



The Brazilian Journal of INFECTIOUS DISEASES

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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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ARTICLE INFO

Article history:

Received 20 February 2014

Accepted 24 February 2014

Available online 3 April 2014

Keywords:

Brazil

HIV testing

MSM

Self-testing

Home-based testing

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^{1,2} and may decrease risk behaviors following diagnosis.³⁻⁷ 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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<http://dx.doi.org/10.1016/j.bjid.2014.02.002>

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infection,^{8,9} and that increased testing alone could optimally reduce new infections by as much as 1/3 in one year.¹⁰ 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.¹¹ 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%.^{11–13} Nevertheless, studies have demonstrated that only about half of Brazilian MSM report any history of testing,^{13–15} and that only 30% report testing in the past year.¹⁶ Currently the US Centers for Disease Control and Prevention recommend that testing for most-at-risk MSM be conducted every 3–6 months.¹⁴ In a recently conducted national respondent driven sampling study, nearly 50% of MSM who tested seropositive were unaware of their infection.¹³ Late diagnosis continues to be pervasive in Brazil, particularly for men.¹⁷ 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 testTM (OraSure Technologies, Inc., Bethlehem, PA).¹⁸ 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 2014,¹⁹ the United Kingdom recently lifted the ban on HIV home test kits, which should become available through commercial channels by April 2014.²⁰ 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.

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.^{21,22} 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.²³

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).¹⁸ 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.

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.²⁴ Other U.S.-based studies have demonstrated that MSM would use self-tests when given the opportunity and that they used them accurately.^{25,26} 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.²⁷ Similarly, acceptability studies conducted in the US among MSM demonstrate substantial interest in using HIV home tests.^{25,28}

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