HIV home-based testing: Potential benefits and ongoing concerns

By Logan Broeckaert

The idea of HIV home-based testing has been debated for decades, almost as long as HIV testing has been available, but it has not been widely endorsed. Recently, the debate about home-based testing has been ignited again, with the approval in the United States of the oral testing kit, OraQuick.

This article explores HIV home-based tests (with a focus on OraQuick), how they work, where they are available, their acceptability and accuracy, and the potential benefits and ongoing concerns surrounding home-based testing.

What HIV home-based tests have been approved in the United States?

HIV home-based tests, also known as self-tests, allow people to test themselves for HIV in their home without a healthcare provider present. Currently, two HIV home-based tests have been approved by the Food and Drug Administration (FDA) for use in the United States.

The Home Access HIV-1 Test System is the only finger-prick blood test approved by the FDA (in July of 1996). This test detects HIV antibodies in blood. Before doing the test, the user calls a toll-free number to register for the test using an anonymous code, completes pre-test counselling and provides non-nominal demographic information. The user draws a blood sample using a finger prick and the sample is then sent away for testing at a lab. The results are obtained by calling the toll-free number and using the anonymous code number to access the results. Positive results are given by a counsellor. Results do not need to be confirmed by an additional test, since confirmatory testing is performed by the manufacturer before results are offered to clients.

OraQuick is an in-home oral swab test that detects HIV antibodies in saliva. This oral test was approved in July 2012 by the FDA and has been available for sale in the United States since April 2013. The test requires users to swab their upper and lower gum line for the saliva sample. The swab is placed in a solution, which allows the test reaction to develop. The test produces a result within 20 to 40 minutes. Unlike blood-test kits, OraQuick can be read at home by the user. Positive results received at home are considered preliminary and must be confirmed by clinic-based testing. OraQuick provides a 24-hour toll-free telephone counselling service and helps link people who test positive to a nearby clinic.

In addition to FDA-approved home-test kits, there are a number of HIV tests available on the Internet that claim to be clinically proven but do not have FDA approval. These kits can’t be trusted to offer accurate and reliable test results.

What HIV home-based tests have been approved in Canada?

No home-based tests have been approved for sale in Canada. Although neither OraQuick nor Home Access Health Corporation will accept orders from Canada, it is possible for Canadians to order HIV self-tests (both finger prick
and oral swab) online and have them delivered to their homes. Canadians can also cross the border and purchase self-test kits in US pharmacies.

Are self-tests acceptable to potential users?

Research has shown that HIV self-tests are acceptable to users. A systematic review published in 2013 on supervised and unsupervised HIV self-testing that included studies of general populations as well as populations at high risk – gay men and other men who have sex with men (MSM), people who use inject drugs, patients in emergency departments – found that between 74% and 96% of participants in all populations found HIV self-testing, either with oral swabs or finger-prick blood tests, acceptable.¹

Research shows that self-tests are convenient and easy to use. In a study of students seeking care at the McGill University Health Centre, 98% of students rated an oral self-test as convenient.² In a study of “at-risk” individuals in Singapore, 95% felt that the OraQuick test kit instructions were easy to understand and the kit convenient to use.³ In another study in the U.S., 96% of participants reported that the OraQuick test was “not at all hard to collect.”⁴

Are oral swab tests as accurate as blood-based testing?

In research studies, the OraQuick test is as accurate (99.9% of the time) at identifying HIV-negative results as blood-based testing done in a lab by trained professionals.⁵ OraQuick is 91.7% accurate at identifying HIV-positive test results.⁶ This means that almost 10% of people who are HIV positive may be incorrectly identified as HIV negative using the OraQuick test. Oraquick is not as accurate as blood-based testing in a lab, which has been shown to be 99.7% accurate at identifying positive test results.⁷

False-negative results – when the test comes back negative but a person is actually HIV positive – can occur with OraQuick if a risk event (unprotected sex or borrowing injection equipment, for example) occurs within the three-month window period (as with the standard blood HIV antibody test). This happens because the test relies on the detection of antibodies in the saliva, which may take up to three months to develop. Clients considering self-testing need to be counselled about the window period.

False-negative results may also occur if the test is incorrectly read by the user as negative; if the test instructions are not followed carefully and the user does not swab the gum line; or if the user is wearing a dental product, such as dentures that cover their gums, while they use the swab.⁸

HIV home-based testing may improve access to testing

HIV self-tests could provide improved access to HIV testing among people who may not otherwise access testing. Research shows that HIV self-testing is acceptable among MSM who have never tested for HIV, a key population to reach for HIV testing.⁹ ¹⁰

HIV self-testing could provide convenient and anonymous HIV testing to anyone who wants to test. In particular, depending on cost and availability, self-tests could benefit people who experience significant barriers to health care and people living in rural and remote communities where health care isn’t always anonymous or confidential.

Despite potential benefits, concerns remain

Some service providers in Canada have expressed concerns about HIV home-based testing. The concern is that the conditions under which testing might be performed at home are not ideal to receive a positive result. Although the maker of OraQuick staffs a 24-hour hotline with trained counsellors to offer support to its clients, this is not a substitute for robust pre- and post-test counselling for individuals who need it, especially first-time users, people with low literacy and people who receive preliminary positive results.⁹ ¹⁰ ¹¹ More traditional forms of HIV testing also offer healthcare providers an opportunity to start a conversation with individuals about risk reduction, something that is lost when individuals choose to test at home.

There is also concern that individuals getting positive results at home will not access confirmatory testing, partner-notification services and/or care and support.¹⁰ Research on self-testing and linkage to care for people testing
positive is sparse. Although one study found that 96% of participants testing positive for HIV after a self-test stated they would seek post-test counselling,\(^1\) there remains a need to research how to best engage those people who test positive at home in additional services.

There is also some concern that HIV self-testing kits could potentially be used to test sex partners before sexual intercourse. This may lead, in certain circumstances, to situations where testing is coercive and puts individuals at risk for violence if they refuse. More research on this unintended consequence is needed.

If used correctly, the use of home-based tests to test potential partners could correctly identify an HIV-positive partner, prompting additional risk-reduction strategies. However, if there is a false-negative result, a person could have unprotected sex with a HIV-positive partner who they mistakenly believe to be HIV negative.

There is a concern about the cost of the test.\(^9\)\(^10\)\(^11\) OraQuick costs about $40 in the United States and we can expect that if it were ever available in Canada for home-based testing, it would be at least the same price. Currently, all HIV testing in Canada is free. Introducing a cost-based self-test may create barriers between the test and those who may benefit most from it.

**Self-tests aren’t available in Canada, but there’s still work to be done**

As of December 2013, no application has been submitted to Health Canada for approval of an HIV home-based test. However, tests can be purchased across the border or ordered over the Internet and delivered to Canadians. Although the numbers of people doing this may be low, service providers should be prepared to provide information to clients about self-tests if asked.

Service providers should be prepared to talk about:

- **Trustworthiness of home-based-tests.** Clients accessing home-based tests on the Internet should be counselled that none of these tests have been approved in Canada and that if they want to test themselves, they should only access tests that are approved by the FDA in the United States, such as OraQuick.

- **OraQuick’s limitations.** It will be critical for service providers to develop messages that underscore the limits of home-based tests, including the lack of in-person pre- and post-test counselling, the possibility of false-negative test results and the accuracy of self-tests during the three-month window period.

- **Importance of follow-up care.** Messages about the importance and location of confirmatory testing for preliminary positive or indeterminate results should also be developed. This process of confirmatory testing and post-test counselling will be critical to the process of engaging HIV-positive individuals with care and support and HIV-negative individuals with prevention counselling.

Although Health Canada has not approved any home-based testing kits, it may be time for policy makers and public health professionals to start a discussion about the wider value of OraQuick as an additional testing tool both at home and/or in additional settings.

Research shows that OraQuick is preferred over finger-prick HIV tests.\(^4\) One way to improve access to testing could be to introduce OraQuick at existing HIV testing locations, and offer it as an alternative to existing finger-prick rapid tests.

Offering private space in healthcare settings for self-testing may be another way OraQuick could be used in clinical settings. Research from the United States shows that incorporating self-testing into health care in emergency departments may be a way to increase access to HIV testing for some, while allowing clients to receive immediate counselling and follow-up care.\(^12\) Used in this way, self-testing technology could maximize client anonymity and confidentiality, while balancing the need for robust post-test counselling and follow-up care.

**HIV self-tests could be an additional testing tool**

The debate over self-testing in Canada will continue for some time, spurred by other national governments around the world starting to endorse self-tests as additional HIV testing tools. Self-testing technologies have the potential to reach individuals at high risk for HIV infection but who experience barriers to HIV testing in traditional spaces. However, significant concerns about counselling, confirmatory testing, partner notification, and cost remain.

**Related article**
For a discussion on home-based testing, see Views from the frontlines: Home-based HIV Testing.

**Resource**

Human Immunodeficiency Virus: Screening and Testing Guide – Public Health Agency of Canada

**References**


**About the author(s)**

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