HHS Public Access

Author manuscript

Curr HIV/AIDS Rep. Author manuscript; available in PMC 2022 March 11.

Published in final edited form as:

Curr HIV/AIDS Rep. 2020 August ; 17(4): 281–289. doi:10.1007/s11904-020-00504-3.

The evidence for HIV self-testing to increase HIV testing rates and the implementation challenges that remain

Elizabeth A. Kelvin, PhD, MPH,

Department of Epidemiology and Biostatistics, CUNY Graduate School of Public Health and Health Policy, CUNY Institute for Implementation Science in Population Health, City University of New York, 55 West 125th Street, New York, NY 10027

Bridget Akasreku, MPH

Department of Community Health and Social Sciences, CUNY Graduate School of Public Health and Health Policy City University of New York, 55 West 125th Street, New York, NY 10027

Abstract

Purpose of Review—We describe the evidence regarding the impact of offering HIV self-testing (HIVST) and explore the gaps that need to be filled to design and implement HIVST programs.

Recent Findings—Numerous randomized controlled trials found that offering HIVST increases HIV testing rates. However, these trials used an oral HIVST that was provided for free and there is no research examining the impact of offering blood-based (finger-prick) kits or charging for HIVST kits. The trials also used various methods for distributing the HIVST kits but there is little research comparing distribution methods. Study participants varied in the HIV testing method they chose when given choices, suggesting that offering multiple HIV testing options may be needed to maximize testing rates.

Summary—Despite the consistent finding that offering HIVST increases HIV testing rates, questions remain that need to be answered in order to maximize the potential of this new biomedical technology.

Keywords

HIV; HIV self-testing; implementation science

corresponding author: elizabeth.kelvin@sph.cuny.edu.

Conflict of Interest: Elizabeth A. Kelvin and Bridget Akasreku declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent
The work presented in this article did not involve human or animal subjects.

Introduction

In 2014, the United Nations announced its 90-90-90 targets: by 2020 (1) 90% of all people living with HIV will know their HIV status, (2) 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy, and (3) 90% of all people receiving antiretroviral therapy will have viral suppression [1]. Achieving targets two and three hinge on reaching the first target. It is now the year 2020, and current estimates suggest that only 79% of those HIV-infected world-wide know their status [2]. Clearly more work is needed to increase testing rates, especially among some of the highest risk groups that often face discrimination, such as sex workers, men who have sex with men (MSM) and intravenous drug users, that are hard to reach with traditional HIV testing services [3].

HIV self-testing (HIVST) may be a way to reach those not testing regularly under traditional HIV testing programs and may address the stigma associated with being seen in a testing clinic [4]. The privacy and confidentiality associated with self-testing may also address important barriers [4], especially for groups that experience discrimination [5]. A 2016 systematic review and meta-analysis found that self-administering and interpreting a rapid HIV test was as accurate as provider-administered testing [5], and in 2016 the World Health Organization (WHO) recommended that HIVST be offered as an additional approach to HIV testing services, rating their recommendation as strong and based on moderate quality evidence [5]. However, uptake of any new biomedical technology hinges on human preferences and behavior and the research to date leaves many questions about how to best incorporate HIVST into current testing programs in ways that optimize its potential to increase testing rates. In this paper we review some of the research and highlight those questions and their implications for HIVST roll-out.

Randomized trials evaluating the impact offering HIV self-testing has on HIV testing rates

A number of randomized controlled trials (RCTs) in various countries and population groups have evaluated the impact of offering HIVST (see table 1). Almost all the HIVST RCTs found significantly higher HIV testing rates when HIVST was offered. However, the HIVST trials all offered a free oral swab HIVST, and thus we have little information about the potential impact of other HIVST kits or about the impact of selling kits for a fee. In addition, the findings from these HIVST trials actually make it hard to determine if the increased test uptake associated with HIVST was due to the self-administration aspect of the test, the ability to test at home instead of in a clinic, the use of an oral swab instead of blood, or because of how the test was offered. For example, in the three studies among truck drivers and female sex workers (FSWs) in Kenya, those in the intervention arm were offered choices among (1) the blood-based provider-administered standard of care (SOC) test, (2) an oral HIVST kit for use in the clinic with supervision, or (3) the oral HIVST kit to take for home use. The increased HIV test uptake in the intervention arm might be due to preference for a self-administered HIV test, but it could also be due to preferences for an oral test, preference for home-based testing over clinic-based, or because, when offering testing choices, the question posed to clients changes from “would you like an HIV test?” to “which HIV

test would you like?"[6–8]. In the Zambia and Uganda trials among FSWs, peer educators gave women the oral HIVST kits (intervention) or information about accessing clinic-based provider testing (SOC) [9, 10]. Again, it could be that the increased HIV testing uptake in the intervention group was due to the method of testing (self- administration versus provider-administration), or oral versus blood (the test usually available at testing clinics is blood-based), or mode of test distribution (i.e. from a peer you see during daily activities or from a clinic worker you need to go out of your way to see). If, for example, the peer educators offered to administer the standard HIV test so people did not need to travel to a clinic for testing, the outcome may have been more similar between the groups. Thus the HIVST RCTs to date do not allow us to determine what characteristics of the oral HIVST made it preferred over the SOC.

A discrete choice experiment (DCE), a method used to identify preferred attributes of a product or service, conducted among Kenyan truck drivers participating in one of the RCTs described above found that there were no strong feelings about who administered the HIV test (provider or self), but that there were preferences regarding the biological specimen and type of counseling and that those preferences varied by HIV testing history. Among those who had never tested, there was a preference for oral over blood tests and for phone counseling rather than in-person counseling, while among those who had tested before there was no preference between oral or blood and a preference for in-person counseling [11]. In a DCE with female and male participants in the Uganda antenatal RCT, there was a significant preference for oral over blood-based HIV testing and a preference for nurse-administered over self-administered testing [12]. Other studies suggest that some have more trust of blood-based HIV tests to give accurate results [5, 13], and a South Africa study that made both the OraQuick oral swab and Atomo blood-based HIVST kits available to MSM found that about two thirds chose the blood over the oral HIVST kit [14]. However some people do not like the pain associated with needles and prefer an oral swab test [5]. Randomized trials are needed that allow us to identify the aspects of oral HIVST that drive the consistent increase in testing rates. If the driving factor is that people prefer an oral HIV test, that has implications for designing the optimal HIV testing program as provider-administered oral testing could be rolled-out, but we cannot know this from the research to date.

Furthermore, HIVST can be conducted in the clinic with provider supervision or at home with remote support for questions, counseling and referrals. The studies in Kenya among truck drivers and FSWs found that, when offered choices between SOC HIV testing and HIVST, a sizeable proportion still choose the SOC test (25–40%), and among those who chose HIVST, the majority chose to self-test in the clinic with provider supervision (≈70%) [6, 8, 15]. The Zambian door-to-door study found similar variation in the testing option selected among those offered choices between provider-administered testing, supervised self-testing and unsupervised self-testing [16]. These studies suggest that people differ in which test they chose when offered choices and the optimal HIV testing program might be one that offers a variety of options. Again, this idea of offering multiple HIV testing choices (i.e. provider-administered oral and blood test and self-administered oral and blood tests) has not been tested so we do not know the optimal number or combination of testing options needed to maximize uptake.

National HIV self-testing policies

With the preponderance of evidence from numerous RCTs suggesting that adding HIVST to HIV testing programs will increase testing rates in diverse population groups, the number of countries coming-out with established policies on HIV self-testing is increasing rapidly, from 59 in 2018 [17] to 77 in 2019 [18]. However, implementation of those policies has been slow, estimated at only 28 countries in 2018 [17]. This gap between policy establishment and implementation is to be expected because it takes time to operationalize the new policy, including budgeting, securing funding, selecting, licensing and obtaining products, and determining how to incorporate the new product into the supply chain system for distribution. In some countries, pilot and demonstration projects are planned before country-wide roll-out [17]. However, the lack of implementation science research to guide the design of HIVST integration into current HIV testing programs in a way that maximizes impact efficiently is a challenge. As described above, the trials show that HIVST can increase testing rates, but do not provide adequate information allowing for decisions regarding which test kits to offer, how to distribute them, or pricing, nor ways to ensure linkage to care. The designers of HIVST programs need to make decision regarding these factors but they are doing so in a vacuum.

HIVST kit variation

As described above, most research on HIVST has focused on the oral-swab test, with little information about the acceptability, uptake, and ease of use of blood-based HIVST kits. To date, one HIVST kit has been preapproved by WHO (OraQuick® HIV Self-Test), which uses an oral swab specimen. However, four blood-based (finger-prick) HIVST kits have been approved by the Expert Review Panel for Diagnostics (ERPD) (Atomo HIV Self-Test, BioSURE HIV Self-Test, INSTI® HIV Self-Test, SURE CHECK® HIV Self-Test), which provides temporary, time-limited eligibility for procurement by major international funders of HIV programs prior to a WHO prequalification determination. Three additional test kits have national approvals, including OraQuick® In-Home HIV Test, which is similar to the WHO prequalified OraQuick® HIV Self-Test but with a different packaging for marketing in the US, and the blood-based Autotest VIH® and Exacto® Test HIV tests, which are available in Europe [17].

While the availability of multiple HIVST kits may lead to competition and price reduction, it also creates challenges in designing HIVST programs. HIVST kits vary not only in terms of the biological specimen used (blood or oral swab), but also in the number of components in the kit, the complexity of kit administration, and time to results. For example, three HIVST kits were approved for use in Kenya: OraQuick® HIV Self-Test (OraQuick), Atomo HIV Self-Test (Atomo) and INSTI® HIV Self-Test (INSTI) [19]. OraQuick uses an oral swab sample, the kit includes three parts and administration involves four steps and requires a 20 minute wait before results are ready [20]. Atomo uses a blood sample from a finger prick, the kit includes two parts, administration involves four steps and it requires a 15 minute wait for results [21]. INSTI also uses blood from a finger prick but the kit is a bit more complicated, including six parts and more than ten steps for administration, but results are available immediately upon completing the final step so there is no wait [22]. Organizations

aiming to incorporate HIVST into their programs need information about which test kits would be preferred by their clients. Some may have preferences regarding biological specimen, wait time for results, and some may be uncomfortable self-administering some of the more complicated test kits. It is also likely that these preferences will not be the same across all clients and some may prefer one test kit while others prefer a different kit. Offering choices among multiple kits may be the best way to maximize uptake. But with so many different test kits currently available or becoming available in the future, it is probably unfeasible to offer all options in a testing program and therefore research is needed to help providers make the best choices for the populations they serve.

HIVST kit distribution options

There are many different possible approaches for distributing HIV self-testing, which can include distribution through healthcare facilities, work places or schools, retail venues such as pharmacies or vending machines, community-based distribution, which could be in-person (i.e. door-to-door) or through the mail, as well as secondary distribution mechanisms through peers, partners or other social networks [17]. Which distribution method is best will likely vary by target population.

The self-testing trials to date have distributed test kits directly through clinics [6–8], indirectly through clinics via coupons [9, 10], door-to-door [23], through peer educators [9, 10], partners [24–26], and by mail [27–29], but there has been little research comparing distribution methods to identify the most effective options. The one exception are the trials in Zambia and Uganda among FSWs which found that direct provision of HIVST kits by peer educators was more effective than offering coupons to access HIVST kits from healthcare facilities [9, 10]. While not a trial, one study did offer HIV self-test kits in pharmacies in Kenya for the price of $1 US. The study found that most who agreed to self-test had come to the pharmacy specifically to access HIV testing (84% versus 11% who had not come for testing). The study also found that among those who self-tested, 34% did so while still in the pharmacy, where help was presumably available, which is similar to supervised self-testing, while 66% took the test kit to use elsewhere. Only 4% of customers who refused HIV self-testing stated they could not afford the cost [30]. However, we should note that HIVST kits in low-income countries like Kenya are expected to cost $7-$12 US [17], much more than what was charged in the study. Counterfeit drugs sold in pharmacies in Africa may make pharmacy-distribution a challenge if people mistrust the products they sell [31]. In the US, the FDA approved OraQuick® In-Home HIV Test is available at pharmacies for in-store or online purchase [32]. The price online varies but seems to fall within the upper level of the published range for developed countries of $20-$48 US [17]. Even in the US this cost is likely prohibitory for many.

Charging fees for HIVST kits

Studies suggest that HIVST needs to be free or low cost, although the specific findings vary by population. Using DCE methodology, a study in Zambia suggests that people who had tested recently were willing to pay $3.30 US for a test kit, while those who had not tested recently were willing to pay more, at $4.60 US, presumably because self-testing has

some attributes that overcome the barriers that prevented these people from testing under the currently available program [17]. A DCE among women in antenatal care and their male partners in Uganda found that the cost of testing had the biggest effect on preferences, with free testing being preferred over a cost of $2.00 or $2.90 US. Offering an incentive of $3.40 US was preferred by men over free testing but not by women [12]. Another DCE among male truck drivers in Kenya found that there was a strong preference for HIV testing to be free of cost over the charge of a small fee and free testing was even preferred over receiving payment to test [11]. As that study was among truck drivers who have middle-income employment in the formal sector, it suggests that even among some who can pay for an HIVST kit, there may be reluctance to do so. The long tradition of free HIV testing services may have created a norm that will be difficult to overcome, and charging for HIVST kits may limit the potential impact of this new testing modality. In fact, a meta-analysis of qualitative research identified cost as an important potential barrier to HIVST uptake and most study participants felt that HIVST should be free of charge, subsidized by the government as traditional HIV testing services are in many countries [4]. As described above, HIVST kits are being sold at retail for $7-$12 US in low-income countries and for $20-$48 US in high-income countries [17]. In the trial among MSM in the US, Only 42% said they would pay $20+ US, and 12% would only use a HIVST if it were free [29]. Thus in low and high-income environments, the high prices make it unlikely that HIVST will become a regular testing method for large segments of the population. Instead, the current testing modes, many of which are free, will continue to serve the majority and those not accessing testing now who might test if self-testing were free or lower cost but are unable to access this option at the current price will remain untested. This likely includes many in the highest HIV risk groups, such as sex workers, injecting drug users and MSM, which tend to be lower income and experience discrimination when accessing current HIV testing services [3]. This is a huge barrier to reaping the potential of this new technology to help us reach the 90-90-90 goals and end the epidemic.

However, the cost of an HIVST program is substantially higher than the cost of the traditional provider-administrated testing programs, driven primarily by the higher cost of the HIVST kits [15, 23], even with the Gates Foundation subsidies that have lowered the whole sale price of an OraQuick self-test kit to $2.00 per kit for 50 low-income countries [19]. This likely makes it financially unfeasible for many healthcare systems to make free self-testing available to all. Free HIVST programs could be targeted to only those high-risk groups among whom they are likely to have the greatest impact. A targeted HIVST program would allow providers to offer the less expensive standard HIV testing to the majority of clients and the more expensive self-testing only to those who would not test otherwise, thus maximizing the program cost effectiveness. A targeted HIVST program was conducted by the New York City Department of Health, in which free HIV self-test kits were made available to New York City residents who fell within one or more high-risk population groups [33]. Unfortunately, little is known about the subgroups among whom the offer of HIVST can have the greatest impact. The Zambia door-to-door trial found that offering HIVST increased testing rates only among men and had no impact on rates among women [23]. As men are considered a hard to reach group [34], this is certainly suggestive, but more data is needed on what other factors modify the impact of making

HIVST available on testing rates. The Australian trial among MSM found a much larger impact among non-recent testers (RR=3.95) than recent testers (RR=1.99) [28], and one of the RCTs among truck drivers in Kenya found that the intervention impact was much stronger among those who had never tested for HIV but it was not statistically significant (OR=4.2 p=0.280 compared to 2.8 for the whole study sample), likely due to the small sample size (never-tested n=25) [7, 35]. However, in the RCT among FSWs in Kenya there was no significant interaction by HIV testing history [8]. Studies have also found that age [23, 26] and education [26] were not modifiers of the intervention impact. Additional explorations to identify modifiers of the intervention effect might be fruitful avenues for secondary analysis of the data from the trials that have already been conducted.

Long term impact of HIVST

Testing rate over time

There is little evidence that the higher HIV testing rate associated with HIVST will continue over time. It could be that the offer of a new product for free makes people want to try it, but when the novelty has worn off, testing rates will go back to baseline. In fact, in one of the Kenya truck driver trials, the majority (89.3%) of those in the intervention arm who chose supervised self-testing said that they did so because they were curious to try a new test [35]. The follow-up periods in the RCTs have mostly been short, no longer than four months in most cases [6, 8–10, 23–26]. In the Kenya truck driver trial, participants were also allowed to pick-up HIVST kits for a six month follow-up period. While there was a significantly higher testing rate among participants at baseline after recruitment into the study[7], there was no difference in testing rates during the six month follow-up (OR=1.0, P=0.97)[35]. The trials among MSM were somewhat longer, ranging from six to fifteen months [27–29], but these studies did not look at changes in the intervention impact over time. Thus decisions about rolling-out HIVST are being based on relatively short periods of follow-up with little evidence that the impact will be sustained over the long-term.

Linkage to care

The higher testing rates among those offered HIVST will only help achieve the 90-90-90 goals if those who self-test positive link to care. There is little evidence that linkage to care rates among HIV self-testers is similar to that of the SOC. In fact, since the HIVST RCTs were powered to detect differences in HIV testing, there was an insufficient number of HIV-positive results to look at outcomes further along the treatment cascade in most studies and, therefore, many did not compare linkage to care rates [6–8, 23, 24, 29]. In addition, the three MSM trials made concerted efforts to ensure that everyone who tested HIV-positive was actively linked to care, making comparisons between groups impossible [27–29]. Those few trials that did look at linkage to care were based on small numbers and likely underpowered, but in all cases they found reduced linkage rates among those who tested HIV-positive in the HIVST arm compared to the SOC. In the Uganda RCT, FSWs who received direct provision of HIVST kits by peer educators had a non-significant lower risk of linkage to care than those in the SOC (RR=0.65, P=0 0.28) at month one, but the difference was reduced by month four [9]. The similarly designed FSW RCT in Zambia pooled data from the two intervention arms (direct delivery of HIVST kits by peer educators

and coupon for pick-up of HIVST kit from a clinic) and compared linkage to care rates to the SOC, finding significantly lower rate at month one (RR=0.73, P=0.03) [10]. In the Uganda RCT that gave women in antenatal care HIVST kits to give their male partner, among 32 men who were reported to have tested HIV-positive, those in the intervention arm had 0.35 (95% CI: 0.14, 0.85) times lower risk of linking to care compared to those in the SOC by month three, which was statistically significant [26]. In the similar study in Kenya, among the eight male partners in the intervention group and four in the SOC who tested HIV-positive, linkage to care was lower in the HIVST group (0.2% versus 0.7%) at three months [25].

There is also little research on ways to link those who self-test HIV-negative to appropriate preventive services, such as risk reduction counseling and pre-exposure prophylaxis (PrEP). While risk reduction counseling is included in pre and post-test counseling in traditional HIV testing programs, ensuring that this information is transmitted when people self-test may be more difficult. The studies that provided a hotline number to help people access risk reduction counseling and linkage services generally found that few used the resource [9, 28, 29]. However, in the Kenya trials among FSWs and male truckers, half of those who took test kits for home use called the clinic after testing as directed for posttest counseling and referrals [6, 8]. The difference might be related to being given a phone number for a specific counselor who the client had met during the baseline interview versus an impersonal hotline number. Thus more research is needed to identify ways to ensure linkage to care for those who self-test HIV-positive and HIV-negative.

Conclusions

There is an abundance of evidence suggesting that offering free oral HIVST increases HIV testing rates over the SOC in the short term and among diverse populations. However, the design of the trials evaluating the impact of HIVST make it difficult to determine what aspects of the HIVST make it preferable and even when HIVST is offered, some still choose the SOC test, suggesting that choices may be key to increasing HIV testing rates. With the availability of multiple HIVST kits that vary in biological specimen, mode of administrations and wait time, numerous possible modes of distribution for HIVST kits, and financial considerations that may make is unfeasible to provide HIVST kits for free to everyone, more research is needed to compare various program designs. Research looking at longer term outcomes, including linkage to care, are also needed to guide program design. There is no doubt that HIVST is a new biomedical technology with potential, but this potential will only be maximized if we have a better understanding about people’s preferences and behaviors when offered HIVST in different ways.

Funding

Elizabeth A. Kelvin is supported by Einstein-Rockefeller-CUNY Center for AIDS Research [P30-AI124414] which is supported by the following National Institutes of Health (NIH) Co-Funding and Participating Institutes and Centers: NIAID, NCI, NICHD, NHBL, NIDA, NIMH, NIA, FIC and OAR. Ms. Akasreku is supported by a CUNY Graduate School of Public Health and Health Policy Dean’s Fellowship award.

References

Papers of particular interest, published recently, have been highlighted as:

•• Of major importance

1. UNAIDS. 90-90-90 An ambitious treatment target to help end the AIDS epidemic Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2014 [Accessed April 30, 2018]. Available from: http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf.
2. Status of HIV self-testing (HIVST) in national policies (situation as of July 2019) Geneva, Switzerland: UNITAIDS/WHO/UNICEF; 2019 [Accessed February 14, 2020]. Available from: https://www.who.int/hiv/topics/self-testing/HIVST-policy_mapjul2019-a.png?ua=1.
3. HIV prevention among key populations Geneva, Switzerland: UNAIDS; 2016 [Accessed February 5, 2020]. Available from: https://www.unaids.org/en/resources/presscentre/featurestories/2016/november/20161121_keypops.
4. Njau B, Covin C, Lisasi E, Damian D, Mushi D, Boulle A, Mathews C. A systematic review of qualitative evidence on factors enabling and deterring uptake of HIV self-testing in Africa. BMC Public Health 2019;19(1289):1–16. Doi: 10.1186/s12889-019-7685-1. [PubMed: 30606151]
5. (WHO). WHO. Guidelines on HIV Self-testing and partner notification Geneva, Switzerland: WHO Pres; 2016 [Accessed February 14, 2020]. Available from: https://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf;jsessionid=A4502F66DB65552D95D583F71AC7468D?sequence=1.
6. Kelvin EA, George G, Kinyanjui S, Mwai E, Romo ML, Oruko F, Odhiambo JO, Nyaga EN, Mantell JE, Govender K. Announcing the availability of oral HIV self-test kits via text message to increase HIV testing among hard-to-reach truckers in Kenya: a randomized controlled trial. BMC Public Health 2019;19(1):7. Doi: 10.1186/s12889-018-6345-1. [PubMed: 30606161]
7. Kelvin EA, George G, Mwai E, Nyaga E, Mantell JE, Romo ML, Odhiambo JO, Starbuck L, Govender K. Offering self-administered oral HIV testing to truck drivers in Kenya to increase testing: a randomized controlled trial. AIDS care 2018;30 (1):47–55. Doi: 10.1080/09540121.2017.1360997. [PubMed: 28826229]
8. Kelvin EA, George G, Mwai E, Kinyanjui S, Romo ML, Odhiambo JO, Oruko F, Nyaga E, Govender K, Mantell JE. A Randomized Controlled Trial to Increase HIV Testing Demand Among Female Sex Workers in Kenya Through Announcing the Availability of HIV Self-testing Via Text Message. AIDS and behavior 2018;22(2):580–92. Doi: 10.1007/s10461-018-2248-5. [PubMed: 28540563]
9. Ortblad K, Kibuuka Musoke D, Ngabirano T, Nakitende A, Magoola J, Kayiira P, Taasi G, Barresi LG, Haberer JE, McConnell MA, Oldenburg CE, Barnighausen T. Direct provision versus facility collection of HIV self-tests among female sex workers in Uganda: A cluster-randomized controlled health systems trial. PLoS medicine 2017;14(11):e1002458. Doi: 10.1371/journal.pmed.1002458. [PubMed: 29182634] **One of only two studies that compred HIVST kit distribution methods (Direct provision by peer educators versys indirect provision whereby peer educators give coupons redeemable at clinics for HIVST kits).
10. Chanda MM, Ortblad KF, Mwale M, Chongo S, Kanchele C, Kamungoma N, Fullem A, Dunn C, Barresi LG, Harling G, Barnighausen T, Oldenburg CE. HIV self-testing among female sex workers in Zambia: A cluster randomized controlled trial. PLoS medicine 2017;14(11):e1002442. Doi: 10.1371/journal.pmed.1002442. [PubMed: 29161260] **One of only two studies that compred HIVST kit distribution methods (Direct provision by peer educators versys indirect provision whereby peer educators give coupons redeemable at clinics for HIVST kits).
11. Strauss M, George G, Lansdell E, Mantell JE, Govender K, Romo M, Odhiambo J, Mwai E, Nyaga EN, Kelvin EA. HIV testing preferences among long distance truck drivers in Kenya: a discrete choice experiment. AIDS care 2017:1–9. Doi: 10.1080/09540121.2017.1367086.
12. Korte JE, Strauss M, Ba A, Buregyeya E, Matovu JK, Kisa R, Musoke W, Chemusto H, Vrana-Diaz CJ, Malek AM, Wanyenze RK, George G. HIV testing preferences among pregnant women attending antenatal care and their male partners: a discrete choice experiment in Uganda. African

journal of AIDS research : AJAR 2019;18(4):332–40. Doi: 10.2989/16085906.2019.1686032. [PubMed: 31779576]

13. Kelvin EA, Cheruvillil S, Christian S, Mantell JE, Milford C, Rambally-Greener L, Mosery N, Greener R, Smit JA. Choice in HIV testing: the acceptability and anticipated use of a self-administered at-home oral HIV test among South Africans. African journal of AIDS research : AJAR 2016;15(2):99–108. Doi: 10.2989/16085906.2016.1189442. [PubMed: 27399040]
14. Lippman SA, Lane T, Rabede O, Gilmore H, Chen YH, Mlotshwa N, Maleke K, Marr A, McIntyre JA. High Acceptability and Increased HIV-Testing Frequency After Introduction of HIV Self-Testing and Network Distribution Among South African MSM. Journal of acquired immune deficiency syndromes 2018;77(3):279–87. Doi: 10.1097/QAI.0000000000001601. [PubMed: 29210826] **The only study that has compared uptake ofr oral versus blood-based HIVST kits.
15. George G, Chetty T, Strauss M, Inoti S, Kinyanjui S, Mwai E, Romo ML, Oruko F, Odhiambo JO, Nyaga E, Mantell JE, Govender K, Kelvin EA. Costing analysis of an SMS-based intervention to promote HIV self-testing amongst truckers and sex workers in Kenya. PloS one 2018;13(7):e0197305. Doi: 10.1371/journal.pone.0197305. [PubMed: 29979704]
16. Pebody R Can self-testing engage 'hard-to-reach' men with HIV testing? 2017 [Accessed September 13, 2017]. Available from: http://www.aidsmap.com/Can-self-testing-engage-hard-to-reach-men-with-HIV-testing/page3159550/.
17. World Health Organization (WHO). Market and technology landscape HIV rapid diagnostic tests for self-testing Geneva:, Sitzerland: Unitaid; 2018 [Accessed February 14, 2020]. Available from: https://unitaid.org/assets/HIVST-landscape-report.pdf.
18. Status of HV self-testing (HIVST) in national policies (situation as of July 2019) Geneva, Switzerland: UNAUDS.WHO/UNICEF; 2019 [Accessed February 14, 2020]. Available from: https://www.who.int/hiv/topics/self-testing/HIVST-policy_mapjul2019-a.png?ua=1.
19. WHO. Market and technology landscape HIV rapid diagnostic tests for self-testing Geneva, Switzerland: UNITAIDS; 2017 [Accessed November 4, 2017]. Available from: http://www.who.int/hiv/pub/vct/hiv-self-testing-2017-thirdedition/en/.
20. OraQuick HIV Self Test Bethlehem, PA: ORaSure Technologies, Inc.; 2017 [Accessed February 14, 2020]. Available from: https://www.orasure.com/products-infectious/products-infectious-oraquick-self-test.asp.
21. Atomo HIV Self-Test English Kenya: BeSure Kenya; [Accessed February 7, 2020]. Available from: https://www.youtube.com/watch?v=PydT-HBR6Dc.
22. Insti English Version: Pharmaceutical Sociaty of Kenya; [Accessed February 13, 2020]. Available from: https://www.besure.co.ke/Home/videos.
23. Mulubwa C, Hensen B, Phiri MM, Shanaube K, Schaap AJ, Floyd S, Phiri CR, Bwalya C, Bond V, Simwinga M, Mwenge L, Fidler S, Hayes R, Mwinga A, Ayles H, Team HS. Community based distribution of oral HIV self-testing kits in Zambia: a cluster-randomised trial nested in four HPTN 071 (PopART) intervention communities. The lancet HIV 2019;6(2):e81–e92. Doi: 10.1016/S2352-3018(18)30258-3. [PubMed: 30584047] **One of very few studie to explore heterogeneity of HIVST intrvention effect, finding that the intervention increased HIV testing only among men and that there was no age-difference.
24. Gichangi A, Wambua J, Mutwiwa S, Njogu R, Bazant E, Wamicwe J, Wafula R, Vrana CJ, Stevens DR, Mudany M, Korte JE. Impact of HIV Self-Test Distribution to Male Partners of ANC Clients: Results of a Randomized Controlled Trial in Kenya. Journal of acquired immune deficiency syndromes 2018;79(4):467–73. Doi: 10.1097/QAI.0000000000001838. [PubMed: 30148731]
25. Masters SH, Agot K, Obonyo B, Napierala Mavedzenge S, Maman S, Thirumurthy H. Promoting Partner Testing and Couples Testing through Secondary Distribution of HIV Self-Tests: A Randomized Clinical Trial. PLoS medicine 2016;13(11):e1002166. Doi: 10.1371/journal.pmed.1002166. [PubMed: 27824882]
26. Korte JE, Kisa R, Vrana-Diaz CJ, Malek AM, Buregyeya E, Matovu JK, Kagaayi J, Musoke W, Chemusto H, Mukama SC, Ndyanabo A, Mugerwa S, Wanyenze RK. HIV oral self-testing for male partners of women attending antenatal care in central Uganda: uptake and linkage to care post-test in a randomized trial. Journal of acquired immune deficiency syndromes 2020. Doi: 10.1097/QAI.0000000000002341.

27. Wang Z, Lau JTF, Ip M, Ho SPY, Mo PKH, Latkin C, Ma YL, Kim Y. A Randomized Controlled Trial Evaluating Efficacy of Promoting a Home-Based HIV Self-Testing with Online Counseling on Increasing HIV Testing Among Men Who Have Sex with Men. AIDS and behavior 2018;22(1):190–201. Doi: 10.1007/s10461-017-1887-2. [PubMed: 28831616]
28. Jamil MS, Prestage G, Fairley CK, Grulich AE, Smith KS, Chen M, Holt M, McNulty AM, Bavinton BR, Conway DP, Wand H, Keen P, Bradley J, Kolstee J, Batrouney C, Russell D, Law M, Kaldor JM, Guy RJ. Effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection (FORTH): a waiting-list randomised controlled trial. The lancet HIV 2017;4(6):e241–e50. Doi: 10.1016/S2352-3018(17)30023-1. [PubMed: 28219619]
29. Katz DA, Golden MR, Hughes JP, Farquhar C, Stekler JD. HIV Self-Testing Increases HIV Testing Frequency in High-Risk Men Who Have Sex With Men: A Randomized Controlled Trial. Journal of acquired immune deficiency syndromes 2018;78(5):505–12. Doi: 10.1097/QAI.0000000000001709. [PubMed: 29697595]
30. Mugo PM, Micheni M, Shangala J, Hussein MH, Graham SM, Rinke de Wit TF, Sanders EJ. Uptake and Acceptability of Oral HIV Self-Testing among Community Pharmacy Clients in Kenya: A Feasibility Study. PloS one 2017;12(1):e0170868. Doi: 10.1371/journal.pone.0170868. [PubMed: 28125699]
31. Aminu N, Sha'aban A, Abubakar A, Gwarzo M. Unveiling the Peril of Substandard and Falsified Medicines to Public Health and Safety in Africa: Need for All-Out War to End the Menace. Medicine Access @ Point of Care 2017;1(1):e145–e15. Doi: 10.5301/maapoc.000002.
32. OraQuick where to buy Bethlehem, Pennsylvania: OraSure Technologies, Inc.; 20220 [Accessed February 7, 2020]. Available from: http://www.oraquick.com/where-tobuy.
33. Pebody R How should HIV self-testing services be provided? London: NAM Publications; 2017 [Accessed Jan 9, 2019]. Available from: http://www.aidsmap.com/How-should-HIV-self-testing-services-be-provided/page/3118526/.
34. Blind Spot reaching out to men and boys Geneva, Switzerland: UNAIDS; 0117 [Accessed February 14, 2020]. Available from: https://www.unaids.org/sites/default/files/media_asset/blind_spot_en.pdf.
35. Kelvin E, Mwai E, Romo M, George G, Govender K, Mantell J, Strauss M, Nyaga E, Odhiambo J. Evaluating oral HIV self-testing to increase HIV testing uptake among truck drivers in Kenya New Delhi: International Initiative for Impact Evaluation (3ie); 2017 [Accessed]. Available from: http://www.3ieimpact.org/media/filer_public/2017/07/19/ie64-truck-drivers-kenya.pdf.

Table 1

Summary of randomized trials evaluating the impact of offering HIV self-testing

Author, Year	Country	Population Group	Recruitment	Intervention	Control	Primary outcome	Findings
Kelvin, 2018[7, 35]	Kenya	Male truck drivers	Recruited from waiting room of two North Star Alliance roadside wellness clinics	Offered a Choice among the SOC HIV test, an oral HIVST kit for use with supervision in the clinic or, among those who refused the first two in-clinic options, an HIVST kit to take for unsupervised home use	SOC arm, offered only a provider- administered rapid finger- prick HIV test	HIV testing uptake at baseline and 6 months follow-up	At baseline, those in the intervention arm had greater odds of testing uptake (OR=2.8, p=0.002). Over 6 months follow-up there was no difference (OR=1.0, P=0.97)
Kelvin, 2019[6]	Kenya	Male truck drivers	All eligible clients registered with the North Star Alliance East Africa roadside wellness clinic network	Sent three text messages announcing the availability of oral HIVST. Those who came to the clinic were given a choice among (1) the SOC test, (2) an oral HIVST for supervised use in the clinic or (3) an oral HIVST kit to take for unsupervised home use.	Sent three text reminders about the availability of HIV testing in general at the clinics. Those who came to the clinics were only offered the provider- administered finger-prick HIV test (SOC)	HIV testing over two months after sending the first text message	Those in the intervention group had significantly higher odds of coming to a clinic and testing than those in the control group (OR = 2.7, P=0.009)
Masters, 2016[25]	Kenya	Male partners of women in antenatal care	Women recruited during antenatal care clinic visit	Women given oral HIVST kits to take home to male partner for testing	Referral card encouraging male partner to come to a clinic for provider-administered testing	Proportion of male partners testing	The proportion of male partners who tested was significantly higher in the intervention group (RR=1.8, p<0.001)
Gichangi, 2018[24]	Kenya	Male partners of women in antenatal care	Women recruited during antenatal care clinic visit	Women given oral HIVST kits to take home to male partner for testing	Referral card encouraging partner to come to a clinic for provider-administered testing	Proportion of male partners testing	The proportion of male partners who tested was significantly higher in the intervention group (RR=2.3. 1-sided p<0.001)
Korte, 2020[26]	Uganda	Male partners of women in antenatal care	Women recruited during antenatal care clinic visit	Women given oral HIVST kits to take home to male partner for testing	Women received education about how to encourage their male partners to go to a health facility for HIV testing	Proportion of male partners testing	The proportion of male partners testing was significantly higher in the intervention group at month 1 (RR=4.19, 95% confidence interval [CI]: 3.49–5.05) and month three (RR=1.27, 95% CI:1.02–1.57)
Chanda, 2017[10].	Zambia	Female sex workers (FSWs)	Peer educators recruited FSWs	Oral HIVST kits were distributed directly via peer educators and indirectly (peer educators gave coupons redeemable for an HIVST kit at a clinic)	Peer educators gave information about where to access standard facility-based HIV testing.	HIV testing at one and four months	The difference between each intervention and the control was not significant at month one (direct distribution: RR=1.07, P=0.10; coupon distribution: RR=0.95, p=0.29) and at month four (direct distribution: RR=1.11, P=0.11; coupon distribution: RR=1.06, p=0.42).
Ortblad, 2017[9]	Uganda	FSWs	Peer educators recruited FSWs	Oral HIVST kits were distributed directly via peer educators and indirectly (peer educators gave coupons redeemable for an HIVST kit at a clinic)	Peer educators gave information about where to access standard facility-based HIV testing.	HIV testing at one and four months	More FSWs tested for HIV at one month in each intervention arm compared to the control, but it was only significant in the direct distribution arm (direct distribution: RR=1.33,

Author, Year	Country	Population Group	Recruitment	Intervention	Control	Primary outcome	Findings
							P<0.001; coupon distribution: RR=1.12, p=0.15) and the difference was significant in both arms at four months (direct distribution: RR=1.14, P<0.001; coupon distribution: RR=1.11, p=0.002)
Kelvin, 2018[8]	Kenya	FSWs	All eligible clients registered with the North Star Alliance East Africa roadside wellness clinic network	Sent three text messages announcing the availability of oral HIVST. Those who came to the clinic were given a choice among (1) the SOC test, (2) an oral HIVST for supervised use in the clinic or (3) an oral HIVST kit to take for unsupervised home use.	Sent three text reminders about the availability of HIV testing at the clinics. Those who came to the clinics were only offered the provider- administered finger-prick HIV test (SOC)	HIV testing over two months after sending the first text message	Significantly more FSWs came to the clinics and HIV tested in the intervention group than the control (OR=1.9, P=0.001).
Mulibwa, 2019[23]	Zambia	Community residents	Door-to-door in community	Door-to-door offer of choices among (1) SOC test, (2) oral HIVST for supervised use or (3) oral HIVST for unsupervised use.	Door-to-door offer of the provider- administered rapid finger prick HIV test (SOC) only	Knowledge of HIV status after three months	Those in the intervention arm had 1.3 (p-0.03) times higher odds of knowing their HIV status compared to those in the control arm
Wang, 2018[27]	Hong Kong	Men who have sex with men (MSM)	Outreach in gay-friendly venues, advertisements on websites that cater to MSM, and referrals from other study participants	Sent oral HIVST kits via mail with mandatory online supervision, counseling and support (i.e. supervised self-testing)	facility -based testing with a video promoting testing and encouragement to test	HIV testing over 6 months	The HIV testing rate at 6 months among those in the intervention group was 1.77 (P<0.001) times higher than in the control group
Katz, 2018[29]	USA	MSM	Participants were recruited from a sexually transmitted disease clinic waiting room, internet advertisements and local listservs that cater to MSM.	Provision of oral HIVST kits, the first kit was provided in-person at a study visit and subsequent kits were available upon request at the clinic or by mail.	Healthcare facility-based HIV testing	Number of times HIV tested over 15 months	Those in the intervention arm tested 1.7 (p<0.001) more times, on average, than those in the control arm over 15 months
Jamil, 2017[28]	Australia	MSM	Participants were recruited from large urban public sexual health clinics and community- based organizations	Participants were given four oral HIVST kits in-person at enrollment and subsequent kits were available upon request at the clinic or by mail	Healthcare facility-based HIV testing	Number of HIV tests over 12 months.	Those in the intervention group tested 2.08 (p<0.001) more times over 12 months, on average, than those in the control group.