

HIV Self-testing in Sub-Saharan Africa: Strategies to Enhance and Measure Linkage to Care

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ABSTRACT: HIV self-testing is gaining traction as an additional strategy for increasing access to knowledge of HIV status in sub-Saharan Africa. This approach may reinforce individual autonomy and is potentially more convenient compared to other HIV testing techniques. Given the global push toward early antiretroviral therapy, HIV self-testing may appear ineffective in assuring linkage to HIV care. Approaches to improve this critical outcome of HIV self-testing include utilization of unique personal identifiers, fingerprint scanning, phone-based reminders and queries, and centralized databases to follow up clients who test themselves. To enable jurisdictions in sub-Saharan Africa to measure coverage of HIV self-testing and the associated linkage to care, the centralized databases ought to be linked to HIV care clinic data. Current information systems like household surveys can also be adapted for surveillance of linkage to care post self-testing. However, the affordability and cost-effectiveness of these innovations need to be evaluated. Since self-testing is a new behavior, a deeper understanding of the trajectory of clients after testing is necessary in order to design appropriate interventions for linkage to care. Policy makers, implementers, researchers, and technology experts in sub-Saharan Africa should seize the opportunity to scale-up high-quality self-testing programs, improve the HIV care cascade, and contribute to the decline of new HIV infections.

KEYWORDS: HIV, self-testing, linkage to care, surveillance, implementation science

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Introduction

HIV self-testing is increasingly gaining momentum as an additional tool for screening and diagnosing HIV infection. This is demonstrated by an upsurge of publications and reviews in the last 3 years, the approval by the Federal Drug Administration, and the inclusion of self-testing in the World Health Organization (WHO) HIV Testing and Counseling (HTC) framework.^{1,2} Indeed, the WHO recently convened an advisory group on HIV self-testing that among other things suggested that additional efforts should be made to promote self-testing programs.³ Furthermore, various implementation science and basic science studies are under way to expand self-testing options and explore feasible ways of scaling up HIV

self-testing in sub-Saharan Africa.⁴ Specifically, these studies are designed to determine the accuracy of self-tests in implementation settings and identify potential user characteristics, as well as packaging and labeling attributes of self-test kits. Importantly, these studies will demonstrate effective methods for linkage to HIV care.

Advocates for self-testing cite the widening role of HIV testing in primary and secondary HIV prevention. Interventions such as early antiretroviral therapy (ART) for HIV-infected persons and preexposure prophylaxis (PrEP) for the HIV-uninfected require universal and cost-effective testing technologies for them to be optimized. Self-testing may be less stigmatizing particularly for some higher risk subpopulations



and for those who tend not to use the health system as much, such as men, and members of high-risk groups or key populations and could enhance individual autonomy and privacy.^{5,6} Furthermore, it can be considered as the ‘ultimate task shifting’ and is potentially less demanding to the health system. These attributes may facilitate accurate knowledge of HIV status and more importantly access to treatment for HIV-infected persons in sub-Saharan Africa.

Several challenges to self-testing have been documented. Oral fluid-based tests, though more convenient and with minimized risk of transmission of blood-borne pathogens,⁷ have been reported to be up to 2% less sensitive than blood-based tests. Additionally, the positive predictive values of oral fluid-based tests in low-HIV prevalence settings are significantly lower.⁸ This may limit the utility of self-testing in detecting acute HIV infection in such settings and necessitate routine confirmatory tests for any HIV-positive result. However, linkage to HIV treatment remains difficult and yet the single most desirable outcome of self-testing for those who test HIV positive.^{8,9} The importance of linkage to and retention in HIV clinical care systems is underscored by the need to achieve high coverage of viral suppression and to eliminate potential viral resistance. Yet, there are limited data in sub-Saharan Africa on critical outcomes of self-testing including posttest

counseling impact and models, ART initiation, and linkage to care.¹⁰ As a new approach, self-testing will require innovative implementation and surveillance techniques to assure effective follow-up and entry into HIV care. In this paper, we explore potential strategies to enhance and measure linkage to care outcomes in self-testing programs in sub-Saharan Africa. We also propose certain implementation science questions for consideration in these settings.

Strategies to enhance linkage to care. HIV self-testing may be delivered either as supervised [onsite testing and counseling aided by a health care professional (HCP)] or unsupervised (testing by client without help but counseling and linkage may be offered by HCP).¹⁰ Both these programmatic approaches are challenging but offer unique opportunities for linking self-testing clients to appropriate services. In addition to these programmatic approaches, individuals or couples may just purchase test kits and do the entire process on their own, creating more challenges for ensuring access to care.

Supervised HIV self-testing. It is felt that HCP-supervised self-testing should be the default model for any initial test (Fig. 1). This approach could leverage on existing HTC initiatives in facility and community settings and may include group or couple-based pretest information, testing, or counseling. If the client or a member of a couple tests negative,

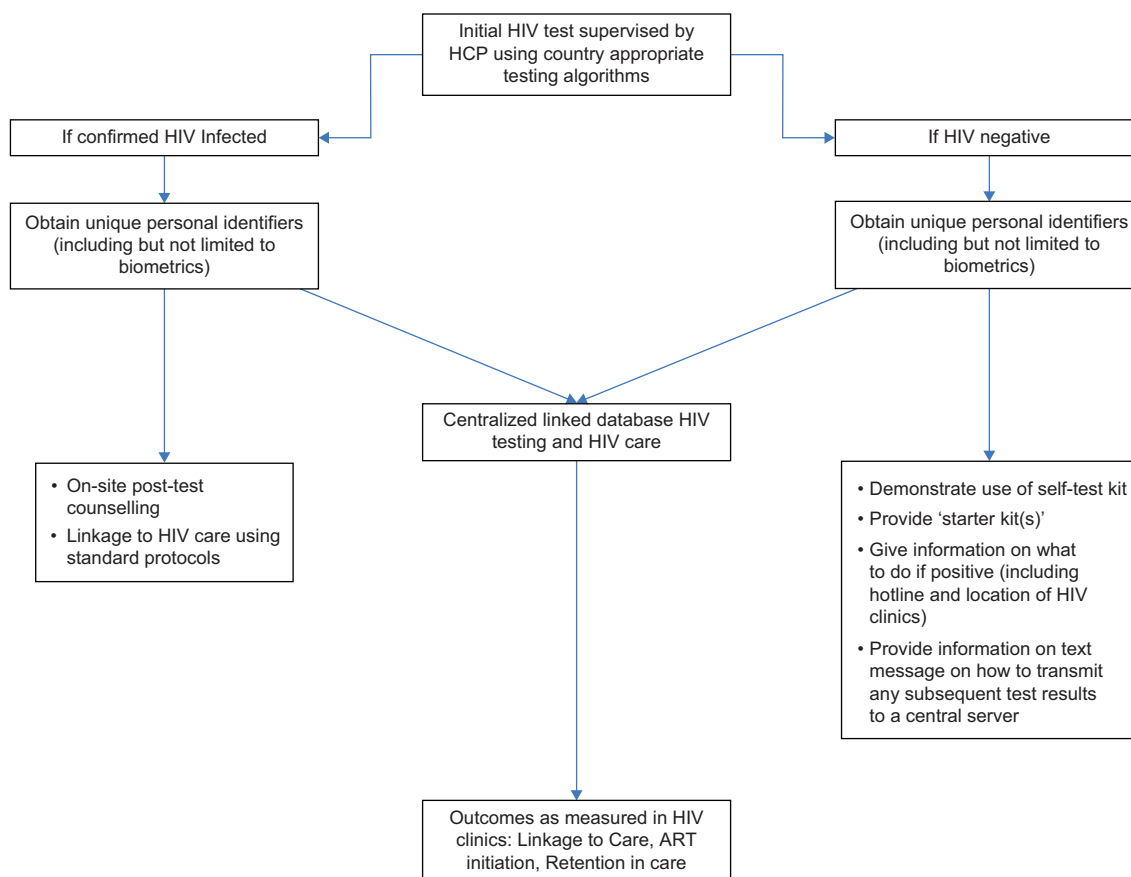


Figure 1. Supervised HIV self-testing.



the HCP gives instructions and demonstrates how to use a self-test (like counselors now do for condom demonstration). The goal of the demonstration is to make clients proficient in self-testing and enable them to perform subsequent tests in the privacy of their homes or offices. The client is then given a free “starter” test kit for future self-testing along with a number to call in case of any questions. In the event that couple-testing is desired, the HCP may issue more than one self-test kit at this initial encounter. The client is also given information on what to do if the next test is positive (including confirmatory testing options). As per WHO recommendations, those HIV-negative clients with ongoing risk of HIV infection (sex workers, injecting drug users, etc.) and those who report a specific incident of HIV exposure in the last three months would need to be counseled on the need for retesting¹¹ and where to buy additional self-test kits for themselves or their sexual partners after using the first free one.

Unsupervised HIV self-testing. For those clients or sexual partners who choose to self-test as their initial or normative test, the vendor/distributor should obtain contact information and demonstrate the use of the kit prior to sale or distribution (Fig. 2). Regulatory and government agencies in sub-Saharan Africa should establish guidelines that

facilitate the purchase of testing kits for sexual partners. If the client agrees, the kits could be bar-coded to send interactive text messages to the client with instructions on how to conduct the test, how to transmit test results to the relevant HCP or hotline number, and how to obtain immediate follow-up in case of testing HIV positive. It is important to emphasize the need for a confirmatory test following an initial positive self-test. Distribution of self-testing kits should be accompanied by clear educational materials such as a paper or digital instruction sheets. It is desirable that these educational materials are visuals and not just text, to minimize literacy issues. Such instructional sheets should contain storage conditions for kits, self-testing procedures, and follow-up information including the need to confirm positive results, whether retesting is applicable for those testing negative, and how to manage invalid self-test results. Specifically, the available oral fluid-based kits have a shelf life of 18–24 months, and clients should be informed to confirm the expiry date of each kit prior to use. Vendors or distributors should therefore be appropriately trained and accredited as HTC providers. However, in settings where self-testing is already established and quality assurance mechanisms are optimal, training of vendors may not be applicable.

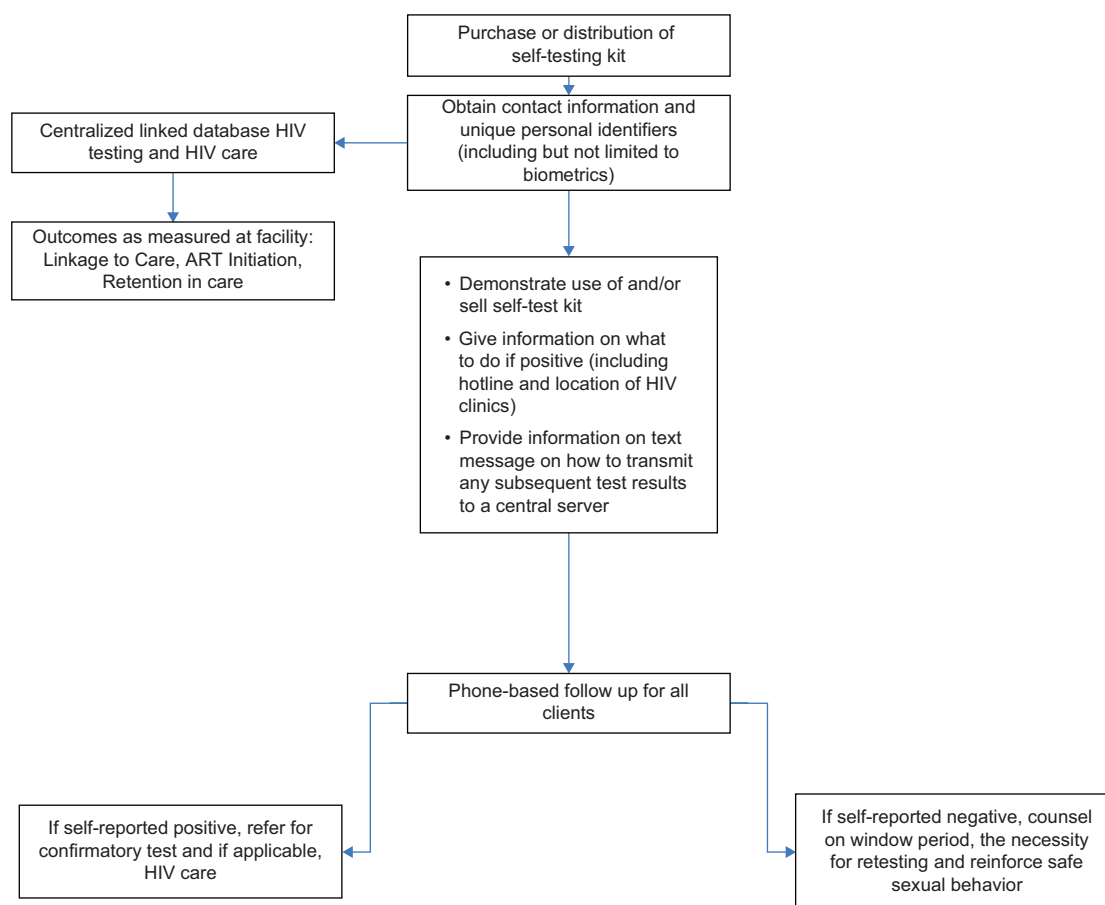


Figure 2. Unsupervised HIV self-testing.



Phone-based counseling. Several mobile phone applications are now available to support the provision of information and counseling for clients who choose self-testing.¹² In sub-Saharan Africa, mobile phone penetration is rising, calling rates are affordable, and Internet access is increasing, making the utilization of these technologies feasible. At the point of initial testing or at test-kit purchase, clients should be given an option of obtaining phone-based or in-person counseling. Counseling messages should be explicit about the value of attending clinic especially for HIV-infected persons and should contain factual information on physical location of HIV clinics.

Phone-based reminders. For those who purchase or obtain self-test kits, phone-based follow-up may enhance timely linkage to care. Phone-based reminders have been used successfully and extensively in HIV care and treatment as summarized in a recent meta-analysis, as well as for partner notification, sexually transmitted diseases' (STD) screening, and clinic appointment reminders.^{13–15} In recent times, these have been used to follow up clients who have undergone male circumcision and who are those on ART.^{16,17} Automated text messaging open-source platforms are now widely available.¹⁸ These platforms can be adapted to send preprogrammed text messages (with delivery notifications) at preagreed times and format to clients who have obtained self-test kits. In combination with text messages, voice calls may also improve uptake of HIV care.

Strategies to measure linkage to care. Facility-based surveillance may not be generalizable. Given that self-testing entails minimal or no contact with a health facility, innovative surveillance is required to document linkage and retention in care after an individual has obtained a self-testing kit. Several possibilities emerge. As indicated above, interactive text message surveys such as Rapid SMS can be used to evaluate these outcomes. Population-based HIV registries also offer the potential for surveillance of self-testing.

Once a client has been issued with a kit, an automatic bar-code-generated text message could be sent to the client informing them of the steps necessary to transmit the results. This message is then relayed to a central database that will generate reminders at regular intervals. Text message surveys will broadcast to clients, and they will be expected to respond to when and where they conducted the test, the result outcome, and if they shared the results with sexual partners. If positive, a list of phone numbers for counseling and those of treatment sites will be generated for the client's information. This service can be configured for longitudinal follow-up of HIV-infected persons in care and also potentially for HIV-uninfected persons receiving HIV prevention interventions like PreP. For this to be successful, high mobile phone penetration, as well as incentives for sending one's data, may be required. Encryption and security concerns would also need to be addressed. Additionally, the private sector has to collaboratively share data with national HIV registries, though it must

be recognized that persons fearing stigma, discrimination, or legal consequences may refuse to participate. Legal reforms to make HIV a notifiable disease and to ensure there is no state-sanctioned discrimination, especially for persons in criminalized relationships or occupations, are warranted.

Surveys. In order to determine the population coverage of self-testing, this question should be made routine in all household surveys. The Kenya AIDS Indicator Survey 2012, for example, included the question thus: *have you ever tested yourself for HIV in private using a self-test kit?* An additional question among HIV-infected persons may be added as follows: *the first time you tested positive how did you learn your status?* Linkage to care can also be assessed using centralized registries that link pharmacy/clinic HTC data and HIV clinic data. However, these registries and surveys can only be feasible if jurisdictions have a centralized data utilizing unique personal identifiers (UPI) and monitoring and evaluation systems that are versatile.

UPIs and centralized databases. Documentation of linkage and retention in HIV care is hampered by lack of a UPI that is capable of tracking an individual through the HIV care cascade. Current paper-based approaches are insufficient and inefficient. To protect privacy, each person receiving a self-test kit should be provided with an anonymous and meaningless numeric code generated either from a combination of personal identifiers like name, age, date of birth, or a biometric measure such as fingerprints. This UPI would be made available in a nationally managed centralized or linked databases that are able to query date of purchase of self-test and date and place the client showed up for HIV care. This is particularly advantageous in self-testing because beyond provider or phone reminders, there are limited mechanisms to know if someone who has obtained a self-testing kit actually tested. Taking advantage of advances in biometrics and health informatics, it is now feasible to generate UPIs. However, it must be acknowledged that breaches of computerized data are occurring frequently and many clients may defer using a UPI.

Biometrics. At the point of purchase or distribution, the clients' basic details such as phone number and fingerprints may be taken, though this will require careful explanation to persons fearing criminalization. Already in many settings, smart card readers are a prerequisite to obtain certain services at clinics. Several open-source software options are now available that are either computer or smart phone compatible.¹⁹ The fingerprint software translates a fingerprint into a code containing numbers and letters; no image of the fingerprint will be stored or shared with police or other authorities, which may be of concern to some clients. Once data are uploaded, they are no longer available on the phones, minimizing risk that submitted data might be lost or inadvertently shared. These details can then be matched in an anonymous central longitudinal database that is accessible to program managers and, with appropriate safeguards, to HCPs. Missing data and



errors are also minimized due to built-in features on forms and reports. These systems enable real-time feedback data for counselors and testing sites regarding their clients' HIV status and follow-up status.

Other potential biometric scans include iris/retinal scans and DNA samples. However, these are not widely available for public health use. Establishing centralized databases and electronic platforms may be expensive. The feasibility and cost of the combination of UPI in linkage to HIV care should therefore be evaluated.

Indicators to measure linkage to care. To measure the proportion effectively linked to care, we propose the following denominators: the number of clients receiving a self-test kit and the number of respondents who report ever testing themselves for HIV in private using a self-test kit disaggregated by age, gender, and service delivery point and measured over a defined time period.

The following numerators may provide an indication of confirmed linkage to the clinic if there is adequate integration of HIV testing and HIV care information systems.

- The number of respondents who report ever testing themselves for HIV in private using a self-test kit;
- The number of respondents initiating treatment who report ever testing themselves for HIV in private using a self-test kit;
- The number of respondents initiating treatment who report ever testing themselves for HIV in private using a self-test kit AND who learnt their HIV-positive status for the first time as a result of the self-test.

Implementation science questions on linkage to care. Self-testing for HIV is a new behavior, and it is not clear how current theoretical models that are validated for HIV prevention will apply. The health belief model, the social-cognitive theory, and the theory of reasoned action are potentially useful.^{20–22} However, each of these has relatively limited focus on factors impacting behavioral change. Recently, the social action theory has been proposed as a superior theoretical framework that emphasizes the context in which health behavior occurs, the social interaction processes, and the mechanisms by which these variables result in health-promoting behavior.²³ Regardless of their specificity, these models should be validated in the context of HIV self-testing to determine their applicability. Unlike other HTC strategies, the provider-client interaction is limited or totally absent in self-testing and interventions to improve care seeking such as strengths-based case management, intensive posttest counseling, and motivational interviewing may not be feasible.²⁴ Additionally, clients who choose to self-test may exhibit different health-seeking behaviors from clients who undergo provider-supervised testing. Indeed these clients may require a deeper level of personal involvement in the interpretation and access to care compared to other HTC strategies.¹⁰ It is not known what would moti-

vate clients who obtain self-test kits to seek further interaction with a provider for test result confirmation or initiation of therapy. Behavioral studies using qualitative research methods to evaluate client risk profiles, HIV testing behaviors, and test appropriate theoretical models are required.

There are limited data on the potential cost-effectiveness of self-testing in sub-Saharan Africa. While the 'ultimate task shifting' may appear favorable from a payer perspective, the actual cost of the test may counterbalance any advantage gained by minimizing contact with the health system.²⁵ Willingness to pay data suggest that subsidization of HIV self-test kits or making the kits free for low-income and/or marginalized populations will be critical. If self-testing results in worse outcomes for linkage to care, or leads to a higher proportion of false-negative tests, the economic rationale of this strategy may be brought to question. Economic evaluation of self-testing and effective linkage to treatment and prevention services is required to inform policy-making decisions in Africa.

In anticipation of a private sector model for the sale and distribution of self-test kits, appropriate branding and social marketing of self-test kits should be considered. Any social marketing without information on location, availability, and cost of treatment and prevention services should be considered unethical. It would be desirable therefore to explore how to effectively communicate the message that "testing itself is not enough."

In conclusion, HIV self-testing is gradually gaining momentum and may inevitably be routine in sub-Saharan Africa. Current strategies of linkage to care may not work for self-testing programs and innovations including UPIs, text message surveys, and biometrics and possibly incentives may be useful in assuring this critical outcome. Although concerns around feasibility, cost, acceptability, and confidentiality of such systems are valid, these issues are addressable. Importantly, well-grounded behavioral interventions that enhance linkage to care need to be designed to improve self-testing approaches. Policy makers, implementers, researchers, and technology experts in sub-Saharan Africa should seize the opportunity to scale-up high-quality self-testing programs, improve the HIV care cascade, and contribute to the decline of new HIV infections. This is more pertinent in resource-limited settings, where the burden of HIV is high and access to HIV testing and coverage of ART is suboptimal.

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Author Contributions

Wrote the first draft of the manuscript: PC. Contributed to the writing of the manuscript: PC, AK, HM and NK. Agree with manuscript results and conclusions: PC, AK, HM, NK and WM. Developed the structure and arguments for the paper: PC



and WM. Made critical revisions and approved final version: PC, AK, HM, and NK. All authors reviewed and approved the final manuscript.

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