The idea of home-based self-testing for HIV has existed for over two decades; however, its implementation has not been without debate and controversy. With accurate, rapid point-of-care tests, newer, simplified and optimized antiretroviral regimens, and an imperative to widen HIV testing to the general population, the idea of providing individuals with a tool for home-based self-testing deserves renewed consideration. Although test results are rapid, some issues to consider are: test results are considered ‘preliminary positive’ and requiring confirmatory testing, obtaining accurate results consistently, particularly in low-prevalence populations is challenging, and risk of adverse psychological outcomes (i.e., stress and suicide) with erroneous test results is always a possibility. Barring one study, there has only been limited evaluation of the impact of self-testing for HIV. Thus, in the absence of evidence, is it plausible to think that these concerns could be overtly exaggerated? Is HIV self-testing too stigmatized and protected? In view of the advances in HIV treatment such as effective once-a-day dosing treatment options, isn’t it time to empower people with an HIV test? This editorial examines issues and challenges with the use of home-based HIV tests.

Lifelong management of chronic HIV infection is now a reality with the introduction of newer, optimized, antiretroviral treatment regimens [1]. An HIV-positive diagnosis today, although stigmatized, is not considered a death sentence. Timely ascertainment and knowledge of sero-status, however, is essential to availing treatment benefit. Evidence to date supports the notion that early detection and diagnosis expedites early treatment and linkage to care, and also facilitates the modification of risk behavior [2]. Thus, early diagnosis may additionally aid in prevention of HIV transmission, providing an important public-health benefit.

Although HIV testing technologies may have expanded over the past few decades, implementing HIV testing in public-health settings (i.e., sexually-transmitted disease clinics, hospitals and outreach settings) has been a challenging endeavor. High standards of privacy and counseling required for HIV testing often act as a barrier to the uptake of testing [2]. Furthermore, concerns about confidentiality, high visibility and emotional vulnerability of receiving results in public facilities [3], unwillingness to learn the test result in public [3], as well as stigma and discrimination have deterred people from getting tested publicly. Not surprisingly, therefore, of those who do test in public facilities, 30–31% in the USA/UK fail to pick up and follow-up on their test results [4]. For these individuals, rapid point-of-care HIV tests offer a convenient home-based, self-testing option. For example, the US FDA-approved Oraquick® ADVANCE test is a simple, user friendly, accurate and convenient point-of-care HIV test for use on oral fluid, blood and plasma specimens, with the possibility of obtaining test results within 20 min [5]. Many FDA-Approved Clinical Laboratory Improvement Amendments law of 1988 (CLIA)-waived tests such as Oraquick, Reveal®, Uni-gold Recombigen® and Home Access® require minimal training for their conduct and interpretation [101,102]. Despite availability, these tests have not yet been introduced for home-based, self-testing for HIV. The question is: why are we hesitant in offering a self-testing option to people?

Offering self-testing to the public is controversial and has been considered too risky. Numerous hearings have been conducted by the FDA on self-tests where public health concerns have been raised [6,102]. Few field studies, however, have evaluated the feasibility of the introduction of these tests for home-based self-testing and, therefore, there is a paucity of evidence on which to base policy decisions. The question to
The question to consider is: are we being too overly concerned about the introduction of these home-based self-tests?

The idea of having a home-based HIV self-test kit was first proposed by Elliott Millenson, an entrepreneur in 1986 [7]. Two decades later, there are no signs of FDA-approved home-based self-tests. This article examines the arguments as they relate to issues and challenges with home-based HIV self-tests.

Differences between home self-test & home sample-collection test

Currently, FDA-approved tests (Home Access® HIV test system) are home-based sample-collection tests [8]. With these tests, a finger-prick blood sample is collected on a card using a retractable lancet and mailed to a central facility. Consumers call a toll-free number to register their 11-digit test number, obtain pretest, post-test counseling and, later, confirmatory test results and referrals to community resources. Counseling services are offered by professional counselors. The first home-based sample collection test in the series was Confi de (Johnson & Johnson Direct Access Diagnostics), first introduced in 1996 [9] in the states of Texas and Florida, USA, with the hope of changing testing patterns in these states [9,10]. Confi de faced some legal issues and was withdrawn from the market a few years later. The next in line, and currently in use, is the Home Access HIV-1 test system or HIV-1 Home Express test (Home Access Health Corp., USA), an FDA-approved, CLIA-waived test-kit system [8].

On the other hand, home self-tests, similar to pregnancy tests, if introduced, will enable individuals to self-test using oral fluid or finger-stick samples, and know their serostatus in 20–40 min. The only test that has come close to being considered for home self-testing is the first FDA-approved oral/blood-based rapid point-of-care test, Oraquick® ADVANCE HIV-1/2 test (Orasure Technologies Inc, USA).

Arguments in favor of self-testing

Advantages of self-testing

Self-testing is a powerful, novel tool for HIV diagnosis [12]. Self-testing offers individuals a chance to know their status in the privacy of their homes, ensuring confidentiality, empowers and promotes proactivity in healthcare decisions, avoids the issue of stigma and visibility in public settings, provides an early knowledge of sero-status, potentially aids future prevention of HIV transmission and, lastly, provides possible public-health benefits by modifying the trajectory of the HIV epidemic [13].

Populations that may benefit from its use

Populations that may benefit from self-tests range from those at a low, average and high risk for HIV acquisition. Walensky et al., have further categorized populations into:

- ‘Worried well populations’, those who are at average risk and wish to know their status [5];
- ‘Couples entering relationships’ to prevent risky exposure [5];
- ‘College binge drinkers’ after a risky sexual encounter [5];
- Positive persons seeking confirmation [5];
- Immigrants from high-burden countries;
- Marginalized populations (i.e., intravenous drug users, sex workers and men who have sex with men populations).

Issues to consider

Test performance

Test performance relates to diagnostic accuracy, reliability, erroneous test results, correct test interpretation and preliminary-positive test results. According to the package insert, the diagnostic accuracy of the OraQuick test is a sensitivity of 99.6% and specificity of 100% [14]. It is a known fact that no rapid test is perfect and the diagnostic accuracy and positive-predictive values vary with prevalence of disease [15]. Tests have a
high likelihood of being falsely positive in low-prevalence settings and among low- or average-risk individuals. A reactive test result is to be considered ‘preliminary positive’ and requires additional confirmatory testing [36]. Although a high overall accuracy of rapid tests has been reported, there is always room for an erroneous test result and misinterpretation. Recently, a false-positive rate of 1.1% with Oraquick® rapid tests was reported from select testing sites in New York, USA, leading to discontinuation of HIV self-testing [4,17,18]. The CDC recommends a parallel testing strategy in such instances. This parallel algorithm requires using two diagnostic tests (i.e., an oral test followed by a finger-stick test) or two tests of different antigen specificities on the same patient. We have evaluated a parallel strategy successfully in two studies in rural settings [2,19,20]. In the context of self-testing, a parallel strategy to rule out inadvertent test results may be a consideration. But before we propose that, an evaluation of its feasibility and cost-effectiveness is needed in the context of clinical studies.

Thus, before introducing these rapid tests as self-tests, we must raise the level of knowledge about their limitations. For example, self-testers must be informed of the possibilities of a false-negative, false-positive or erroneous test result [17]. The fact that rapid tests are antibody-based and unable to detect acute infection requires emphasis. In instances where a patient suspects a risky exposure but obtains a negative test result, he/she will need to consider additional blood-based confirmatory testing (i.e., western blot and HIV RNA tests) for resolution of test status [21]. Furthermore, retesting in 4–6 weeks may also be needed to account for seroconversion.

### Interpretation of test results

Another issue that has been raised in the context of evaluating rapid tests refers to the interpretation of reactive, nonreactive and weakly reactive test results [22]. To address this issue, clear instructions on reading and interpreting test results have to be provided. Professional help should be sought whenever necessary using a telephone hotline consultation. Other useful aids, such as color-coded cards, flip charts, CDs and pamphlets will aid interpretation. In the information age, innovative use of web blogs and websites with pictures of erroneous results can also be considered. In all such instances, a need for retesting should be emphasized. Studies have been conducted in the USA where test results were conducted with Oraquick and test interpretation was performed by untrained health professionals and compared with researchers for accuracy and concordance [23]. Study results were found to be 100% concordant [23].

> “Although, the risk of an adverse psychosocial outcome is real, an HIV-positive diagnosis in the era of optimized HAART is very different from what it was two decades ago.”

### Post-test counseling

Post-test counseling involves triage to care, social support, prevention services, prevention of adverse psychological outcomes and risk of suicide and litigation. Testing without the presence of a healthcare professional and/or counselor can prove to be stressful. Thus, counseling services are essential to accurately understand and comprehend the implications and interpretations of a test result. Counselors may help deal with reactive, false-positive/-negative or indeterminate test results. A serious risk of adverse psychological outcomes in some individuals (i.e., suicide) exists [13]. In 1986 during the pre-HAART era, after discovering his test status, one man committed suicide in San Francisco, USA. This event was widely publicized and led to individuals and policy makers fearing the introduction of self-tests [24]. A decade later, however, 175,000 Conﬁde HIV test kits were purchased, and no case report of suicide was reported [24]. Although, the risk of an adverse psychosocial outcome is real, an HIV-positive diagnosis in the era of optimized HAART is very different from what it was two decades ago [24]. However, to rule out the possibility of such an occurrence, careful planning and decision-making on mode and delivery of counseling and provision of community referrals and linkages to care are needed ahead of time.

The FDA-approved Home Access test utilizes a telephone-counseling service [25,26]. This counseling approach (compared with a face-to-face counseling approach) was criticized by the public for its automation and insufficiency [25,27]. Thus, innovative post-test counseling strategies have to be explored in the context of studies. Establishing links and direct access to medical care in the community is especially important.
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for marginalized populations attempting self-testing. To conclude, a follow-up plan for care and referral is essential for home self-testing.

**Inadvertent use of tests**

Genuine concerns on inappropriate use of tests are:

- Testing under coercion [13];
- Testing without confirmatory testing and additional rapid testing;
- Testing of minors without adult supervision [13];
- Testing without partner notification owing to fear of domestic violence;
- Testing partners before the initiation of sexual relationships [13];
- Discrimination and loss of reputation upon knowledge of test status;
- Loss of insurance benefits [13].

**Costs**

Cost will be a decision-making criteria for individuals considering self-testing. High costs of self-tests may limit their availability to needy, at-risk populations [13]. In the past, Home Access and Confide kits have been marketed at high prices (range: US$20–60). Oraquick, the most popular CLIA-waived test, has also been criticized for its high costs (approximate cost US$17). In view of widespread uptake and acceptability, a revised cost strategy may be necessary.

“Cost will be a decision-making criteria for individuals considering self-testing.”

**Evidence of self-testing for HIV**

The only study to evaluate the feasibility of self-testing with Oraquick was conducted by Spielberg et al. in 240 HIV-positive patients in Seattle, USA [12]. Participants were asked to self-test without training or assistance. Information on difficulties with specimen collection, test performance, interpretation and acceptability was collected. Participants found specimen collection with the finger stick (9–14%) more difficult than with oral fluid (4%). However, failure to put the test device in the vial with developer solution (n = 17) often led to invalid results [12]. Self-testing with Oraquick was performed and interpreted with fairly good accuracy by untrained people. Overall, participants had less difficulty performing oral fluid tests (95%) as compared with finger-stick tests (89%), and more difficulty in interpreting oral-fluid tests (95%) than finger-stick tests (97%). Difficulty in interpretation was related to weak positive oral-fluid test results [12]. The majority (61%) of participants preferred self-testing. Regarding costs, 70% of the participants were willing to pay US$15, and 40% of the participants were willing to pay US$20 for self-test kits [12].

**Related evidence on home sample collection-based HIV tests**

Some evidence from research studies (n = 8) on Home Access is available. In a study in high-risk populations, a bimonthly home collection of oral fluid and dried blood samples was evaluated. The study was considered feasible, but led to no alteration nor modification of risky behaviors [28]. In another study (n = 126), attitudes towards home sample collection and telephone counseling were evaluated by counselors and participants [29]. Home specimen collection (92%) and telephone counseling (73%) were preferred by study participants [29]. In a study in the USA, approximately 70,000 individuals reported successful transition to care and referral with the use of home-based tests [11]. In another study, home-based testing was compared with publicly funded testing initiatives [21]. Fewer people were found to access home-based testing in comparison with public testing [21]. In another large study (n = 1255), participant-collected samples for the Home Access test compared favorably (96%) with health professionals [30]; so did the test performance (100% sensitive, 100% specific) [30]. Telephone counseling was provided to test positives with no reporting of adverse events. Anonymous HIV home-collection kits with pre- and post-test counseling was considered a feasible alternative to conventional testing [30]. In another large study, Osmond et al. successfully evaluated the feasibility of obtaining HIV test results by telephone using the oral home sample collection system in homosexual men (n = 615) [31]. All (100%) self-reported HIV-positive persons tested positive. Participation in the study was associated with self-reported prior HIV test status (i.e., a positive status in 83% participants, a negative test status in 68% participants and no prior HIV test result in 54% participants) [31]. In 2002, the HIV-testing survey on 1600 individuals at high risk evaluated the attitudes and barriers to the use of home-collection systems, before and after the introduction of home-collection kits [32]. Participants cited concerns such as accuracy, lack of in-person counseling and cost of these tests. According to the survey, test kits minimally impacted testing behavior [32].
Evidence on home-based testing & counseling approach in use worldwide
In some African countries (e.g., Uganda), there is evidence to suggest that the home-based testing and counseling approach employed with oral tests has not only increased the uptake of testing, but also led to better utilization of available healthcare services with a decline in HIV prevalence [3].

“...there is limited evidence to make informed decisions about home self-tests for HIV.”

Future research
Future research on home-based self-tests needs to be focused in the following areas:

- The development of counseling and support systems to ensure access to care for people newly diagnosed with HIV [12].

Conclusion
To conclude, there is limited evidence to make informed decisions about home self-tests for HIV. Industry-led trials, or independent investigator-initiated diagnostic studies or trials are needed. The benefits of empowering individuals with information with respect to their test status require evaluation in probabilistic surveys. In view of the paucity of literature in the field, opinions and anecdotes offered against the use of these tests remain unvalidated concerns, in urgent need of external validation from well-designed studies.

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