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## Original article

# Over-the-counter human immunodeficiency virus self-test kits: time to explore their use for men who have sex with men in Brazil



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## ABSTRACT

Increasing access and frequency of human immunodeficiency virus testing are critical to stemming the epidemic. In Brazil's concentrated epidemic, human immunodeficiency virus prevalence in the men who have sex with men/transgender population far exceeds that in the general population, but testing rates fall below what is needed to ensure early detection and treatment. Over-the-counter human immunodeficiency virus self-testing kits, now available in stores in the U.S., have enormous potential to increase testing access and frequency and to facilitate early detection and treatment. With the advent of human immunodeficiency virus self-testing upon us, it is timely to engage the scientific community, government, and civil society in a dialog around how to best utilize this technology in Brazil. We summarize recent research on over-the-counter testing among men who have sex with men, raise potential questions and challenges to using self-tests, suggest implementation strategies, and outline a research agenda moving forward.

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## Introduction

Human immunodeficiency virus (HIV) testing is the primary gateway into HIV/AIDS prevention and treatment, making increased access and frequency of HIV testing critical to

stemming the spread of the epidemic. People with HIV who are aware of their status can begin lifesaving treatment, which in turn decreases HIV infectiousness<sup>1,2</sup> and may decrease risk behaviors following diagnosis.<sup>3-7</sup> Furthermore, modeling studies in the U.S. suggest that a substantial proportion of new infections are spread by persons unaware of their HIV

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infection,<sup>8,9</sup> and that increased testing alone could optimally reduce new infections by as much as 1/3 in one year.<sup>10</sup> Testing remains a high priority and must be made as widely accessible as possible, particularly to populations most at risk of infection.

Brazil's HIV epidemic is concentrated among men who have sex with men (MSM) and transsexual/transgender populations, with elevated prevalence also occurring among sex workers and injection drug users.<sup>11</sup> As compared to the general population, whose prevalence is stable at around 0.4–0.6%, HIV prevalence among MSM in Brazil is estimated to be between 13.6% and 14.4%.<sup>11–13</sup> Nevertheless, studies have demonstrated that only about half of Brazilian MSM report any history of testing,<sup>13–15</sup> and that only 30% report testing in the past year.<sup>16</sup> Currently the US Centers for Disease Control and Prevention recommend that testing for most-at-risk MSM be conducted every 3–6 months.<sup>14</sup> In a recently conducted national respondent driven sampling study, nearly 50% of MSM who tested seropositive were unaware of their infection.<sup>13</sup> Late diagnosis continues to be pervasive in Brazil, particularly for men.<sup>17</sup> Strategies to increase testing uptake and frequency among MSM are needed.

On July 3 2012, the United States Food and Drug Administration (US FDA) approved Over-the-Counter (OTC) licensing for the saliva-based OraQuick In-Home HIV test<sup>TM</sup> (OraSure Technologies, Inc., Bethlehem, PA).<sup>18</sup> These tests are now available in US pharmacies, and a number of European nations are not far behind. In late 2013 the French Health Ministry announced that self-testing kits for HIV will be commercially available in 2014,<sup>19</sup> the United Kingdom recently lifted the ban on HIV home test kits, which should become available through commercial channels by April 2014.<sup>20</sup> The hope of OTC HIV self-testing kits is that they will both facilitate testing for communities at high risk of HIV transmission, particularly those communities which are reticent to test, and increase testing frequency and thus early detection and treatment. This technology is particularly promising for MSM and transgender populations, for whom negative experiences in the public health system, including long queues and discrimination (related to sexual orientation, gender identity, or a positive HIV test), may reduce their likelihood of clinic attendance.

As OTC HIV testing expands, the time to engage the scientific community, government, and civil society in a dialog around how to best utilize this technology in Brazil has come. We provide a brief review of recent research on utilization and acceptability of HIV self-testing for MSM, raise potential implications of the OTC tests, and suggest potential strategies for implementation of self-testing and also a research agenda moving forward.

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### How to target OTC testing?

Since the idea of OTC HIV testing emerged in the nineties, much of the early debate centered on the issue of the quality (sensitivity and specificity) of the kits and the risk profile of populations targeted for test use. There is both the potential for false-negative results shortly after infection (the window period) and an increased burden of false-positive results if

self-testing is adopted by low prevalence populations, such as the “worried well” of repeat testers.<sup>21,22</sup> However, self-conducted HIV tests have generally performed quite well: a recently published systematic review of both oral fluid and finger stick self-conducted rapid HIV tests documented a very high specificity in supervised (with a health care worker present) and unsupervised (with a phone line for questions) settings. The findings on sensitivity varied from 93% to 100% in unsupervised environments.<sup>23</sup>

Targeting home testing to particularly high-risk populations can mitigate poor predictive values. If the OTC tests currently approved in the U.S. were targeted to MSM in Brazil, both the positive and negative predictive values of the test would be approximately 99% (assuming HIV prevalence of 10% and OraSure sensitivity at 92% and specificity at 99.98% in the home environment).<sup>18</sup> The extended ‘window period’ for antibody detection of up to three months remains an unfortunate reality. There is hope that the performance characteristics of the rapid tests will improve in coming years; however, the antibody tests will always have a window period and this limitation will always require careful orientation, particularly for those with recent infections. Of course, the issue of the window period exists for clinic-conducted rapid tests as well as self-conducted tests; community education around the testing window remains a priority whether tests are conducted alone or in clinics. It also must be made clear to consumers that self-tests cannot be used as a confirmatory testing mechanism; the test is not licensed for this purpose. To this end, successful introduction of OTC testing will hinge on increasing awareness around the testing window and the limitations of the current rapid tests, particularly among health care professionals and the non-governmental organizations (NGO) community who may act as gate keepers.

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### Will MSM use OTC testing?

To date, published data indicate that MSM are poised to use self-tests. Utilization data on self-testing among MSM are still somewhat scarce, though a number of studies are currently underway, including one in Rio de Janeiro, Brazil. One landmark study in New York provided home HIV tests to 27 non-condom using HIV-negative MSM with multiple partners to use for partner screening. Uptake of testing was high: 101 partners were self-tested over three months, and the majority of participants wanted to continue using home test kits following the study period.<sup>24</sup> Other U.S.-based studies have demonstrated that MSM would use self-tests when given the opportunity and that they used them accurately.<sup>25,26</sup> There is also ample data on speculative acceptability of self-testing (not based on actual experience). In Brazil, 90% of respondents on a national Internet survey with MSM reported that they would use HIV self-tests if provided the opportunity; over half reported a preference for self-testing as compared to clinic-based testing; and 60% of respondents said they would use self-tests to make choices about unprotected sex with sexual partners.<sup>27</sup> Similarly, acceptability studies conducted in the US among MSM demonstrate substantial interest in using HIV home tests.<sup>25,28</sup>

While the data on acceptability to date are encouraging, there is still much that is unknown about uptake of these tests outside of the research environment and about acceptability within the diverse population that is often grouped as ‘MSM’. For example, there is little information regarding acceptability among transgender populations. Little is known about acceptability among health care providers who may be distributing test kits or attending populations presenting with self-testing results. In fact, whether Brazilian MSM and other at-risk populations use the OTC tests when they become available may depend to a large extent on the support of health care providers and encouragement from the NGO community; a supportive environment can enable MSM to access testing according to their needs. Self-testing may offer an opportunity to bolster not only testing rates but also a sense of autonomy or empowerment in the MSM community as they take control of their health.<sup>23</sup>

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### What about counseling and linkage to care?

Voluntary testing and counseling (VCT) has been a cornerstone of the Brazilian program since the first HIV tests became available in the public system in 1985. In a country where quality counseling has been emphasized, OTC tests raise a number of questions. How will counseling be offered in conjunction with these tests? What counseling is needed before and after the test kit is acquired and conducted? What system can guarantee access to counseling and psychological care if needed? Who will be best positioned to provide the counseling needed? Health care professionals, NGO staff, peer educators? There is no question that availability of OTC tests could mean a more limited counseling experience and less direct contact with the health system.

There has been recent debate globally as to the value of putting diminishing resources into the pre-test counseling and consent processes that were established in the eighties. While data from those who test positive have indicated that a pre- and post-test counseling experience is critical both for support and to create that first critical link with the health system,<sup>29</sup> there is little evidence that typical pre-test counseling impacts behaviors for those who are negative.<sup>30</sup> In fact, one clinical trial found that there was no decrease in STI/HIV incidence among STD clinic patients receiving rapid HIV tests with patient-centered pre-test counseling compared to those receiving a rapid test with information only.<sup>31</sup> Required counseling may even represent an obstacle to testing – both due to experienced stigma in the health establishment and due to the inaccessibility (distance, wait times) of clinics. In light of this fact, some have advocated for eliminating mandated pre-test counseling, which is often of variable quality,<sup>32</sup> to put more resources into effective post-test counseling and facilitating linkage to care for HIV positives.<sup>33,34</sup> An alternative view is that not every test requires the same level of counseling. Instead, MSM could be encouraged to test frequently (two to four times a year), but encouraged to undergo counseling only once a year or on demand. The home testing debate may be instrumental in advancing discussions about the current, traditional counseling model.

There is also a broad debate about how linkage to care would be managed in the self-testing environment. If users of OTC tests understand the need for confirmatory testing, and recent evidence would suggest that many do, then the confirmatory test can serve as the first ‘link’ into the care system.<sup>35</sup> Research on mechanisms to facilitate linkage in the context of self-testing will be critical.

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### What are the potential social harms?

The potential social harms and unintended consequences of using home test kits and approaches to mitigate these potential negative effects require attention. Concerns with self-testing include adverse emotional reactions to positive tests, risk compensation following a negative test, coercion to use tests, and potential partner violence when tests are utilized in relationships. In the recent study of OTC testing conducted in MSM in New York City, use of approximately 100 kits with casual partners prior to initiating sex resulted in 10 positive results and no sexual intercourse nor violent reactions following a positive result.<sup>24</sup> There were no cases of physical violence when the use of a test kit was proposed and declined. Harm to self, though often the centerpiece of the argument against self-testing, has not been documented in the age of ARTs.<sup>36</sup> Because counseling opportunities will necessarily be reduced with self-testing, support mechanisms (including hot lines or 0–800 numbers, informational brochures, web-support [video or chat], and electronic or mobile test result assistance) will need to be developed to accompany test kits.

Whether an HIV negative self-test might encourage unsafe sex (discourage condom use) is an important question to pose, again driving home the importance of education around the window period. To date, the worries around risk compensation have not been substantiated for other prevention technologies in either PrEP trials<sup>37,38</sup> or circumcision trials.<sup>39</sup> There are other risks posed by taking test kits home: family members or friends could find the clearly marked HIV testing kits, threatening privacy. This may necessitate creative packaging and disposal materials. Further, pressure to test from friends or partners is a real concern. For sex workers any forced utilization by clients, pimps, or brothel owners could have severe consequences (as could use by sex workers on their clients). Finally, there is the potential that distribution of home test kits would encourage further withdrawal or alienation from the public health system, particularly for MSM and transgender people already uncomfortable in the public sector.

In order to mitigate potential social harms, partnership with NGOs and other representative institutions related to MSM populations should be sought in fleshing out plans for research and implementation. Community based organizations have long been recognized as an important resource for the implementation and reinforcement of HIV/AIDS prevention and control policies and programs.<sup>40</sup> In Brazil, as well as in other developing countries, NGOs have also built an effective network for social and psychological support for those most affected by HIV.<sup>41</sup>

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## A proposed research agenda

Overall, the net prevention potential for OTC testing for MSM and other populations is still poorly understood. Above all, it remains largely uncertain whether the availability of OTC test kits will bring about the anticipated increase in HIV testing rates. At least one randomized study of the impact of OraQuick test kit distribution on testing frequency among MSM will be launched in the US in 2014. It is also unclear whether the benefits of increases in testing rates would be offset by fewer people testing in clinics, less linkage to care, and the reduced accuracy of OTC tests.<sup>42</sup> It is also unknown whether people will seek confirmatory testing and link to care following use of a self-test. These larger questions will need to be studied regionally – as will aspects of demand and supply of OTC tests, including appropriate distribution channels for test kits that ensure accessible costs or distribution in the public sector, so as not to exclude the populations most in need of testing alternatives.

Specific to Brazil, where there is but one feasibility study (that we are aware of) underway, we propose the following research questions to support safe and accurate use of OTC testing in populations with the greatest need:

- What are the optimal mechanisms to ensure effective linkage to post-test counseling, confirmatory testing, care, and treatment? What referral resources can be included in test kits and can feasibly be used to ensure follow-up for positive tests?
- What are the optimal support mechanisms to ensure safe and accurate use of test kits, minimizing social harms, including in-kit resources, web resources, hotlines, peer-networks, and NGOs?
- What is the optimal distribution system in Brazil to ensure access to test kits for those who most require testing and are less apt to access public services?
- How does availability of self-test kits affect testing decisions (including when, where, and with whom to test), testing frequency, and sexual behavior?
- What are the HIV testing needs of different sectors of the diverse 'MSM' population and how can they be met using OTC tests?

There are currently plans to evaluate the implementation of innovative HIV testing modalities, including self-testing, targeting MSM in Curitiba, in Southern Brazil, in collaboration with the CDC and the PEPFAR Key Population Implementation Science Fund.

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## Implications for policy and practice

Pending research results, we believe that OTC testing might be made available in a hybrid strategy in Brazil. First, self-testing kits could be introduced as an alternative testing option for those identified at health services as high risk (i.e. MSM, transgender populations, those seeking Post-Exposure Prophylaxis (PEP), sex workers, and partners in sero-discordant couples). These individuals could be offered home testing kits within

the SUS as an alternative to coming into the clinic for repeat tests or to take home to cover the window period (testing 2–3 months later following a negative test at a health service). This strategy can both decrease the burden on existing testing services and empower individuals to utilize testing that meets their individual needs.

The second strategy would be to offer kits for sale in pharmacies, which may improve access for those who prefer not to attend clinics. Men tend to utilize services less frequently than women in Brazil, so this pharmacy-based strategy may appeal to MSM. The concern with pharmacy sales is, of course, cost. HIV vulnerability is the highest in resource poor populations who may not be able to purchase tests, which highlights the importance of making OTC tests available through the public system and/or via NGOs and other alternative testing settings, such as mobile units. The subsidized pharmacy system may prove a feasible option for those coming with prescriptions from SUS.

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## Moving ahead

Mounting the suggested research program will necessitate political discussions, including the potential revision of current pre-test counseling practices. Indeed, self-conducted HIV testing will challenge long-held beliefs about the delivery of HIV/AIDS prevention and care and requires a dialog between the public sector, health care providers and civil society. The Brazilian Ministry of Health is currently taking large steps to advance the country's prevention and treatment agenda. In December 2013, the adoption of the test and treat strategy was incorporated into the new national HIV treatment guidelines. All individuals diagnosed with HIV infection will be offered ARV treatment regardless of CD4 count. It is expected that this will lead to at least 100,000 new individuals living with HIV gaining access to combined antiretroviral therapy. In addition, Brazil is taking advantage of the local capacity to manufacture HIV rapid test kits, including oral fluid kits, which should make HIV testing available to high-risk populations outside of health services in settings such as mobile units and NGOs.

As the HIV prevention and care leader in Latin America, Brazil is in the position to explore research and partnerships that will prepare the country and the region for OTC HIV testing. The time has come to explore the potential of OTC testing as an additional tool in the battle against HIV.

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## Conflicts of interest

The authors declare no conflicts of interest.

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