

Home Self-Testing for HIV: Directions for Action Research in Developing Countries

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Introduction

Home self-testing (HST) offers a radically new alternative to voluntary counseling and testing (VCT) centers and is attractive for many reasons. Testing in the home promises more confidential results, more privacy, and ultimately, the chance for a greater number of people to learn their HIV status. As a result, people may be more empowered to seek preemptive medical care, practice safe sex, and plan for the future care of dependents. The possibility of HST is of special relevance in developing countries, where HIV testing services are limited or individuals are discouraged from testing at public sites because of stigma and discrimination.

Dr. Freya Spielberg thinks the time for HST has come. For all the promise the methodology holds, there are no home self-test kits approved by the United States (U.S.) Food and Drug Administration (FDA). The technology is close though, and scientific support for HST is increasing, built on research on two other testing methods, rapid HIV testing and home sample collection (HSC).

The efficacy and acceptability of rapid HIV tests have been confirmed by a decade of studies. Rapid testing provides results within 30 minutes, making it a practical testing method in outreach settings. A single FDA-approved rapid test exists on the market, and administration only requires a person trained to draw blood and a portable centrifuge. However, technology already exists for a new generation of rapid tests that will be non-invasive. FDA approval is anticipated soon for two simple finger-prick rapid tests, and clinical trials for a simple rapid oral fluid HIV test are underway.

As for HSC kits, the FDA struggled for a decade with technical and ethical issues and finally approved these kits for the commercial market. Individuals collect blood samples through a finger-prick test, mail in the specimens, and learn of their anonymous test results by telephone.

HST goes one step further, combining the privacy and at-home convenience of HSC with the fast results of rapid HIV tests. The issue of follow-up is the single biggest barrier. Conventional HIV testing and rapid HIV testing both provide face-to-face onsite counseling. In the HSC model, counseling is done by telephone. However, unless HST is strategically linked into counseling and referral programs, the burden will be on the individual to seek follow-up.

Crucial human rights questions also exist. Studies indicate that HIV-positive women in developing countries are especially vulnerable to partner violence and instability in primary relationships. Will HST place more women at risk or provide them with a confidential method for testing? And will programs develop strategies to safeguard these women, through provision of extended couples counseling, individual counseling, and referrals to social welfare organizations (Grinstead et al. 2001)?

Current State of Research

This paper explores the potential of HST to become an acceptable, feasible, and cost-effective method for HIV prevention and looks at the concerns that arise around access to counseling, follow-up care, and partner violence. Many of the relevant studies were conducted in the United States and will need to be undertaken in developing countries. More research is also needed that is specific to HST, in order to move the methodology from concept to reality.

Would Home Self-Testing Be Acceptable?

High-risk populations desire faster HIV tests, and secondly, they prefer HST to HSC (Spielberg et al. 2001; Spielberg et al. 2003a.) Individuals recruited for qualitative and survey studies at a sexually transmitted disease (STD) clinic, a needle exchange program for injecting drug users (IDUs), and bathhouses for men who have sex with men (MSM) in Seattle, Washington, reported a strong preference for quick test results, alternatives to face-to-face counseling, and non-invasive testing methods.

In survey responses to a set of hypothetical questions about testing preferences, the aforementioned risk groups favored HST over HSC because of the increased anonymity and the rapid test results (Spielberg et al. 2003a.) Likewise, people who had never tested previously were more likely to prefer HST or urine tests to standard serum tests, rapid clinic-based serum tests, oral fluid tests, and HSC.

In a 1999–2000 survey study, clients at four public HIV testing sites in San Francisco, California, preferred HST (24 percent) to HSC (1 percent) (Skolnick et al. 2001). It should be noted, however, that among these participants who had all sought testing in public clinics, 63 percent selected that venue as their first choice, in part because of the provision of in-person counseling. HST will likely appeal more to people who are not comfortable testing in public clinics, or who do not seek counseling.

Similar studies are needed in developing countries to measure the preferences for HIV testing methodologies and gauge the acceptability of rapid HIV testing and HST. As a beginning point, Wolff et al. (2002) explored issues around home versus facility-based post-test counseling in rural Uganda. Home settings were generally regarded as more private and comfortable for receiving test results. However, even home-based counseling did not quell worries among some respondents about privacy issues or stigma at the community level. HST may address some of these concerns.

Detecting HIV

Several methodologies are available for detecting HIV. In all cases, an enzyme immunoassay process is used to detect antibodies to HIV and any reactive or preliminary positive results are then confirmed by a Western blot or an immunofluorescence assay.

- Standard HIV tests use serum or plasma; results take up to two weeks.
- Rapid tests use serum, plasma or whole blood; results available within 30 minutes.
- HSC uses dried blood spot samples that are mailed into a central laboratory; results take one week.
- Two less-invasive tests exist. One uses oral fluid from mucous membranes in the mouth and the other, urine; results take up to two weeks. Both oral fluid and urine can also be confirmed by FDA-approved Western blots.

Source: CDC/MMWR 2001.

Would Home Self-Testing Be Feasible?

There are no data on the feasibility of HST. However, as a first step in this direction, a study by Spielberg et al. (2000) found HSC to be feasible in terms of specimen collection and quality. In 1996, researchers conducted a multi-site study of 241 participants drawn from the U.S.-based HIV Network for Prevention Trials. The participants—high-risk heterosexual women, IDUs, and MSM—were randomized to collect dried blood spot specimens (DBS) or oral fluid (OF) samples bimonthly. Participants sent in 96 percent of the expected OF specimens and 90 percent of the expected DBS specimens. Of the samples collected, 99 percent were suitable for testing.

Almost 100 percent of the enrollees expressed a strong preference for receiving test results by telephone, rather than in person. While telephone results were regarded as more convenient, on-site counseling was considered more private (although 40 percent regarded both models as similar in this aspect), supportive, and comfortable for talking with a counselor (Spielberg et al. 2000). For people experienced in HIV counseling and testing, convenience guided their choice of HSC, despite the preferred attributes of face-to-face counseling.

The use of HSC would be problematic in some developing countries, as it depends on reliable mail and telephone systems. HST would be ideal because of the simple technology, but it requires the development of an easily accessible counseling and confirmatory testing network.

How Would Home Self-Testing Impact Follow-Up Among People with HIV?

One of the main concerns around the use of HSC or HST is the potential for loss to follow-up among people who receive positive test results by telephone or at home. However, U.S. data (Branson 1998) suggest that people who receive their tests results by telephone do accept referrals for follow-up care. Branson retrospectively analyzed data from two U.S. post-marketing evaluations of HSC kits manufactured by Home Access Health Corporation (HAHC) and Direct Access Diagnostics. Individuals mailed in DBS specimens to a laboratory and called a toll-free number for test results. Negative test results were delivered via a prerecorded message, while a counselor provided all positive or indeterminate results and offered counseling and referrals.

The pool of data from the two manufacturers represented 174,300 tests. About 95 percent of the samples were of high enough quality to be analyzed in the laboratory. Follow-up among the test-takers was high, with 97 percent of the individuals calling for results. According to data from HAHC, almost 60 percent were test-takers for the first time. Among those newly diagnosed HIV-positive, 49 percent were first-time testers. Based on the HAHC telephone log, 65 percent of the newly diagnosed HIV-positive callers accepted referrals, 23 percent already had access to follow-up care, and the remaining 12 percent were on antiretroviral therapy and simply checking their HIV status. These data suggest that the majority of people in similar contexts who receive results at home will follow up for face-to-face counseling and care.

A recent study by Spielberg et al. (2003b) suggests that rapid testing may improve follow-up for early treatment counseling and partner notification, as compared to testing methods that have a 7- to 14-day delay in results. A randomized trial compared the acceptability of rapid testing, OF testing, and standard blood

What is Voluntary Counseling and Testing?

The model recommended by the Centers for Disease Control and Prevention follows a two-step counseling process. At the first visit, counselors help individuals evaluate high-risk behaviors and articulate strategies for reducing risk, and clients are then tested. At the second visit, counselors discuss tests results, reinforce risk reduction approaches, and provide referrals for medical care and support. With rapid testing the content of these two sessions is combined into a single session.

Source: CDC/MMWR 2001.

testing in two Seattle, Washington, bathhouses for MSM. Rapid testing provided preliminary positive results within 30 minutes and confirmed results within 3 days. In contrast, the standard serum and oral fluid test both had longer waits for results. Although few people were newly diagnosed with HIV in this study, those assigned to rapid testing had a better rate of following up for confirmation of results and were more emotionally prepared to discuss treatment options and the issue of notifying partners.

In another study, Kroc et al. (2002) examined the acceptability and feasibility of rapid testing in an emergency department of a large Chicago, Illinois, hospital. Of the 410 patients who elected rapid HIV testing and pretest counseling, 98 percent followed up to receive results and counseling.

These studies suggest that people who pursue HSC and rapid HIV tests are motivated to follow up for confirmatory testing and are receptive to counseling. However, longitudinal studies of HST are needed to verify this in developing and industrialized country settings.

Would Home Self-Testing Bolster HIV Prevention Efforts?

With HST there is a risk that fewer people would receive HIV prevention counseling. On the other hand, the increased diagnosis of people with HIV could be of great benefit. Evidence shows that VCT is an effective intervention strategy in developing countries, especially for those who are HIV-positive. The Voluntary HIV-1 Counseling and Testing Efficacy Study, conducted during 1995–98 in Nairobi, Kenya; Dar es Salaam, Tanzania; and Port of Spain, Trinidad, randomly assigned 586 couples and 3,120 individuals to counseling and HIV-1 testing or to a basic health information session (The Voluntary HIV-1 Counseling and Testing Efficacy Study Group 2000). In men, VCT resulted in a 35 percent reduction in unprotected sex with nonprimary partners, as compared to a 13 percent reduction among those receiving health information. The results were striking in women as well. Those receiving VCT had a 39 percent reduction in unprotected sex with nonprimary partners versus a 17 percent reduction in the health information arm. In couples, VCT also proved more effective than health information in reducing unprotected sex with enrollment partners.

Knowledge of positive HIV status can be a powerful motivator for change. A multi-site, U.S.-based study conducted by the Centers for Disease Control and Prevention in 1997–98 found that among 180 newly diagnosed HIV-positive individuals, 90 percent reported changing their sexual behavior, including more frequent condom use (60 percent), reducing the frequency of sex (36 percent), and abstaining from sex (10 percent) (CDC/MMWR 2000). In this same study, self-reported condom use increased dramatically among women engaged in vaginal sex with men and men engaged in anal sex with men; consistent condom use increased from 6 percent prediagnosis to 47 percent postdiagnosis in these populations (CDC/MMWR 2000).

HST may also benefit HIV prevention efforts by making it possible to choose sex partners based on their HIV status. Varghese et al. (2002) found that selecting an HIV-negative partner accounted for a more dramatic decrease in HIV infection risk than condom use or type of sexual act. In populations with a 1 percent HIV prevalence, heterosexual individuals who selected known HIV-negative partners as compared with untested partners reduced their relative risk of infection 47-fold. In populations with 40 percent HIV prevalence, the relative risk of infection was reduced 30-fold.

These studies show that HST has the potential to be a powerful tool for HIV prevention, but additional studies will be necessary to assess the tradeoffs.

Would Home Self-Testing Place Individuals at Risk for Violence?

A key concern surrounding implementation of HST is whether it will place more individuals at risk for violence. Grinstead et al. (2001) examined the social impact on those participating in The Voluntary HIV-1 Counseling and Testing Efficacy Study by exploring positive and negative life events seven months after

VCT. Researchers found that HIV-positive women were particularly vulnerable to family ostracism and the break-up of marriages or sexual relationships. In contrast, HIV-positive and HIV-negative men, and HIV-negative women who shared their status with partners more often reported a strengthening of their relationships. Based on these preliminary findings, researchers recommend that programs target additional resources to HIV sero-discordant couples (in which the female partner is HIV-positive and the male partner is HIV-negative).

Maman et al. (2002) tracked the history and prevalence of partner violence among 245 women who sought VCT at a clinic in Dar es Salaam, Tanzania, in 1999, and found not only a tolerance of violence at the community level but increased risk of violence toward HIV-positive women. Among the group surveyed, 46 percent of the women reported having had a verbally abusive partner in their lifetime and 38 percent a physically abusive partner. About 27 percent of the women indicated that violence was a problem in their lives presently. HIV-positive respondents reported a higher number of physically violent partners overall, and greater physical and sexual violence with current partners. Additionally, researchers found that HIV-positive women under 30 years of age had dramatically increased odds of reporting violence as compared with their HIV-negative peers.

These studies point to the need for interventions that will help reduce violence toward HIV-positive women. HST will raise the profile of this issue even higher, as ways must be found to effectively link HIV-positive individuals, and particularly women, to counseling, social support, and social welfare organizations.

Would Home Self-Testing Be a Cost-Effective Method for HIV Prevention?

Sweat et al. (2000) estimated the cost-effectiveness of HIV-1 VCT in an urban East African setting, using a model based on data from The Voluntary HIV-1 Counseling and Testing Efficacy Study. VCT was estimated to have cost \$266,500 annually in Kenya and \$289,300 in Tanzania per 10,000 clients, and to have avoided 1,104 HIV-1 infections and 895 infections, respectively. The cost to avert one HIV-1 infection was estimated to cost \$369 in Kenya and \$425 in Tanzania. The cost-effectiveness can be improved by targeting specific groups and high HIV-prevalence populations. Although HIV-1 VCT had a higher cost per DALY (disability-adjusted life-year) than some prevention strategies, it was still considered a cost-effective, public-health intervention by World Bank standards.

Alternative staffing may also help improve the feasibility of testing and counseling programs that are under heavy demand. At a KwaZulu, Natal, South African VCT center, Campbell (2002) found that exhausted health care staff were spending far less than the recommended counseling time per individual. In addition, the standard serum test and its 10-day waiting period resulted in fewer clients returning for results. In response, 10 lay counselors were trained to work collaboratively with nurses. Together, they provided rapid HIV testing and counseling to 8,700 clients, half of whom were HIV-positive, thus improving the cost-effectiveness of their testing program.

HST has the potential to be less costly and more effective than currently available testing programs. Studies are needed to compare the cost-effectiveness of HST to traditional VCT models to determine the relative cost per HIV infection averted.

Recommendations for Practice: Research Implications for HIV/AIDS Programming

In order to better evaluate the potential application of HST in developing countries, studies are needed to explore the following questions:

- 1) What are the acceptability and feasibility of HST?
- 2) What is the relative impact of HST on HIV prevention? Does making HST available result in more and earlier detection of HIV infection? Are written materials and other alternatives to counseling effective in reducing risk behavior and HIV incidence, as compared to traditional VCT models? And if not, are there innovative ways of linking HST initiatives to successful counseling and referral programs?
- 3) Do the positive outcomes of HST outweigh the negative outcomes, such as increased violence, vulnerability, and discrimination?
- 4) What is the relative cost, effectiveness, and acceptability of HST as compared to other alternative testing models (i.e., home staff rapid testing or clinic-based testing)?

Conclusion

Market forces may soon make HST kits available over-the-counter in industrialized and developing countries alike. Home self-testing has the potential to be a broadly implemented component of community-wide HIV prevention plans. Although untried, it is a potentially powerful tool for breaking through the barriers of stigma and reaching populations who do not have access to standard VCT services or who, because of privacy concerns, do not make use of facility-based, standard HIV testing. Research on the acceptability, feasibility, safety, effectiveness, and cost of HST in developing country settings will be necessary to realize the full potential of this new technology.

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The Expert

Freya Spielberg, MD, MPH, is an assistant professor in the Department of Family Medicine at the University of Washington. She is principal investigator on a grant funded by the National Institute on Drug Abuse, “Counseling strategies to reduce risk among intravenous drug users.” In 2000–01, Dr. Spielberg was principal investigator on a clinical trial for OraQuick, a rapid oral fluid HIV-1 test, funded by OraSure Technologies Inc. (formally Epitepe), and during 1997–2000, she was principal investigator on a grant funded by the Centers for Disease Control and Prevention (CDC) titled “Alternative strategies to reduce barriers to HIV testing at an STD clinic, a bath house, and a store-front needle exchange.” Dr. Spielberg has authored several papers on the acceptability of alternative HIV testing strategies. In 1993, she studied HIV enzyme immunoassay testing of saliva and urine in tropical conditions as part of a Thailand-based project for the CDC and headed a USAID-funded research project evaluating the efficacy of five rapid HIV tests in Zaire in the late 1980s. Dr. Spielberg is medical director of the People of Color Against AIDS Network HIV Counseling and Testing Program in Seattle, Washington.

The Staff

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