

HIV self-testing among key populations: an implementation science approach to evaluating self-testing

Joseph D Tucker*^{1,2}, Chongyi Wei³, Razia Pendse⁴, Ying-Ru Lo⁵

¹UNC Project China, School of Medicine, University of North Carolina at Chapel Hill, Guangzhou, China

²Institute of Global Health and Infectious Diseases, University of North Carolina at Chapel Hill, Chapel Hill, USA

³Department of Epidemiology and Biostatistics, University of California San Francisco, San Francisco, USA

⁴HIV AIDS Unit, Department of Communicable Diseases, World Health Organization Regional Office for South-East Asia, New Delhi, India

⁵HIV and Sexually Transmitted Infection, Division Combating Communicable Diseases, World Health Organization Regional Office for the Western Pacific, Manila, The Philippines

Abstract

Objectives: To review methods for measuring HIV self-testing (HIVST) among key populations, including both conventional approaches and implementation science approaches.

Methods: We reviewed the literature on evaluating HIVST among key populations.

Results: Simple HIV self-tests have already entered markets in several regions, but metrics required to demonstrate the benefits and costs of HIVST remain simplistic. Conventional measurements of sensitivity, specificity, acceptability, and behavioural preferences must be supplemented with richer implementation science measurement tools and innovative research designs in order to capture data on the following components: how self-testing affects subsequent linkage to confirmatory testing, preventive services and onward steps in the HIV continuum of care; how self-testing can be marketed to reach untested subpopulations; and how self-testing can be sustained based on overarching organisational and financial models. We outline an implementation science research agenda that incorporates these components, drawing from evaluation study designs focused on HIVST and testing in general.

Conclusion: HIVST holds great promise for key populations, but must be guided by implementation research to inform programmes and scale up.

Keywords: HIV, self-testing, implementation science, evaluation, metric, testing

Background

Achieving the global goal of having 15 million individuals on antiretroviral therapy by 2015 [1] will require substantial expansion of HIV testing and counselling (HTC) because over half of HIV-infected individuals are unaware of their serological status [2]. Suboptimal awareness of HIV serostatus is especially problematic among key populations [3–5]. Key populations are defined as vulnerable and most-at-risk populations [6] and have a higher risk of acquiring and transmitting HIV infection. Key population HTC is a key component of comprehensive HIV service provision [5]. Delayed testing is associated with increased mortality and morbidity [7]. Despite the known importance of HTC, there are many systems level barriers to expanding key population HTC services. Fear of testing [8], test-associated and other stigma [9], concerns about confidentiality [8,10], and inadequate follow-up services [11] delay key population testing.

HIV self-testing (HIVST) may help decrease some of these barriers associated with HTC in key populations. We use the definition of self-testing that specifies the collection, performance, and interpretation in private by the individual who wants to know their serological status. HIVST does not confer knowledge of serological status or provide a definitive diagnosis [12]. Self-testing could help decentralise testing, safeguard confidentiality, and make HIV service delivery systems more responsive to key populations [13]. Data from key populations suggest that willingness to HIVST may be high [14,15]. Technological advances in point-of-care technology have also facilitated the shift towards diagnostic testing outside centralised facilities [16]. There are a variety of approaches to implementing HIVST that differ based on the level of support (supervised or unsupervised), level of access (restricted by health services,

semi-restricted, open access), and venues for distribution. HIVST has been piloted at facility-based clinical sites [15], emergency departments [17,18], mobile clinics, non-governmental organisations [19], pharmacies, vending machines [20], street-based testing [21], and home testing [15,22,23]. As HIVST is implemented at a wide range of sites, there is an increasing need to develop comprehensive evaluation measures.

Implementation research is a useful framework for evaluating the advantages and disadvantages of HIVST among key populations. Here we define implementation science as the study of methods to improve the uptake, implementation, and translation of research findings into routine and common practices [24]. Implementation science is often conceived as research necessary to bridge the ‘know-do’ or ‘evidence to programme’ gaps [25]. This commentary examines current measurement of HTC impact and then considers how an implementation science perspective can enrich this monitoring and evaluation among key populations.

Current measurement of HTC

Most HIV testing evaluation examines test kit sensitivity, test kit specificity, health professional acceptability and preferences among key populations [15]. These are all critical variables that are necessary, but alone insufficient, to inform comprehensive evaluation of HIV testing strategies. HIVST evaluations need to clarify study design, reasons for testing, and the local HIV testing policy guideline. First, there is no established randomised control trial-like gold standard study design for evaluating testing strategies because testing is a node in a clinical decision tree and not a novel therapeutic intervention. While there is no placebo condition for a test, there are several relevant counterfactuals

*Corresponding author: Joseph D. Tucker, UNC Project-China, 2 Lujing Road, Guangzhou, China, 510095

worth considering such as delayed testing [26], never HIV tested [26–28], and algorithm-based testing (based on clinical symptoms versus screening asymptomatic individuals). Earlier research evaluated test uptake, knowledge of HIV status, and effects on sexual behaviours [29]. Second, there are multiple potential test functions, including testing for triage, screening asymptomatic individuals, diagnosis, confirmation, surveillance, and blood safety. Testing for triage refers to an initial test that can help to expedite subsequent referral, confirmatory testing and prevention services [5,30]. It is important to note that HIVST are not typically used for definitive diagnosis and should be situated within the local guidelines for HIV testing. Differentiating the test function is important for moving beyond test kit evaluation and towards testing algorithm and strategy evaluation. Research trials need to clearly specify the function of testing under evaluation in order to clearly understand the broader implications. Third, understanding local HTC guidelines is necessary for interpreting the baseline testing characteristics of the key population.

New approaches to evaluating HIVST

The general challenges of HIV testing evaluation and the more specific context of evaluating HIVST highlight the need for new models of evaluation that could be used by researchers and/or public health agencies. We first introduce an implementation science approach to evaluating HIVST. Then we use this approach to consider the influence of self-testing on engagement within the HIV care continuum, the role of self-testing in reaching and retaining untested populations, and the potential for self-testing to catalyse new organisational and financial models. The term HIV care continuum or cascade refers to the series of services required for HIV-infected individuals to achieve complete viral suppression [31].

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Using implementation science to evaluate HIVST

Unlike clinical trials, which test the efficacy of interventions, implementation science aims to evaluate the effectiveness and efficiency of interventions in real world settings. This involves examining the entire cycle, including the following stages (Figure 1): identifying gaps in existing HTC service provision, developing new HIVST interventions, implementing and disseminating interventions, measuring effectiveness and efficiency, and reviewing data to inform improved service provision. In particular, evaluation of implementation research projects focuses on two main components: evaluation of implementation fidelity during implementation and dissemination stages, and outcomes evaluation that assesses intervention effectiveness [32]. Measurement of implementation fidelity is the measurement of the degree to which organisations responsible for service delivery adhere to the intervention. This includes

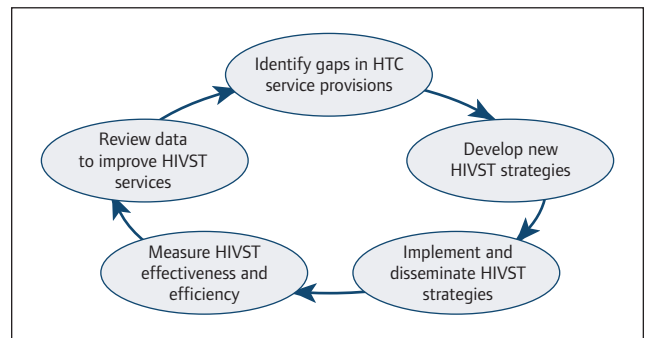


Figure 1. General implementation science framework for HIVST evaluation

intervention content, frequency, duration and coverage. Implementation fidelity or adherence can be affected or moderated by a range of factors: (1) intervention characteristics including complexity, design quality and packaging, and costs; (2) outer setting including target population’s needs, peer pressure, and external policies and incentives; (3) inner setting such as an organisation’s structural characteristics, its networks and culture, which directly impact quality of delivery of an intervention; and (4) characteristics of the target population including knowledge and beliefs about the intervention, self-efficacy, and individual identification with organisation [33]. All of these implementation fidelity characteristics have implications for the evaluation of HIVST. Incorporating evaluation of these implementation fidelity characteristics is therefore important to the overall measurement of HIVST programs.

Outcome evaluation is the second key aspect of implementation evaluation. Alternative research designs dedicated to measuring intervention effectiveness are important because the focus is on external validity and practical issues in addition to efficacy [34,35]. While a detailed discussion is beyond the scope of this paper, some suggested designs include simulation modelling, pragmatic trials, rapid learning studies, and integrative studies combining community data and public health data [34]. Data from mathematical models were essential in the original approval of the HIVST by the US Food and Drug Administration [13] and remain useful in understanding the potential influence of self-testing [36]. Pragmatic trials are distinguished by their focus on real-life contexts in order to expand the generalisability of the results [37–39]. Pragmatic trials have been used to evaluate HIV interventions [40–42], but have not yet been applied to the case of HIVST. Rapid learning studies refer to generating real-time feedback for organisations that is then used to guide subsequent implementation [43]. These study designs have been used to help extend HIV treatment access [44]. Integrative evaluation that draws together community-based data as well as clinical data from public health organisations may also be useful for self-testing. The expanding capacity of HIV community-based organisations related to HTC suggests new opportunities for incorporating these data sources into implementation science evaluations.

HIVST and engagement in the HIV care continuum

Evaluating HIVST will require data on key population testing, linkage to care and retention in care within the HIV care continuum. The receipt of an HIV test used to be considered the ‘end’ of the evaluation, but the results of HPTN 052 [45] now suggest that it is really only the beginning of a complex set of services that require measurement. Self-testing may increase first-time testers and testing frequency [13] and subsequently increase key population engagement across the HIV care continuum.

However, demonstrating this will require not only data about testing experience and frequency, but also reliable data on previous key population interactions with health facilities, non-facility testing sites, mobile clinical services and other testing sites. Tracking individuals through the HIV system (testing, confirmation, linkage, retention) is fundamentally about implementation within the health system. Such evaluation may be more feasible within smaller systems (e.g. Denmark), more centralised systems (e.g. China), more unified payer systems (e.g. United Kingdom) and systems where unique health identifiers have been implemented (e.g. global north, China, Thailand). HIVST removes the opportunity for a formal, structured clinic visit that more easily collects identifying information for evaluating linkage to care. Comparing linkage and retention between individuals who enter the HIV care continuum through an HIVST test of triage compared to individuals who enter the HIV care continuum using an HIV facility-based test will be important, especially in light of the challenges in tracking self-testers. Evaluating individuals who enter the HIV care continuum through HIVST provides a strong foundation for identifying gaps in service provision

HIVST and social marketing

Social marketing is the systematic application of commercial marketing concepts and techniques to the analysis, planning, execution and evaluation of programmes designed to influence the voluntary behaviour of target audiences in order to improve their personal welfare [46]. Social marketing is a potentially powerful tool to increase demand for HIVST and organise evaluation programs. A systematic review found that social marketing campaigns increased HIV testing uptake significantly among MSM populations [47]. Social marketing campaigns to promote testing are sometimes branded [48,49], similar to how companies brand individual products with distinctive packaging, tag lines and promotion materials. Similarly, branding HIVST would also be feasible through unique packaging and promotional materials, but would need to be sustained over time. Social marketing campaigns are usually delivered through multimedia platforms, with or without incentives [50], at venues where key populations congregate. These campaigns are often specific enough to aid in evaluation programs [49]. For example, we can ask key populations if they have seen the promotional materials associated with the campaign. In this respect, social marketing provides a new denominator of individuals exposed to a behavioural intervention promoting HIVST, enhancing capacity to measure effectiveness. Understanding the social marketing messages that are most effective in promoting HIV testing among specific key populations can help scale up HIVST services among those populations.

HIVST and organisational/financial models

The effectiveness of HIVST may depend on organisational and financial characteristics of implementation. Organisational and financial models play a large role in determining whether HIVST programs are sustained over time. From an organisational perspective, there are several different organisational models for HIVST, including the following: home-based testing; community-based organisation testing; mobile clinic testing; facility-based clinic testing, pharmacy testing and online testing [13]. Each of these organisational structures has advantages and disadvantages in terms of scaling up testing and they are not mutually exclusive within comprehensive HIV control strategies. More detailed data about testing for triage as HIV-infected individuals receive their confirmatory tests could

help better understand those individuals in care, but more information is also needed about the period between test for triage and confirmatory testing. From a financial perspective, the price of self-testing and the financial model will be critical for testing sustainability in the long term. Our empirical data from South China suggest at least two financial models may be feasible to support HIVST [19]: the social enterprise model [51] and the social franchise model.

Social enterprise model

Social enterprise refers to organisations that apply entrepreneurial strategies to maximise improvements in human well-being rather than maximising profits for shareholders [52]. In the context of HIVST, social enterprises could charge modest fees for supervised self-testing services (testing, counselling and referral services) in order to generate revenues that would be re-invested in the organisation and ensure sustainability as public sector support decreases.

Social franchise model

Social franchising refers to using a commercial franchising system for social purposes instead of generating profit [53]. This model would allow individual community-based organisations to join into a franchise network to provide HIVST in accordance with quality and other standards.

Both social enterprises and social franchises have advantages and disadvantages that need to be considered in the context of HIVST. New organisational and financial models may expand the limits of HIVST implementation.

HIVST limitations

Several limitations of HIVST are worthy of further consideration. First, oral HIV tests have a lower sensitivity than blood-based HIV tests [54]. This will lead to false negative HIV test results for key populations that could be particularly worrisome among acutely infected individuals who have some of the greatest potential for onward HIV transmission. The potential for false negative HIVST to contribute to behavioural disinhibition should be considered as well. Second, the gradual decentralisation of HIV services as HIV is integrated into local health systems introduces many challenges, including individuals receiving services at multiple sites, non-clinical sites and from multiple nurses or physicians. This makes it challenging to differentiate first-time testers from re-testers [5], which is critical for evaluating HIVST. Third, tracking individuals following self-testing as they link or delay care is a fundamental issue within HIVST. Data from a systematic review suggesting that community-based HIV testing compared to facility based testing resulted in higher uptake among men who have sex with men and female sex workers and comparable linkage to care rates is encouraging [11], but further research tracking retention in care over time will be important. Finally, we use the term key populations, but there is much more data available from HIVST studies among MSM and sex workers compared to transgender individuals and people who inject drugs.

Summary

HIVST may be a promising intervention as part of a comprehensive HIV control strategy. Rigorous evaluation is needed to address how self-testing can be scaled up in several contexts. In particular, heterogeneous legal/regulatory environments, social and cultural testing norms (e.g. family-based testing and couples-based testing), policy environments (e.g. human rights frameworks), regulatory and guidance environments (e.g. norms established by professional institutions and regulatory

bodies), and financial environments (cost of self-testing to clients) raise important questions for scaling up self-testing services. Further research is needed to evaluate HIVST and bring the full advantages of implementation science to bear on HIVST among key populations. Implementation science is not a panacea for evaluation, but may help to enhance existing HIVST evaluation. Expanding the scope of evaluation beyond examining test kit characteristics and towards a richer measurement of test strategies is critical.

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Competing interests

The authors declare no competing interests.

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