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# Home Testing for HIV Infection in Resource-Limited Settings

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## Abstract

Among an estimated 33 million individuals who are infected with HIV worldwide, only 10% are aware of their status. HIV testing is the cornerstone to preventing further transmission and to caring for those infected, particularly as access to treatment improves in resource-limited settings. However, efforts to expand testing through facilities-based testing have not achieved adequate testing coverage, prompting efforts to reach more individuals through strategies such as home-based HIV testing. Home testing is showing promising early results in some high-prevalence, resource-limited settings. This article reviews the mechanisms and literature to date of this door-to-door approach.

## Introduction

HIV/AIDS remains a massive global pandemic, with an estimated 33 million people infected worldwide in 2007, yet only 10% of these HIV-infected individuals are aware of their status [1,2]. Once a predictably fatal diagnosis, HIV disease has now become a treatable chronic condition [3]. Because favorable clinical outcomes are contingent upon timely treatment, there is new focus on the early identification of HIV-infected individuals, particularly in resource-limited settings where antiretroviral therapy (ART) is increasingly available.

To this end, efforts to scale up HIV testing have included expansion of voluntary counseling and testing (VCT) centers and launching of antenatal testing programs and hospital-based screening initiatives. These efforts are in keeping with 2006 World Health Organization (WHO) guidelines to promote provider-initiated HIV testing in high-prevalence settings [4]. Although VCT centers provide a reliable testing resource, this approach has elicited concerns about the feasibility of reaching all individuals at risk, as well as associated stigma, inconvenience, and lack of privacy [5,6]. Provider-initiated testing in health care facilities has been relatively well-received and has had considerable success in identifying HIV-infected individuals by capitalizing on existing health care relationships. However, the strategy only reaches a defined subset of the population: those with access to health care. Both strategies are less likely to capture partners and family members of HIV-infected people, as well as lower socioeconomic groups [7•].

These gaps have prompted the development of complementary models of HIV testing that attempt to bypass these shortcomings and target a wider audience by bringing diagnostic tools to individuals' homes; home-based HIV testing shows promising early results in resource-limited settings. In this review, we discuss home-based HIV testing in such settings, including the types of tests used, demographic populations that are reached by this



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method, effectiveness compared with other testing strategies, and important next steps in optimizing this approach.

## Overview of HIV Diagnostics

### United States

In the United States, the first HIV diagnostic test was approved by the US Food and Drug Administration (FDA) in 1985. Since their inception, these tests have undergone substantial improvements in accuracy, convenience, and speed. Still, the gold standard test for HIV diagnosis remains the enzyme-linked immunoassay (ELISA) antibody test, performed in duplicate and followed by confirmation with a Western blot [8].

Rapid HIV testing can now be performed within 20 minutes on a sample of whole blood, plasma, or oral mucosal transudate using the OraQuick Advance Rapid HIV 1/2 Antibody Test (OraSure Technologies Inc., Bethlehem, PA), which detects both HIV-1 and -2. Although this test has become one of the most commonly used point of care tests, it, like all rapid tests, remains only a screening test that requires follow-up Western blot confirmation when results are reactive [8]. Reported clusters of high false-positive rates in major US cities have demonstrated the potential for poor positive predictive value of such screening tests in low-prevalence settings and emphasized the need to clearly label test results as preliminary [9].

### Resource-limited settings

The translation of US testing kits to clinical use in resource-limited settings requires consideration of several issues. First, an appropriate test must detect HIV subtypes and clades that are prevalent in these regions. For example, while the HIV-1 group M clade B is most common in the Americas, Europe, and Australia, clade C is most common worldwide, and HIV-2 must be detectable in west Africa, where it is most prevalent [8]. The test must be heat-stable with a long shelf-life at ambient temperatures. Because most HIV testing in resource-limited settings occurs in a clinical venue, outside a standard laboratory, the test should also be easy, safe, and quick to use, as well as simple to interpret [10]. Maximizing test sensitivity is critical, because false-negative results may be of particular concern in high-prevalence settings [11–13].

The current testing strategy in most resource-limited settings is rapid tests or dual standard ELISA tests (in series or in parallel) from different manufacturers [14]. Rapid testing effectively precludes the need for confirmation with venipuncture samples and Western blot, which are often inaccessible, and saves individuals the time and cost required to retrieve test results days later. In Botswana, for example, testers begin with parallel rapid tests: UniGold Recombigen HIV (Trinity Biotech, Bray, Ireland) and Determine HIV 1/2 (Abbott Diagnostics, Abbott Park, IL). If the results of these tests are discordant, they are both repeated. If they remain discordant, the OraQuick test is used to make the final determination [15]. According to a 2004 report from the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the WHO, such combinations provide the same reliability as an ELISA supplemented with Western blot, and do so at much lower cost [10].

The high incidence of HIV in resource-limited settings and the long distances patients must often travel to access health care also mandate ready identification of acute HIV syndrome, which is not detectable by traditional antibody-based tests. New tests that detect p24 protein forming the HIV capsid are sensitive to both acute and chronic disease [16] and will soon be more widely available.

## Home Testing in the United States and in Resource-Limited Settings

In the mid-1990s, some advocates promoted the availability of over-the-counter HIV tests to improve suboptimal testing rates in the United States [17]. As with home pregnancy testing, the concept of home HIV testing was motivated by consumer desire to learn one's HIV status through personal initiative in the convenience and privacy of home, and then to seek follow-up care if and when it was needed. The first two home-collection kits were approved by the FDA in 1996, only one of which—the Home Access HIV-1 Test System (Home Access Health Corporation, Hoffman Estates, IL)—is still commercially available. Using these over-the-counter kits, clients obtain dried blood samples, send them to a laboratory for processing, and call to anonymously receive their results within a week [17,18]. Although current "home" HIV tests involve home collection of a sample that is subsequently sent out for analysis, the FDA is currently considering the over-the-counter sale of rapid tests that could be performed as well as interpreted at home [19].

Surveys on home collection kits for HIV testing in the United States demonstrated that they were highly acceptable among nearly 175,000 customers in the first year of use. Ninety-five percent of this group collected testable specimens, while 97% of them subsequently called to learn their results. Most users who responded to an associated survey were white men between 25 and 34 years old. Nearly 60% of home kit users and 49% of the 0.9% testing positive had never been tested before [18]. In another study that evaluated bimonthly testing on 241 high-risk individuals, including men who have sex with men, injecting drug users, and women at heterosexual risk, 90% to 96% of expected samples were received by the laboratory and 95% of users had test results disclosed over the telephone [20].

The FDA is currently considering the OraQuick Advance Rapid HIV 1/2 Antibody Test for over-the-counter availability and self-administration. This test has undergone an observed use study for over-the-counter use and is awaiting review by the Blood Products Advisory Committee [19,21,22]. In a survey of nearly 3000 California residents, 37% of respondents showed willingness to use an over-the-counter test [23].

In the United States, benefits of home testing include convenience, privacy, anonymity, and potentially increased access to tests [18]. Home specimen collection with telephone counseling may lead to earlier detection of disease [24]. Use of the kits has also been associated with improved outcomes: fewer high-risk behaviors in those testing positive and increased linkage to care [17,25]. In the study of bimonthly testing noted above, 98% reported their risk behaviors remained the same (77%) or became less risky (21%) as a result of testing [20]. Post-marketing analysis of the tests approved in 1996 found that 65% of those testing positive accepted referrals for care, whereas 23% of HIV-positive users already had a source of follow-up care [18].

Still, in 2009, home testing is met with controversy, in large part because it challenges the FDA's standard of linking diagnostic testing to professional counseling [21,26]. Critics also cite difficulty in conveying the implications of a positive screening test, which can lead to psychological distress, and conversely, those of a negative screening test early in infection, which can provide a false sense of security [17,26]. Some have raised concerns that this modality will not target the high-risk populations that are in greatest need and will instead be used by groups including the affluent and the worried well. The test is currently priced at about $40, above what most can afford or are willing to pay: survey data suggest that Americans are unwilling to spend more than $15 on a test [17,18,22,26,27].

In resource-limited settings, home-based testing currently means door-to-door implementation of rapid tests by lay counselors or community health workers, although other approaches for distribution of self-administered tests are being considered [28]. In

studies evaluating the home testing approach, counselors administer varying combinations of rapid tests that can be developed in a client's home within 20 minutes, allowing receipt of results at the same visit. Other studies evaluate the home delivery of HIV test results that have been developed in clinical settings.

## Early Examples of Home Testing Success in Resource-Limited Settings

Home-based testing, part of a wider effort to identify and therefore treat more HIV-infected individuals in resource-limited settings, is showing early signs of success. Surveys and trials that assess home-based testing as well as home delivery of test results have had high test acceptability and uptake compared with facility-based testing in both urban and rural resource-limited settings, particularly among those who cannot afford the cost and time required to travel to a testing center [6,29,30]. In a randomized controlled trial of 2445 adults in urban Zambia, participants were offered testing in a clinic or an alternate location; among the latter group, 84% chose home as the venue for testing. A greater proportion of participants who were offered clinic-based testing expressed willingness to be tested, compared with those offered an alternate location (40% vs 30%). However, 56% of those willing participants in the alternate site group actually completed the testing process, compared with 12% among the clinic group. Greater initial willingness to undergo clinic-based testing may be explained by greater familiarity with this approach. The 4.7-fold overall testing completion rate of home testing was attributed in surveys to greater ease of access and privacy [5].

In a cohort study in the Rakai district of southwestern Uganda, testing completion nearly doubled from 35% in 1994 to 1995 to 65% in 1999 to 2000 with the availability of counselor-initiated home-based testing [31]. Another cohort study conducted in rural southwestern Uganda found that 1868 participants in four villages were more than five times more likely to receive results during the intervention year—in which they were offered home delivery of results obtained from annual door-to-door blood collections—compared with the year in which these results were only available in health care facilities. The confirmed receipt of test results by participants increased from 10% to 37% with the availability of home testing [29].

Another door-to-door testing program that was implemented over 2 years across the Bushenyi district of Uganda reached 63% of all households. Population-based surveys of about 1500 adult participants conducted before and after the program found that the proportion of individuals who had ever been tested increased from 20% to 63% [32].

Further studies in countries including Uganda, Botswana, Zambia, and Mozambique have shown increased comfort level and more frequent completion of the testing process with home-based compared with clinic-based testing [33–36].

### Home testing and access to specific populations

Studies suggest that home-based testing achieves its goal in reaching populations previously untapped by standard testing programs. One study in Uganda found that home-based testing by counselors most efficiently reached individuals with low rates of prior testing and those with higher CD4 counts, compared with hospital-based and other strategies [37•]. Differential rates of testing uptake and acceptance have also been shown along a number of demographic variables.

**Socioeconomic status—**Demographic and health surveys in sub-Saharan Africa show a strong socioeconomic gradient in the use of traditional, facility-based VCT, with lowest uptake among the poorest individuals. Home testing may be especially effective for this

population [7•]. In a home-based testing campaign on Likoma Island, Malawi, members of households in the lowest income quartile were significantly less likely to have used facility-based testing and counseling services compared with the rest of the population (OR = 0.60), but more likely to use home-based services during the study (adjusted OR = 1.70) [7•]. Although sicker individuals—those frequently HIV-infected—may be expected to access health care facilities more often, the study results may be better explained by the potentially prohibitive travel and other costs required to access health care facilities, which would be particularly burdensome to this subpopulation.

**Age—**Studies have shown conflicting results on the age distribution of those who are tested at home. In one Ugandan study, individuals between 15 and 24 years of age were less likely to test either at home or in a clinic, when compared with other age groups [38]. Home testing may be less appealing to youth who live with their families, due to privacy issues [29]. However, a study in Zambia found highest uptake among rural males aged 15 to 19 years (3%–26%), a promising finding given that this population has been challenging to target with other testing strategies [39]. In a Mozambique study, home testing was the most effective at reaching children, compared with other community-based testing modalities [40]. Among 25- to 49-year-olds, poor self-rated health doubled the likelihood that an individual was willing to be tested at home, suggesting that ease of testing via home access would be particularly beneficial to this population [5].

**Gender—**Women are more likely than men to complete HIV testing in any given testing site [15,41], and in most countries, are more likely to be aware of their HIV status [42]. In studies evaluating home testing in particular, women were more likely to undergo testing than men [33,35,38,43–45]. The proportion of women who were initially offered testing was as high as 75% in urban Kenya [35]. These findings may be explained by the greater likelihood of women to remain at home during the day.

**Family and partners—**Home-based testing may target couples and families more efficiently than other strategies, although social considerations may complicate this benefit.

In a Mozambique study, home testing reached more couples than other community-based strategies, such as mobile testing units [40]. In kind, the home-based approach may be particularly effective at identifying household members of known HIV-infected individuals. A Ugandan study randomized 7184 household members of HIV-infected persons to be offered free home-based or clinic-based testing, counseling, and care. Reported results indicate that 56% of all HIV-infected household members in the home-testing arm were identified, compared with 27% in the clinic arm [38]. Although some studies show that couples with conflicting attitudes toward testing may be less amenable to a home visit, others suggest that for some HIV-discordant couples, home-based testing may foster family support and aid in risk reduction [6,29].

A 2007 meta-analysis by the *Cochrane Library* concluded there is still insufficient evidence to recommend large-scale implementation of the home-based testing model [6]. However, several of the more promising studies on this approach have been published since the analysis was performed; it will be important to revisit these conclusions in light of emerging data [7•,37•].

## Impact on Stigma and Behavior

Fear of stigma is often cited as a major deterrent against the use of VCT centers [6,29]. Home-based testing was conceived in part to reduce the stigma associated with visiting a publicly visible, dedicated HIV testing center, by precluding this visit and normalizing the

testing process. Interviews and focus groups conducted with participants report that the home-based approach has been successful not only in reducing the fear of stigmatization, but also in minimizing the emotional vulnerability associated with traditional methods [29]. In a district-wide Ugandan study, the proportion of persons willing to buy vegetables from an HIV-infected vendor increased from 74% to 83% following a 2-year home-testing program, and the proportion of persons not desiring their infected family member's serostatus to remain secret increased from 59% to 70% after this program. The proportion of persons reporting disclosure of serostatus rose from 72% to 81%, suggesting increased comfort with testing outcomes [32].

Home-based testing may also be associated with fewer high-risk behaviors. In the same Ugandan study, condom use during the previous sexual act increased from 15% to 40% among HIV-infected individuals who learned their serostatus through a home testing protocol [32].

## Barriers to Home Testing

Despite its increasingly recognized benefits, wide-scale implementation of counselor-initiated home-based HIV testing in not imminent due to several important barriers that may be more pronounced in resource-limited settings. These obstacles include less awareness of testing options, more difficulty acquiring these tests due to high costs and remote settings, limited availability of confirmatory tests that require serum sampling, and difficulty preserving any cold chain that may be necessary to maintain test kit viability [46].

Concern about confidentiality is an additional obstacle. Because home testing is often conducted in hard-to-reach areas, local residents are frequently employed as counselors to perform the tests. Although this approach expands testing outreach, those being tested may fear a confidentiality breach by local counselors. A few studies have addressed this concern by employing counselors from separate geographic locations [5,7•].

Some have speculated on the feasibility of self-administered home-based tests provided free of charge in resource-limited settings, similar to self-administered tests now being considered for FDA approval in the United States [19]. One potential benefit of self-testing is that it may allow overworked hospital staff members to focus on providing patients with other critical services. Some public health innovators suggest using new technologies such as mobile phone messaging to efficiently inform the public about home self-tests, as well as to improve linkage to care [47]. However, the difficulty in using and accurately interpreting tests may be a major challenge to self-administered testing. A cross-sectional study of 350 participants across two Singapore HIV testing centers found that while nearly 90% reported that the blood sample rapid test was easy to use, 85% failed to perform the steps—especially blood sampling—adequately, leading to invalid results for 56% of participants. Twelve percent were unable to correctly determine results, as confirmed by trained personnel [48]. Data have yet to be published from high HIV-prevalent regions, although extant reports suggest that self-administered testing should be approached with caution.

As with most HIV testing efforts, home self-testing without counselor involvement raises the concern of adequate consent procedures. Some argue that rapid self-tests may be more easily used without an individual's consent—particularly for women, adolescents, or the debilitated—and that physical abuse stemming from testing may be more difficult to police [49]. In developing countries, there may also be fewer legal protections against abuse of home testing, for example by family members or employers wishing to know an individual's status without his or her consent [30].

## Effect on Linkage to Care

Expanded HIV testing through modalities including home-based testing is only beneficial to individuals and to the public if testing is linked with effective prevention, medical care, and psychosocial support. Linkage of traditional VCT to these services has been a major challenge in the past, and experience suggests that testing initiatives are most efficient if linkage to care is improved, even before scale-up of testing [8,50]. Furthermore, if home testing particularly reaches populations who have difficulty accessing health care facilities, as studies have suggested, intensified outreach for linkage to clinical care will be essential for those who are identified as infected at home.

Although data on home collection for testing in the United States suggest improved linkage, studies have not adequately addressed this issue in resource-limited settings. Individuals burdened with the knowledge of a positive home test are susceptible to poor psychological outcomes, particularly if follow-up care is difficult to access. What's more, delayed initiation of ART following diagnosis is associated with high mortality rates in resource-limited settings [51]. Linkage to care is a critical reportable outcome, essential to accurate assessment of the individual benefits, costs, and impact of home testing.

## Cost Effectiveness

Identification and treatment of a greater percentage of HIV-infected individuals in order to save more lives—the ultimate goal of testing scale-up—necessarily comes at a price. In a Ugandan study comparing four testing approaches, door-to-door testing was the least expensive, costing $8.29 (2007 US dollars) per client compared with the costliest approach, stand-alone counseling and testing ($19.26). Door-to-door testing also had the lowest ratio of cost per new client tested ($9.21 per client). However, because home-based testing identified a much lower HIV prevalence than hospital-based testing (5.1% vs 27.2%), hospital-based testing had the lowest ratio of cost per case identified ($43.10 vs $163.93) [37•].

Although home-testing may be associated with a higher cost per case identified, it is important to note that a year of health-preserving ART costs about the same amount ($130) [52]. At such costs, ART has previously been noted to be a cost-effective intervention [53]. Formal cost-effectiveness analyses are required to fully understand the economic value of home-based testing, particularly as one component of a several-pronged approach to both prevent and treat the infection.

If self-administered home testing is implemented in resource-poor settings, as some have suggested, its success is contingent upon the affordability of the test to its consumers; ideally, the tests would be free to patients or accessible at considerably reduced cost [54]. As with the expansion of any testing effort, political will is critical to make such self-tests both feasible and effective: the introduction of self-testing kits will require collective efforts by local governments, nongovernmental organizations, the WHO, and the United Nations Education, Scientific, and Cultural Organization to ensure test affordability, availability of support services, and linkage to care [30,55].

## Conclusions

HIV testing is a critical gateway to care and secondary prevention, particularly in resource-limited settings burdened with high disease prevalence. Current strategies that rely on facility-based testing have proven inadequate for the goal of universal identification and treatment over the past 10 years, demanding the use of alternate methods such as home-based testing. Home testing in resource-limited settings has met with early success, based on

studies demonstrating improved access to testing, acceptability, effective case identification, behavior risk reduction, and disclosure of status, particularly among women and those of low socioeconomic status. However, the impact of this method on linkage to care, the critical last step in the testing process, remains to be seen.

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