]. In the 2006 Community Health Survey in New York City, most "high-risk" respondents (i.e., African-Americans, Hispanics, MSM, persons with multiple concurrent or sequential sex partners, and young adults) expressed interest in using HIV self-test kits if available; however, it was estimated that approximately half had a financial barrier to kit purchase as a large proportion of respondents were below 200 % the federal poverty level [36]. Groups with the highest prevalence of undiagnosed HIV infection are often those with low socioeconomic status [35]. In a study in New York City that sought to identify facilitators and barriers to HIV-testing among young MSM and transgender women, the cost of the oral HIV test kit was a significant barrier to uptake [48]. In a randomized controlled trial comparing HIV oral self-testing to clinic-based testing in Seattle among MSM, 46 % of participants stated they would pay $20 or less. Similarly in a study in Philadelphia, 74 % of participants were not willing to pay over $20. In Baltimore, participants were not willing to pay more than $10 for an HIV oral self-test [42].

In a Seattle study, most participants stated they would test ≥4 times per year if the test cost $5 compared to less frequently if the test cost $50 [49]. Three studies in China among high-risk individuals suggested uptake of oral HIV self-testing was dependent on pricing [50–52]. In another study in China of the 85 % of MSM who were willing to use an oral HIV self-test, the median amount for test purchase was US $8 [53]. In San

Francisco, participants reported not willing to pay more than $20 for an oral HIV self-test [43]. Those data are corroborated by a literature review of 11 articles which found that in all US studies reporting willingness to pay, there were concerns around the cost of the self-test kit. Willingness to pay in high income settings ranged from ≤$20 to ≥$50. In middle income settings willingness to pay ranged from $1 to $20 [45]. Furthermore, in another review, persons of a lower socioeconomic status preferred a free HIV self-test compared to persons of a higher socioeconomic status who were willing to pay up to US $20 [28]. Other reviews on the topic consistently identify cost as a significant barrier to HIV oral self-testing [35, 38, 42, 45].

In an international systematic literature review, multiple studies identified cost as a barrier. Cost affected the potential impact of HIV self-testing, willingness to test, frequency of testing, and purchase at the current US retail price. In a study in Spain only 17.9 % would pay the current US price for an HIV self-test [42]. In a small study in Peru among MSM and transgender women willingness to pay for oral HIV self-testing ranged from $3 to $29 with a mean of $7 [37]. In a pilot study that evaluated the acceptability and dissemination of HIV self-testing through vending machines, study participants reported not willing to pay more than $5 a kit [38]. Collectively, those studies suggest if HIV self-test were low or no cost—as are tests provided in most facilities, the uptake of HIV oral self-testing among at-risk populations might greatly increase.

In addition to costs, ease of accessibility may also impact adoption by high-risk users. As noted in our discussion of dissemination, the number of venues disseminating oral HIV test kits in environments that intersect with high-risk populations is crucial to obtaining high levels of reach. Accessibility, however, may depend on more than just having good reach. People, for instance, have to be motivated to seek out self-testing, even if it is highly available.

Implementation

HIV self-testing is useful a public health strategy to increase case identification only if target populations can implement it with fidelity. Implementation fidelity [29] as used here refers to the ability of users (or providers) to perform all core procedures and perform them competently (compliance and competence fidelity). As with most public health programs oral HIV self-testing may require adaptations of the kit, specifically instructional materials, to fit the specific needs of the target population (e.g., language, culture, and literacy). That process of adaptation requires that changes be made to key components of the test kit without jeopardizing implementation fidelity.

In this section, we review studies examining people's ability to self-administer oral HIV self-tests and suggest a general conceptual approach for organizing further research in this area. The majority of this research has been conducted with OraSure's self-test kit, OraQuick. OraQuick is a self-implemented HIV testing program (other public health examples include self-implemented pregnancy testing and malaria-mosquito net programs [54–57]). The success of translating self-implemented public health programs to diverse population segments depends, in part, on identifying efficacious training approaches to self-implementation.

OraQuick users are trained through printed instructions and an online video; instructions address correct use of testing materials, how to interpret results, and contraindications (linkage-to-care and related topics are also covered but are not the subject of this review). Self-implementation steps include swabbing upper and lower gums once with a specimen stick, opening a test tube without spilling the contents, correctly placing the specimen stick into a test tube, waiting at least twenty but not more than forty minutes, and then reading and interpreting the test results that appear on the specimen stick. Pre-testing contraindications (e.g., not eating 30 min prior to testing) add another implementation layer to test fidelity.

The earliest fidelity work with OraQuick was conducted by OraSure during the FDA approval process. In their studies most participants understood the procedural instructions, and executed them properly (<2 % failure) [58]. The major flaw with that work, as with all other studies examining self-testing fidelity, is that it was based on convenience samples of participants of unknown generalizability to the larger at-risk populations. Further, although those trials have examined self-testing fidelity for some high-risk groups (e.g., MSM); other at-risk populations are poorly represented (e.g., African-American youth in low-income urban areas).

Subsequent studies provide mixed results suggesting that, although a majority of people in literate societies probably can perform the OraQuick test with high fidelity given current training tools [59, 60], there remains a segment for whom there are challenges. For instance, Hurt and Powers [61] observed that the sensitivity for OraQuick was lower in the hands of US adult users than when administered by a trained provider (92.9 vs. 99.3 %), providing evidence that there remain challenges translating oral self-testing even to a literate public [62]. Furthermore, in a study in New York City, young MSM and transgender women expressed concerns around correct test operation and identified proper instruction as a facilitator for oral HIV self-test uptake [48].

A number of fidelity studies have focused on particular sources of performance error. A study conducted in Singapore by Ng et al., found that participants had difficulties reading the OraQuick results stick, and, in particular, had challenges correctly interpreting a negative result (approximately 7 % error; $n = 994$) [63]. Marley et al., also conducted work in China, found that non-OraQuick oral testing kits were

associated with difficulties swabbing correctly (10 %; $n=229$), and challenges reading results correctly (17.5 %) [64]. Although those studies point to specific errors, they do not describe the sources of user error.

Peck et al. (2014) evaluated a multi-method set of instruction materials in an oral self-testing study conducted with adults in Kenya, Malawi, and South Africa. Participants were given materials with graphic and written instructions in English and the local language. Despite a multi-method approach, only 25 % ($n=150$) of participants were able to correctly perform each step of the self-test, and 47 % made multiple errors throughout the testing process. Investigators determined that the instructions needed further adaptation for low-literacy participants [65]. The question remains, however, as to what precisely needs adaptation. To address that problem investigators need to turn to qualitative and simulation studies that lend themselves to teasing apart the instructional components in systematic ways. Missing from current research is a conceptual framework for organizing research in this area. Translation theorists concerned with adaptation issues offer a conceptual framework that may be applied to the study of strategies for adapting oral HIV self-testing to diverse consumer populations [34]. A key concept in this regard is program fit.

The problems in achieving good fit between the current HIV oral testing product and at-risk populations in the USA and abroad are not necessarily unique to the specific product. Best practices for performing self-implemented programs with high fidelity are, in general, not well researched. Implementation of the FDA-approved at-home pregnancy test provides an instructive example. Although those tests have been sold for over 40 years, and clinical trials research suggested at-home pregnancy tests could be implemented with high fidelity, subsequent studies provide convincing evidence that various population segments continue to have significant challenges with implementing at-home pregnancy tests [54, 66–68]. Both HIV self-testing and at-home pregnancy testing require that program features fit the diverse populations that may use them. That type of translation research underscores the need for phase 3 studies, as highlighted in Glasgow et al.'s implementation framework [69], that involve research directed at understanding uptake and implementation of evidence based programs or technology in everyday settings across diverse populations.

The translation of self-testing to diverse populations requires that the "program," particularly the instructional materials, fit key characteristics of the population [34]. Good program "fit" occurs when program components are aligned with the psychological (e.g., cognitive abilities, task relevant experiences, and health beliefs), socio-cultural (e.g., social class, language, sexual orientation, and ethnicity/race), and environmental (e.g., privacy and technology access) characteristics of the target population. Poor fit is hypothesized to lead to low fidelity (e.g., procedural errors in self-testing). Despite recognition of the need for adaptation strategies that address program fit [1, 70], research in this area is limited. Several HIV-prevention studies have shown that poor program-client fit results in low fidelity [71–75] but few studies to date have examined self-implemented programs.

Achieving good fit between the instructional components of the OraQuick HIV test requires that the instructional materials be evaluated with regard to performance fidelity in high-risk populations that may differ in significant psychological, socio-cultural, and environmental ways. Prior translational studies have been significantly limited in the breadth of adaptation-fit factors examined. For instance, OraQuick has been primarily evaluated in its English and Spanish instructional forms that are not relevant to populations in some countries hardest hit by HIV (e.g., Tanzania, Kenya, and South Africa). Attention to translating key concepts to other languages is also limited. For instance, in the Peck et al., study (2014) it is unclear if the low fidelity observed is due to challenges in translating self-testing concepts to "local languages" or to limited experience by participants with these types of materials [65]. The kits have also not been adapted for individuals with limited levels of education or for those with lower incomes who may have poor access to computer technology (i.e., the training video is available only through the Internet). Hunn et al have conducted work indicating that pictorial instructions may have some utility with low-literacy populations (in Tanzania) [76], although we also note that Peck et al did not achieve a very good result with graphic representations combined with other strategies [65]. Research is needed on the particulars of these approaches if we are to move beyond simple "guess work".

Qualitative research may be useful in this regard. For instance, recent qualitative work with low-income urban African-American youth [34] found that these youth perceive the OraQuick's written instructions to be overly complex and difficult to understand. Work underway is expanding those observations using mixed-method simulations to evaluate specific challenges with written OraQuick instructions and mediators of these challenges.

Conclusion

HIV self-testing provides a novel and currently severely underutilized supplement to facility-based testing. Facility-based testing for HIV infection has advantages which may include the use of more sensitivity assays, on-site counseling and face-to-face linkage-to-care or prevention services. However, it is important to emphasize HIV self-testing has the potential to be an effective option for at-risk populations who would otherwise infrequently or never test for HIV infection using currently available services. Globally, HIV

self-testing has been shown to be an acceptable and feasible addition to facility-based testing across low, middle, and high income settings, racial/ethnic backgrounds, and transmission risk groups [35, 38, 44, 45, 77]. Although HIV self-testing is widely acceptable, there are critical gaps in the process of dissemination, adoption, and implementation.

Current literature suggests the market for HIV self-tests is extensive. However, significant challenges exist due to the high kit cost, low market competition, and non-user friendly instructional material which may adversely affect oral HIV self-test kit dissemination and adoption [78]. Among most studies in this literature review evaluating HIV self-test uptake, cost was one of the most significant barriers to test utilization. Offering HIV self-tests through private and public insurance programs may be an effective strategy to increase uptake among at-risk populations. Integrating HIV self-test kits into biomedical intervention programs for HIV-uninfected persons such as post or pre exposure prophylaxis may provide a method for increased status awareness among persons who engage in high-risk behaviors.

To date, few studies and public health programs have rigorously evaluated non-conventional distribution strategies (e.g., vending machines, vouchers, postal delivery, and online sales) of oral HIV self-test kits among at-risk populations. Further research is urgently needed to identify innovative testing strategies across socioeconomic settings and cultural backgrounds. Developing collaborations between local public health departments, community-based organizations and pharmacies in areas with high HIV prevalence may increase infrastructure (e.g., access, resources, consumer training, and HIV-case surveillance) consequently improving HIV self-test uptake and impact. Public health departments can provide HIV care coordination referrals to ensure timely linkage to care and treatment.

Moreover, there are significant challenges in the implementation of oral HIV self-testing kits as there are differences in test performance obtained by trained compared to untrained testers [61]. Studies evaluating test sensitivity among trained and untrained testers varied across high and low-income settings [28]. Hence the development of adaptable, easy to use and interpretable instructional materials is important. Those materials should be tested in high and low-income settings to be validated for adaptability. Lastly, public health departments can implement a train-the-trainer model for staff members in community-based organizations that can go back to their agency and train consumers as well as other staff on how to perform the test correctly and interpret results. Implementation fidelity is a critical component of HIV self-test implementation.

In an effort to draw closer to the introduction of HIV self-testing in national testing programs, in collaboration with the World Health Organization, Population Services International is currently piloting the largest HIV self-test study to date. That 2-year study will disseminate 2.7 million oral HIV self-test kits in Malawi, Zimbabwe, and Zambia with the goal of increasing access, market demand and address strategic and structural barriers. Those data will be used to provide guidance and technical support to global entities integrating HIV self-testing into national policies [79].

The potential for HIV self-testing uptake is great; recent studies have begun to inform critical gaps in our knowledge base. Using the categories of adoption, dissemination and implementation provides a needed framework for future research.

Compliance with Ethical Standards

Conflict of Interest Kristecia Estem, Joe Catania, and Jeffrey D. Klausner declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

References

1. Chang LW et al. Combination implementation for HIV prevention: moving from clinical trial evidence to population-level effects. Lancet Infect Dis. 2013;13(1):65–76.
2. Obama BH. The white house office of national HIV/AIDS Policy. National HIV/AIDS strategy for the United States. 2010. Retrieved from https://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf.
3. Vermund SH et al. Can combination prevention strategies reduce HIV transmission in generalized epidemic settings in Africa? The HPTN 071 (PopART) study plan in South Africa and Zambia. J Acquir Immune Defic Syndr. 2013;63 Suppl 2:S221–7.
4. Kulkarni SP et al. Clinical uncertainties, health service challenges, and ethical complexities of HIV "test-and-treat": a systematic review. Am J Public Health. 2013;103(6):e14–23.
5. Bradley H, et al. Morbitidy and Mortality Weekly Report. 2014, Centers for Disease Control and Prevention. p. 1113–1117.
6. Wejnert C et al. HIV infection and awareness among men who have sex with men—20 cities, United States, 2008 and 2011. PLoS One. 2013;8(10):e76878.
7. Marks G et al. Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs. J Acquir Immune Defic Syndr. 2005;39(4):446–53.
8. Viall AH, et al. Results of the expanded HIV testing initiative-25 jurisdictions, United States, 2007–2010. Morb Mortal Wkly Rep [serial on the Internet] 2011;60, June 24. Available from: http://www.cdc.gov/mmwr/PDF/wk/mm6024.pdf.
9. Fortenberry JD et al. Relationships of stigma and shame to gonorrhea and HIV screening. Am J Public Health. 2002;92(3):378–81.
10. Hightow-Weidman LB. Missteps, misunderstandings, and missed opportunities: HIV testing among young African-Americans. Sex Transm Dis. 2009;36(9):592–3.
11. Hyden C, Allegrante JP, Cohall AT. HIV testing sites' communication about adolescent confidentiality: potential barriers and facilitators to testing. Health Promot Pract. 2014;15(2):173–80.
12. Johns MM, Bauermeister JA, Zimmerman MA. Individual and neighborhood correlates of HIV testing among African-American

youth transitioning from adolescence into young adulthood. AIDS Education and Prevention. 2010;22(6):509–22.
13. Joseph HA, Fasula AM, Morgan RL, Stuckey A, Alvarez ME, Margolis A, et al. "The anticipation alone could Kill You": past and potential clients' perspectives on HIV testing in non-health care settings. AIDS Education and Prevention. 2011;23(6):577.
14. Peralta L et al. Barriers and facilitators to adolescent HIV testing. AIDS Patient Care STDS. 2007;21(6):400–8.
15. Hamel L, Firth J, Hoff T, Kates J, Levine S, Dawson L. HIV/AIDS in the lives of gay and bisexual men in the United States. Henry J. Kaiser Family Foundation. 2014.
16. Zanoni BC, Mayer KH. The adolescent and young adult HIV cascade of care in the United States: exaggerated health disparities. AIDS Patient Care STDS. 2014;28(3):128–35.
17. Trepka MJ, Kim S. Prevalence of human immunodeficiency virus testing and high-risk human immunodeficiency virus behavior among 18 to 22-year-old students and nonstudents: results of the National Survey of Family Growth. Sex Transm Dis. 2010;37(10): 653–9.
18. Hall HI et al. Estimating the lifetime risk of a diagnosis of the HIV infection in 33 states, 2004–2005. J Acquir Immune Defic Syndr. 2008;49(3):294–7.
19. Centers for Disease Control and Prevention. HIV surveillance report. http://www.cdc.gov/hiv/pdf/statistics_surveillance_report_vol_22.pdf. (2010) vol 22. Accessed 8 Aug 2015.
20. Swenson RR et al. Prevalence and correlates of HIV testing among sexually active African-American adolescents in 4 US cities. Sex Transm Dis. 2009;36(9):584–91.
21. Chen M, Rhodes PH, Hall IH, Kilmarx PH, Branson BM, Valleroy LA. Prevalence of undiagnosed HIV infection among persons aged= 13 years—National HIV Surveillance System, United States, 2005–2008. 2012. MMWR 15 Jun 2013;61 Suppl:57–64.61(02), 57-64.
22. Whitmore SK, Kann L, Prejean J, Koenig LJ, Branson BM, Hall HI, et al. Vital signs: HIV infection, testing, and risk behaviors among youths—United States. Am J Transplant. 2013;13(2):510–515.
23. Centers for Disease Control and Prevention. CDC Fact Sheet. HIV testing in the United States. 2015. http://www.cdc.gov/nchhstp/newsroom/docs/factsheets/hiv-testing-us-508.pdf. Accessed 8 Aug 2015.
24. Catania J. Dissemination of at-home HIV testing to high-risk urban African American youth: barriers and solutions. In: 141st APHA Annual Meeting: Boston. 2013.
25. Dolcini M, Catania JA, Gandelman A. Translating research into practice: the influence of organizational and client factors on fidelity of an evidence-based program. New Orleans, Louisiana: Annual meeting of the Society of Behavioral Medicine; 2012.
26. Mavedzenge SN, Baggaley R, Corbett EL. A review of self-testing for HIV: research and policy priorities in a new era of HIV prevention. Clin Infect Dis. 2013;57(1):126–138.
27. Meyerson BE, Ryder PT, von Hippel C, Coy K. We can do more than just sell the test: pharmacist perspectives about over-the-counter rapid HIV tests. AIDS Behav. 2013;17(6):2109–2113.
28. Pai NP, Sharma J, Shivkumar S, Pillay S, Vadnais C, Joseph L, et al. Supervised and unsupervised self-testing for HIV in high-and low-risk populations: a systematic review. PLoS Med. 2013;10(4): e1001414.
29. Fixsen DL, Naoom SF, Blase KA, Friedman RM. Implementation research: a synthesis of the literature. 2005. Available at: http://nirn.fpg.unc.edu/resources/implementation-research-synthesis-literature.
30. Ogden T, Fixsen D. Implementation science: a brief overview and look ahead. Z Psychol. 2014;222:4–11.
31. Wisdom JP, Chor KHB, Hoagwood KE, Horwitz SM. Innovation adoption: a review of theories and constructs. Administration and Policy in Mental Health and Mental Health Services Research. 2014;41(4):480–502.
32. Bronson H. Self testing initiatives. Conference on Retroviruses and Opportunistic Infections. Presentation, 2015.
33. Marlin RW, et al. Piloting an HIV self-test kit voucher program to raise serostatus awareness of high-risk African-Americans, Los Angeles. BMC Public Health. 2014;14:1226.
34. Catania JA, et al. Bridging barriers to clinic-based HIV testing with new technology: translating self-implemented testing for African-American youth. Transl Behav Med, 2015: p. 1-12
35. Myers JE et al. Rapid HIV self-testing: long in coming but opportunities beckon. AIDS (London, England). 2013;27(11): 1687–95.
36. Myers J. HIV testing in New York City, in Conference on Retroviruses and Opportunistic Infections. 2015.
37. Bustamante MJ, Konda KA, Joseph Davey D, León SR, Calvo GM, Salvatierra J, Brown B, Caceres CF, Klausner JD. HIV self-testing in Peru: questionable availability, high acceptability but potential low linkage to care among men who have sex with men and transgender women. Int J STD AIDS. 2016. doi:10.1177/0956462416630674.
38. Young SD et al. Acceptability of using electronic vending machines to deliver oral rapid HIV self-testing kits: a qualitative study. PLoS One. 2014;9(7):e103790.
39. Klausner JD. Innovations in HIV self testing delivery. Presentation presented at: Conference on Retroviruses and Opportunistic Infections 2015. Seattle, WA. 2015. http://www.hivst.org/directory-list/2015/4/8/innovations-in-hiv-self-testing-delivery-vending-machines-vouches-and-us-mail. Accessed 10 Aug 2015.
40. Katz D, Golden M, Hughes J, Farquhar C, Stekler J. HIV self-testing increases HIV testing frequency among high-risk men who have sex with men: a randomized controlled trial. Eighth Conference on HIV Pathogenesis, Treatment and Prevention. Vancouver, Canada. Abstract MOPDC0103. 2015. http://www.natap.org/2015/IAS/IAS_08.htm. Accessed 10 August 2015.
41. Thirumurthy H et al. Acceptability and feasibility of a novel approach to promote HIV testing in sexual and social networks using HIV self-tests. Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention. Vancouver, Canada. Abstract MOAC0302LB, 2015. 2015. http://www.aidsmap.com/HIV-self-testing-may-help-the-hard-to-reach-learn-their-status-but-uncertainties-remain/page/2988143/. Accessed 10 August 2015.
42. Wood BR, Ballenger C, Stekler JD. Arguments for and against HIV self-testing. HIV/AIDS. 2014;6:117–26.
43. Lippman S et al. Home HIV testing among transgender women in San Francisco: a pilot feasibility and acceptability study. Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Vancouver, Canada. Abstract MOPDC0104, 2015. http://www.aidsmap.com/HIV-self-testing-may-help-the-hard-to-reach-learn-their-status-but-uncertainties-remain/page/2988143/. Accessed 10 August 2015.
44. Krause J, Subklew-Sehume F, Kenyon C, Colebunders R. Acceptability of HIV self-testing: a systematic literature review. BMC public health. 2013;13(1):1.
45. Figueroa C et al. Attitudes and acceptability on HIV self-testing among key populations: a literature review. AIDS Behav. 2015;19(11):1949–65.
46. Petroll AE et al. HIV testing rates, testing locations, and healthcare utilization among urban African-American men. Journal of urban health : bulletin of the New York Academy of Medicine. 2009;86(1): 119–31.
47. OraSure Technologies. Where to buy. 2015. http://www.oraquick.com/where-to-buy. Accessed 8 August 2015.
48. Frye V et al. Just because it's out there, people aren't going to use it. HIV self-testing among young, black MSM, and transgender women. AIDS Patient Care STDS. 2015;29(11):617–24.
49. Katz DA, Golden M, Hughes J, Farquhar C, Stekler J. Acceptability and ease of use of home self-testing for HIV among men who have sex with men. Conference on Retroviruses and Opportunistic Infections

2012. Seattle, WA. http://www.hivforum.org/storage/documents/_2012NationalSummit_Posting/a_044_katz.pdf. Accessed 9 Aug 2015.
50. Li J et al. Analysis on willingness to pay for HIV antibody saliva rapid test and related factors. Chinese J Epidemiol. 2015;36(2):132–5.
51. Xun H et al. Factors associated with willingness to accept oral fluid HIV rapid testing among most-at-risk populations in China. PLoS One. 2013;8(11):e80594.
52. Han L et al. HIV self-testing among online MSM in China: implications for expanding HIV testing among key populations. J Acquir Immune Defic Syndr. 2014;67(2):216–21.
53. Xu Y et al. Willingness to use the oral fluid HIV rapid test among men who have sex with men in Beijing, China. PLoS One. 2013;8(5):e64652.
54. Nettleman MD, Brewer JR, Ayoola AB. Self-testing for pregnancy among women at risk: a randomized controlled trial. Am J Prev Med. 2009;36(2):150–3.
55. Plappally A, Chen H, Ayinde W, Alayande S, Usoro A, Friedman KC, et al. A field study on the use of clay ceramic water filters and influences on the general health in Nigeria. J Health Behav Pub Health. 2011;1(1):1–14.
56. Ouattara AF et al. Transmission of malaria in relation to distribution and coverage of long-lasting insecticidal nets in central Côte d'Ivoire. Malar J. 2014;13:109.
57. Kyu HH et al. Evaluation of the association between long-lasting insecticidal nets mass distribution campaigns and child malaria in Nigeria. Malar J. 2013;12:14.
58. Epstein J. Food and Drug Administration. OraQuick in-home HIV test. Summary of Safety and Effectiveness. 2012. http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM312534.pdf. Accessed 1 Aug 2015.
59. Gaydos CA et al. Use of tablet-based kiosks in the emergency department to guide patient HIV self-testing with a point-of-care oral fluid test. Int J STD AIDS. 2013;24(9):716–21.
60. Nour S et al. Patients can accurately perform their own rapid HIV point-of-care test in the emergency department. Point of Care. 2012;11(4):176–9.
61. Hurt CB, Powers KA. Self-testing for HIV and its impact on public health. Sex Transm Dis. 2014;41(1):10–2.
62. Catania JA et al. Translation of "at-home" HIV testing: response to Katz et al. and Hurt and Powers. Sex Transm Dis. 2014;41(7):454.
63. Ng OT et al. Accuracy and user-acceptability of HIV self-testing using an oral fluid-based HIV rapid test. PLoS One. 2012;7(9):e45168.
64. Marley G et al. Introducing rapid oral-fluid HIV testing among high risk populations in Shandong, China: feasibility and challenges. BMC Public Health. 2014;14:422.
65. Peck R et al. What should the ideal look like? Study of test prototypes in unsupervised HIV self-testing in Kenya, Malawi, and South Africa. AIDS Behav. 2014;18:422–32.
66. Bastian LA et al. Diagnostic efficiency of home pregnancy test kits. A meta-analysis. Arch Fam Med. 1998;7(5):465–9.
67. Hicks JM, Iosefsohn M. Reliability of home pregnancy-test kits in the hands of laypersons. N Engl J Med. 1989;320(5):320–1.
68. Wallace LS, Zite NB, Homewood VJ. Making sense of home pregnancy test instructions. J Womens Health (Larchmt). 2009;18(3):363–8.
69. Glasgow RE, et al. Comparative effectiveness research to accelerate translation: recommendations for an emerging field of science. 2012:72–93.
70. Marshall BDL, Wood E. Toward a comprehensive approach to HIV prevention for people who use drugs. J Acquir Immune Defic Syndr. 2010;55(Suppl 1):S23–6.
71. Catania JA, Dolcini MM, Gandelman A, Narayanan V, McKay V. Impact of the economic downturn on HIV/STI prevention program fidelity. Translational Behavioral Medicine: Practice, Policy and Research. 2014;4:34–45.
72. Dolcini MM, Gandelman AA, Vogan SA, Kong C, Leak TN, King AJ, et al. Translating HIV interventions into practice: community-based organizations' experiences with the diffusion of effective behavioral interventions (DEBIs). Social Science & Medicine. 2010;71(10):1839–1846.
73. Gandelman A, Dolcini MM. The influence of social determinants on evidence-based behavioral interventions—considerations for implementation in community settings. Translational Behavioral Medicine. 2012;2(2):137–148.
74. Remien RH et al. Adherence to medication treatment: a qualitative study of facilitators and barriers among a diverse sample of HIV+ men and women in four US cities. AIDS Behav. 2003;7(1):61–72.
75. Veniegas RC, Kao UH, Rosales R. Adapting HIV prevention evidence-based interventions in practice settings: an interview study. Implement Sci. 2009;4:76.
76. Hunn C, Catania J, Dolcini MM, McKayV,Ndyetabula A, Ndyetabula C. Adaption of a self implemented HIV test among adolescent youth in Tanzania. San Antonio, TX: Society for Behavioral Medicine; 2015.
77. Grinsztejn B et al. Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: results from the phase 3 HPTN 052 randomised controlled trial. Lancet Infect Dis. 2014;14(4):281–290.
78. Johnson C et al. Realizing the potential for HIV self-testing. AIDS Behav. 2014;18 Suppl 4:S391–5.
79. Hatzold K. Stimulating and shaping the market for HIV self-testing in Africa UNITAID/PSI HIV STAR Project. Presentation presented at The Bill and Melinda Gates Foundation. 2015. Available at: http://www.hivst.org/directory-list/2015/3/30/stimulating-and-shaping-the-market-for-hiv-self-testing-in-africa-unitaidpsi-hiv-star-project. Accessed 5 August 2015.