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Rapid HIV Self-Testing

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Key Messages

- Self-testing has become recognizable to most people in Canada as a way to reduce the spread of infections. HIV self-testing has recently become available in Canada and is an approach to HIV screening intended to complement existing HIV testing currently offered in medical and community settings. Self-test kits can be used in the home, alone or in the presence of another person, and they may help overcome barriers to HIV diagnosis, and help Canada achieve its commitments to end the HIV and AIDS epidemics by 2030.
- HIV self-testing is recommended by the WHO, used in countries worldwide. The INSTI HIV-1/2 Antibody Self Test is the first HIV self-test available in Canada. It is a single-use HIV test kit that detects HIV-1 and HIV-2 antibodies from a drop of blood collected by a fingerstick. In 50% of people, the test can detect HIV infection about 22 days after exposure, and in 99% of people can detect HIV infection 12 weeks (3 months) after infection.
- As the INSTI HIV-1/2 Antibody Self Test is intended as a screening test, a positive result must be confirmed with a laboratory-based test. If the result is negative, no further action is required unless the tester has had a potential HIV exposure in the previous 3 months. In this case, a person should self-test at a later date or seek a laboratory-based HIV test that is able to detect HIV in a shorter window of time since potential exposure.
- While the comparability of the INSTI HIV-1/2 Antibody Self Test with traditional lab testing has already been established, when used in real-world settings in Canada, there is a higher than-expected rate of invalid test results (that is, when the test does not produce a result and therefore another test must be taken). Improvements to the content, design, or delivery of the test instructions and other resource materials provided to testers have been offered as possible solutions.
- This report outlines information related to the INSTI HIV-1/2 Antibody Self Test use in Canada and issues for consideration when implementing an HIV self-testing program including cost, support for testers, and providing test access to groups who have historically had lower testing rates.

Purpose and Scope

The purpose of this horizon scan is to present health care stakeholders in Canada with an overview of information related to HIV self-testing, specifically, the INSTI HIV-1/2 Antibody Self Test kit. HIV self-testing is an established and recommended HIV screening practice globally that is new to Canada.^{1,2} As of the writing of this report, 1 HIV self-testing kit, INSTI HIV-1/2 Antibody Self Test kit, is available in Canada; however, its use is not widespread, and it may not be known to all care providers or people seeking HIV testing. As such, this report is limited to a discussion of the evidence related to HIV self-testing in Canada, along with issues for consideration when implementing an HIV self-testing program such as cost, ethical issues, and support for testers.

This report is not a systematic review and does not involve critical appraisal or include a detailed summary of study findings. It is not intended to provide recommendations for or against the use of the technology.

Methods

Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, Embase, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were HIV and rapid self-testing. The search was completed on October 4, 2022 and limited to English-language documents published since January 1, 2020. Regular alerts updated the database literature searches until the publication of the final report.

Study Selection

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention was INSTI HIV-1/2 Antibody Self Test or other HIV self-test and the study was conducted in Canada. Grey literature searches were included when they provided additional information to that available in the published studies.

Peer Review

A draft version of this bulletin was reviewed by 1 clinical expert whose research and clinical work focus on the prevention, diagnosis, and treatment of sexually transmitted infections. The manufacturer of the INSTI HIV-1/2 Antibody Self Test provided comments on a draft of the report.

Background

In Canada, more than 1,500 new HIV infections were diagnosed in 2020 and 10% of the estimated 62,790 people living with HIV in Canada have not been diagnosed.³ Awareness of 1's HIV status is key tool in the prevention of HIV.⁴ People who are aware they are HIV-positive are less likely to transmit HIV by seeking treatment (typically a combination of 3 or more drugs) which reduces HIV viral load (often to undetectable levels) and/or participating in practices that reduce the likelihood of HIV transmission.^{4,5}

Barriers to diagnosis include access to testing (e.g., the cost of testing, open hours of testing facilities), stigma, and in Canada, restrictions on who can order and perform tests.⁴ One way to increase HIV status awareness among people at risk of HIV infection is through HIV self-testing – an approach to HIV testing where a person collects their own sample, performs a rapid test, interprets and records the results, and seeks connections to confirmatory testing and supportive care from a location of their choice.^{4,6}

The WHO recommended HIV self-testing in 2016 as an “empowering, discreet and highly acceptable option for many users” that represented another step toward reaching the first set of global HIV testing, treatment, and prevention targets “by reaching first-time testers, people with undiagnosed HIV or those at ongoing risk who require frequent retesting” (including people who are not reached by current testing options).² By 2018,

HIV self-testing policies were adopted in 59 countries; in Canada HIV self-testing first became available in 2020;^{1,7} however self-testing is not well-established in Canada as of this writing.

The INSTI HIV-1/2 Antibody Self Test is the first HIV self-testing kit available in Canada and may help Canada achieve its commitments to the prevention, diagnosis, and treatment of HIV and end the HIV epidemic in Canada.^{8,1,9}

The Technology

HIV self-testing is an approach to HIV screening intended to complement existing HIV testing services (i.e., laboratory-based testing and rapid testing) offered in medical and community settings across Canada for anyone living in Canada who is at risk of HIV infection.¹ Self-test kits can be used in the home, alone or in the presence of another person (e.g., partner, friend),¹ or in a health care setting, where a care provider can support the tester.

The INSTI HIV-1/2 Antibody Self Test (bioLytical Laboratories Inc. Richmond, BC) is a single-use HIV test kit that detects HIV-1 and HIV-2 antibodies from a 50 µl drop of blood collected by a fingerstick blood draw.⁸ In 50% of people with a new HIV infection, the test can detect HIV infection about 22 days after exposure and in 99% of people can detect HIV infection 12 weeks (3 months) after infection.^{1,10,11} This is similar to other HIV self-tests.¹²

The INSTI HIV-1/2 Antibody Self Test kit consists of^{1,8,11}:

- 1 single-use test device
- 3 single-use bottles of reagents
- 1 single-use lancet.

To use the test, testers are required to complete the following series of steps^{1,11}:

- Wash and dry their hands.
- Use the lancet to obtain a drop of blood from their finger, allow the drop of blood to fall into the first reagent bottle without touching their finger to the opening of the bottle, and cap the bottle.
- For each of the 3 reagents:
 - shake the bottle
 - pour its contents into the test device
 - wait for the liquid to disappear
 - repeat for the next reagent.
 - Interpret the test results (positive, negative, or invalid).
- Dispose of the test according to local instructions for safely disposing of sharps.

Depending on the test result, it is recommended that testers take the following additional steps^{1,8}:

- If the INSTI HIV-1/2 Antibody Self Test is positive, the tester probably has HIV, but this result must be confirmed with a laboratory-based test and the tester should go to a health care provider or service offering confirmatory HIV testing. Should the INSTI HIV-1/2 Antibody Self Test result be confirmed as positive by laboratory-based testing, this is considered a confirmed HIV diagnosis and will begin a series of postdiagnosis processes including public health notification and post-test counselling.^{1,13}
- If the INSTI HIV-1/2 Antibody Self Test is negative, no further action is required unless the tester has had a potential HIV exposure in the previous 3 months. In this case, testers should take another INSTI HIV-1/2 Antibody Self Test later or seek a laboratory-based HIV test that is able to detect HIV in a shorter window of time since potential exposure. People with negative results who are at ongoing risk of HIV infection should test regularly and consider pre-exposure prophylaxis (PrEP) to help prevent HIV infection.
- If the INSTI HIV-1/2 Antibody Self Test is invalid the test did not work, and testers should seek additional testing from a medical or community clinic.

Availability

The INSTI HIV-1/2 Antibody Self Test is licensed as a Class 4 medical device by Health Canada since 2020.¹⁴ In 2022, the Public Health Agency of Canada announced that the federal government allocated \$8 million to purchase HIV self-tests and to increase access to testing by supporting community-based organizations.¹⁵ At the time of publication, the test kit was available to people living across Canada in several ways including:

- to residents of Saskatchewan at no cost to the tester through the provincial health authority (for pick-up at 23 sites).¹⁶
- through no cost to the tester research programs such as I'm Ready (pan-Canadian)¹⁷ and GetaKit (pan-Canadian as of February 2023)¹⁸
- direct purchase from the manufacturer¹⁰ or third-party resellers (e.g., Amazon.ca).^{10,19}

Cost and Administration

INSTI HIV-1/2 Antibody Self Test costs \$34.95 for 1 kit or \$54.95 for 2 kits (plus shipping) when purchased directly from the manufacturer.¹⁰ Test kits are also available at no cost to the public through provincially and federally funded programs in some jurisdictions.¹⁶⁻¹⁸

In the GetaKit program (a no-cost-to-the-tester HIV self-testing program that, as of February 2023, ships tests across the country),¹⁸ reported costs included the cost of the INSTI HIV-1/2 Antibody Self Test kit, "information on HIV prevention, testing, and care, plus resources for other prevention services, condoms, and lubricant" (\$10), and shipping (\$10) for each test delivered.²⁰

Who Might Benefit?

As a complement to existing medical- and community-based HIV testing services, the goals of HIV self-testing are increasing the uptake of HIV testing, connecting people with HIV or at risk of HIV to health services, and helping Canada achieve its endorsement of Undetectable = Untransmissible (U = U) with its 95 to 95 to 95 commitment, indicating that by 2025 “95% of all people living with HIV know their status, 95% of those diagnosed receive antiretroviral treatment and 95% of those on treatment achieve viral suppression.”^{1,4,6,9}

In Canada, groups disproportionately represented in the HIV epidemic include people who are gay, bisexual, and other men who have sex with men (gbMSM), people who use injection drugs, Indigenous people, people who self-identify as African, Caribbean, and Black, and people who have immigrated to Canada from HIV endemic countries.^{3,21} These, and other priority groups at higher risk of HIV infection (e.g., incarcerated persons) and may benefit most from access to HIV self-testing because they are most likely to be unaware of their HIV status.^{1,3,4,21}

Current Practice

HIV testing availability and practices in Canada vary from jurisdiction to jurisdiction.¹³ Before the introduction of self-testing, HIV testing in Canada was performed only by health care providers or people working for community organizations.¹³ Today, most people seeking an HIV test request a test or are offered 1 in medical or community settings where the test is performed.¹³ There are 2 types of HIV-tests available¹³:

- Standard testing, where a blood sample is taken in a vial and sent to a laboratory for testing.
- Rapid point-of-care testing, where a blood sample is taken by fingerstick and the test is performed immediately and results are communicated onsite.

Because results for standard tests are sent away, people tested using this method may have to return at a later date to receive their results.¹³ Results for point-of-care tests are usually available within a few minutes.¹³ A positive result from a standard HIV test requires no additional testing but a positive result from a rapid point-of-care test must be confirmed by standard testing.¹³ In addition to the test, it is recommended that people being tested for HIV should receive tailored information about HIV or counselling before being tested.¹³

In Canada, HIV testing approaches and guidelines have historically emphasized the use of standard testing, with results delivered in 1-week.²² While rapid, point-of-care testing is available in some locations for groups at high risk of HIV infection, rapid testing is not the standard of care in Canada.²² This contrasts with other parts of the world, like South Africa, where rapid testing is standard practice.²²

In Canada, HIV is a reportable disease.¹³ If a person tests positive for HIV the results are sent to local public health authorities. Regardless of the test result, people who receive an HIV test can be connected to other services, including treatment, prevention (e.g., postexposure prophylaxis [PEP] and PrEP), counselling, and other care.¹³

A central tenet of HIV testing in Canada is that the process is voluntary and must only be performed with explicit and informed consent.¹³ With few exceptions (e.g., mandatory public health reporting), HIV testing is also confidential and maintaining confidentiality is an important consideration for people choosing to be tested for HIV in Canada.¹³

Summary of the Evidence

HIV self-testing is an established intervention with a growing global body of evidence endorsed by the WHO as an alternative to conventional laboratory testing.⁶ This section focuses on the emerging evidence base for the INSTI HIV Self-Test in Canada and the primary Canadian program reporting on its use, GetaKit.

We found 1 pre-Health Canada authorization study⁷ and 1 post-Health Canada authorization study²³ of the INSTI HIV Self-Test in Canada. The postauthorization study was reported across 6 publications.^{20,23-27}

Pre-Canadian Authorization

Galli et al.⁷ evaluated the performance, acceptance, and usability of the INSTI HIV Self-Test in 767 adults with unknown HIV status recruited from 4 community sexual health clinics in Manitoba, Ontario, and Quebec from 2019 to 2020 before the authorization of the test by Health Canada. Individuals at both high risk and low risk (based on the evaluation of self-reported risks) of HIV infection participated in the study. Tests were performed by study participants and then interpreted by a trained observer.

For test performance, the authors found the following:

- High agreement (100% positive percent agreement and 99.5% negative agreement) between the INSTI HIV Self-Test compared with the laboratory reference test.
- High overall agreement (93.5% [n = 622]) between participant-interpreted INSTI HIV Self-Test results compared with observer-interpreted results, with the greatest disagreement occurring in the interpretation of invalid or “do not know/not sure” response options.
- 38 (5.6%) interpreted their test results as invalid compared with 22 observer-interpreted invalid results. 18 participants also said they did not know or were unsure of the test result compared with 11 observer-interpreted results.
- 5 individuals previously undiagnosed with HIV received a positive HIV result from the self-test during the study (confirmed by laboratory test).

For test usability, the authors found that of the study participants (n = 708):

- 92% could lance their finger, 88.7% could form a blood droplet (88.7%), and 88.2% could get the blood droplet directly into the test bottle (82.2%).
- 89% of participants performed the steps to complete the test (i.e., mixing, shaking, and so forth.) in the correct order.

Participants (n = 404) were also asked to interpret a series of mock test results. The authors found overall, 97.8% of participants were able to interpret these results correctly.

The authors reported that participants found the test easy to use, participants were confident in its use, indicated they would use the test again, and said they would recommend the INSTI HIV-1/2 Antibody Self Test to others.

Post-Canadian Authorization

The GetaKit program (initiated in 2020 and active as of publication) is reported to be the first Canadian no cost HIV self-testing program in Canada.¹⁸ GetaKit provides INSTI HIV-1/2 Antibody Self Test kits at no cost to residents across Canada.¹⁸ We found 1 prospective real-world observational study of the GetaKit HIV self-testing program (results presented across 6 publications).^{20,23-27} As described by the authors, the evaluation of GetaKit has 4 phases:

- Pilot phase of at-home HIV self-testing in Ottawa designed to understand implementation issues as described in O'Byrne et al. (2021a).²⁴
- Phase I, a continuation of the pilot phase in Ottawa for 6 months to 12 months as reported in O'Byrne et al. (2021b),²³ O'Byrne et al. (2022a),²⁰ and O'Byrne et al. (2022b).²⁵
- Phase II which expanded access to the GetaKit program to additional sites across Ontario reported in part in O'Byrne et al. (2022c)²⁶ and O'Byrne et al. 2023.²⁷
- Phase III which will add full sexually transmitted infection testing to the program (not yet reported).

GetaKit Program Description

As the first program of its kind in Canada and the primary source of Canadian information about the INSTI HIV-1/2 Antibody Self Test kit's use, publications from the GetaKit program offer unique perspectives into the design and implementation of HIV self-testing.

O'Byrne et al. (2021b)²³ describes how the GetaKit program works. Information about, enrolment, and test kit ordering occurs through a website, GetaKit.ca. In addition to the INSTI HIV-1/2 Antibody Self Test kit, the program team developed pre- and post-test counselling materials, resources and information about HIV, and instructions for self-testing to provide to participants. The team also made linkages with local health care pathways to support participants' care after testing. To support HIV prevention, information about PrEP or PEP and where to obtain them was also developed and provided to participants as appropriate.²⁶

Information about the GetaKit program was distributed throughout Ottawa via social media, traditional media, posters, community health organizations, primary care providers, and other places frequented by HIV priority groups in Canada. INSTI HIV-1/2 Antibody Self Test kits were shipped to people eligible for GetaKit who ordered tests and were shipped an unlabelled box that included: the INSTI HIV Self-Test, information about pre- and post-testing counselling, self-testing, and support services, lubricated condoms, packages of lubricant, and promotional cards to give to others to inform them about the program. Tests were shipped to participants by mail or courier in 1 business day to 3 business days.

People who reported invalid results were encouraged to order another test and were provided with written instructions and (beginning May 2021) a link to video instructions explaining how to perform the test.²⁰

Potential participants were excluded from the GetaKit program if they were on PrEP, in an HIV vaccine trial, or had a bleeding disorder. People excluded from participating in the GetaKit program were provided with resources for in-person testing, counselling, and support.

GetaKit Pilot and Phase I Results

O'Byrne et al. (2021a and 2021b)^{23,24} reported findings from the first 6-weeks of data of the GetaKit program. These publications were designed to answer the questions, "would unrestricted HIV self-testing be used by members of HIV priority groups, at what rates, and with what outcomes?" The authors also sought to "understand which participants: 1) had previously completed HIV testing, 2) reported their INSTI HIV-1/2 Antibody Self Test results and 3) completed the INSTI HIV-1/2 Antibody Self Test appropriately (i.e., received a valid result)." During the pilot phase and phase I, people who were known to be HIV negative or people with unknown HIV status older than 18 years of age living in Ottawa with a personal email address and cell phone number were eligible to participate.

The authors reported the following pilot and phase I findings collected between July 20, 2020 and April 1, 2021²³:

- 1,268 people requested to participate (an average of 160 a month)
- 47.3% (n = 600) of people requesting to participate were eligible to register. Living outside Ottawa or being on PrEP were the most common reasons for exclusion
- 67.5% (n = 405) completed the baseline characteristics survey and ordered a test. There were 6 people who responded to all survey questions with they "prefer not to answer" and were excluded from analysis leaving 399 people for the analysis
- 76.4% (n = 305) of participants had 1 or more characteristics of an HIV priority group, and 29% (n = 115) of participants identified as women
- 27% (n = 108) of reported not having previously been tested for HIV
- 57.1% (n = 228) reported their HIV self-test results back to GetaKit.ca
- 77.6% (n = 177) people reported a negative test result; 20.6% (n = 47) people reported an invalid test result; 1.3% (n = 3) preferred not to report their test results; and 0.4% (n = 1) of people reported a positive test result
 - The test positivity in this part of the GetaKit program was 0.44% for reported tests and 0.24% for all tests compared with baseline rate of 0.08% in Ottawa.
 - People who identified as heterosexual were less likely to report results compared with gbMSM.

The authors interpreted these results as follows:

- The GetaKit program reached people in priority groups, and positive test were 3.0 times to 5.5 times higher than the baseline rate in the community.
- Authors concluded that the test was acceptable in priority groups even with low awareness of self-testing in eligible communities.²⁴

- During the phase I study period GetaKit test results accounted for 5.2% of new HIV diagnoses in Ottawa. This may be because the study successfully reached gbMSM who account for more 3/4 of new HIV infections in Ottawa.²³
- The success of phase I indicates a need to scale up the program to reach the full spectrum of HIV priority groups.

The authors identified the following limitations and issues with phase I of the GetaKit program:

- More effort is needed to reach women most at risk of or affected by HIV. Reasons suggested for a lower uptake of the GetaKit program by women included: risk of violence associated with receiving an HIV self-test at home; women are more likely to access health care through traditional health care services (i.e., not where the study was recruiting); women are often not the target of HIV prevention services, which are typically focused on gbMSM.
- There is a need to understand how the COVID-19 pandemic affected uptake. For example, was interest in GetaKit higher because traditional testing options were closed? Was uptake lower because people had restricted sexual practices due to COVID-19 pandemic restrictions?
- Initial surveys did not ask questions about sex work or enough questions about people who identify as trans or gender nonconforming. This may also help to understand why women may have been underrepresented in phase I (these surveys were updated for phase II).
- The online-only registration limited access to those with internet options (phase II allowed paper registration at select locations).

O'Byrne et al. (2021a)²⁴ also looked at the implementation of the GetaKit program in its pilot phase. In this analysis, the authors noted:

- At a cost of \$25 to \$30 a test (including shipping) test instructions needed to be improved to reduce the number of invalid test results submitted by testers.
- A need to engage in different or additional strategies to increase reporting of test results.
- To increase the reach of the program, enrolment could be adjusted to allow people to use an email address only, allow registration at community-based locations, and provide locations where people can pick up test kits.

Rates of Reported Invalid Results

Invalid test results may “waste the single opportunity for someone to test” and potentially undermine the confidence self-test users have in the self-testing process.²⁰ Invalid test results also have cost implications for HIV self-testing programs – an invalid test requires an additional test.^{20,24}

O'Byrne et al. (2022a)²⁰ describes the “uptake of testing, results reporting rates, and details about the number, rate, and frequencies of invalid results” from phase I program data of anyone who registered in the GetaKit program from July 20, 2020 to July 18, 2021. According to the authors, the results of this analysis found: 81 participants reported 89 invalid test results, 76 of whom ordered another test.

- 6 reported 2 invalid results accounting for 13% (n = 12) of all invalid results

- All other participants reported subsequent negative tests (57%), did not report the results of the reordered test (14%), or did not reorder a test (29%)

Invalid results varied across 1-month intervals of the study period from 0% to 22% of all reported tests ordered (average of 12% of all tests ordered) and 0% to 38% of all tests reported (average of 22% of all tests reported).

The authors observed that the rate of invalid results dropped after May 2021 when the study began sending email instructions (including a 90-second video) about how to complete the test immediately after the test was ordered, but it continued at rates higher than 10%.

In this phase of the GetaKit program, the authors noted that the rates of invalid test results were greater than reported in other studies of the INSTI HIV-1/2 Antibody Self Test, including in Gall et al. 2021.⁷ According to the authors, this may be because data from GetaKit participants is collected in real-world settings, whereas studies before GetaKit were occurred in clinics- and involved observation and evaluation of participants. According to the authors, this may mean the results of these clinic-based HIV self-testing studies is not generalizable to the broader population of potential self-testers. However, the authors also noted that the rate of invalid results observed in the GetaKit program may not be elevated compared to other studies. For example, Galli et al. 2021⁷ reported 5.6% of test results as invalid and 2.7% of tests were reported as difficult to interpret by participants for a combined total of 8.3% of all tests, a rate similar to GetaKit.

Based on these results, the authors conclude that the INSTI HIV-1/2 Antibody Self Test is a “good – but not great – test and that modifications need to be made to support users when they use it.”²⁰ This seemed to reflect the usability of the test in real-world settings and that the instructional materials rather than the ability of the test to detect HIV when used under ideal conditions rather than the ability of the test. For example, supplemental instruction materials delivered before users have their tests seem helpful to assist them in properly using the test.

Acceptability of HIV Self-Testing

Using post-test survey data, O’Byrne et al. (2022b)²⁵ reported on “participants’ experiences of, and feedback about, participating in HIV self-testing” during the pilot phase of the GetaKit program to understand the acceptability of HIV self-testing. In 167 (42%) completed post-test surveys received from the 228 (57%) participants who returned a test result, the authors found that:

- participants chose HIV self-testing for convenience 77% (n = 128), privacy 49% (n = 82) privacy, or COVID-19 pandemic restrictions 4% (n = 6)
- 94% (n = 157) tested at home
- 80% (n = 134) found the fingerstick blood draw easy to do, and 87% (n = 146) found it easy to interpret test results

In a thematic analysis of open-ended responses, the authors identified 6 domains for improving tester experience:

- test instructions (including requests for online tutorials)

- test delivery (including requests for discrete packaging and safe-drop delivery)
- increasing test availability (including expanding the geographic area where tests are available and increasing targeted publicity of GetaKit to priority groups)
- supports for doing the test, results management, and interpretation (especially when results are faint)
- requests for additional services such as mailout COVID-19 tests or sexually transmitted infection (STI) tests
- requests for technical changes to test kit (e.g., additional lancet, alcohol swab, making it easier to get blood drop into the test vial) and adjusting the test complexity (number of components).

The authors' interpretation of the results indicates that while satisfaction aligns with other research, there is room for improvement in the GetaKit program. The authors noted it is unclear if favourable responses are related to having access to HIV self-testing, for the INSTI HIV Self-Test kit itself, or because the program provided an HIV testing option during the COVID-19 pandemic when many testing services were closed.

The authors concluded that, based on the results of this analysis, further work is necessary to improve tester experience of self-testing and perceptions of self-testing, and speculated this could be achieved in part by addressing feedback. The results also indicate the following opportunities:

- reach local priority groups by promoting HIV self-testing through a variety of local channels (as informed by local epidemiology)
- for people who choose self-testing to be better supported while testing.
- obtain and develop supports and resources (including nurses) to help connect people in rural and remote locations to self-testing.

Phase II Results

During the first 10 months of the Ontario-wide scale-up of GetaKit program between April 1, 2021 and January 31, 2022, O'Byrne et al. 2022c²⁶ reported on the results of an analysis of GetaKit program data seeking to understand if people of African, Caribbean, and Black ethnicities (ACB), "as a group that is disproportionately affected by HIV, actually use GetaKit, and, if so, what are their characteristics and testing outcomes?"²⁶ Enrolment in GetaKit was expanded to include people 16 years of age and older during this period. To reach ACB persons, subsites of GetaKit.ca ([GetaKit.ca/MAX](https://getakit.ca/MAX) and [GetaKit.ca/BlackCap](https://getakit.ca/BlackCap)) were created to help target priority groups (results reported through these subsites were still part of the centralized collection). During this phase of the study the authors found the following:

- Of the 2,121 people registered for a test, 74% (n = 1,551) were eligible, and 24% (n = 399) self-identified as an ACB person.
- There were no differences in sex, gender, or sexual orientation between groups, ACB participants, and white participants.
- More ACB participants were first-time testers (30%) compared with white participants (21%).
- Drug use was less reported by ACB participants than white participants.

- Fewer ACB participants reported their test results than white participants (62%, n = 962/1,551 reported)
- Positive HIV test results (n = 5) were equally reported during this period between ACB and white participants

Discussing these results the authors concluded that targeted efforts were successful in reaching participants from ACB groups (in 2019 in Ontario ACB persons represented 4.6% of all HIV blood tests done compared with 26% of GetaKit participants). This aligns with other research that has found HIV self-testing is accepted and sometimes preferred across many populations. The authors noted a need to continue work to increase access to testing for ACB women who, in Ontario in 2019 accounted for 59% of new HIV diagnoses in all women. This could mean there is also a need for more research to understand the reason for these results in the GetaKit program (e.g., why this happened and if it was related to anything in the program itself, such as the online portal).

Related to lower reported rates of STI and drug use in ACB participants compared with white participants, the authors observed this may mean current guidelines for PrEP prescribing may not be appropriate for ACB people. Finally, lower reporting of test results by ACB participants may mean there is a need to explore if other strategies are needed in the program to connect ACB participants to PrEP, care, or other services.

First-Time Testers

O'Byrne et al. 2023²⁷ reported on the differences in testing practices in gbMSM participants of GetaKit between April 1, 2021 and January 31, 2022. The study sought to understand the differences between gbMSM participants who reported being first-time testers and gbMSM participants who reported a history of HIV testing. The authors found the following about the 882 gbMSM participants who ordered an HIV self-test kit:

- 69% (n = 608) of the participants reported previous HIV testing, 25% (n = 220) denied previous HIV testing, and 6% (n = 50) said they were uncertain whether they had ever been tested for HIV.
- First-time testers were younger and more likely to report being born outside of Canada.
- A larger proportion of first-time testers identified as Black, Indigenous, or Person of Colour (BIPOC), another racialized group, or multiple racial identities (64%, n = 133) compared with the first-time testers who identified as white (36%, n = 75)
- First-time testers were more likely to report invalid test results compared with participants who reported any prior history of HIV testing.

According to the authors, these results reinforce existing evidence that has found that young gbMSM and people from BIPOC and other non-white ethnic groups disproportionately face barriers to accessing traditional HIV testing and care and will therefore seek out other paths of care, such as GetaKit. Due to the timing of the study (during the COVID-19 pandemic when testing was harder to access) it is unclear whether this type of testing is a preference or was a necessity of the time. The authors conclude that HIV self-testing programs may be viewed as an acceptable way for underserved groups, like those included in the study, to learn about their HIV status.

Safety

We did not identify any studies of the INSTI HIV-1/2 Antibody Self Test kit that specifically examined the safety of the kit.

Galli et al.⁷ reported the INSTI HIV-1/2 Antibody Self Test performed at a level that met Health Canada performance standards. However, as noted by O'Byrne et al. (2022a),²⁰ in real-world situations the INSTI HIV-1/2 Antibody Self Test may return higher than acceptable invalid test results.

Two other potential safety issues reported by Galli et al.⁷ to consider were handwashing (less than half of participants washed their hands before using the lancet) and the observation that blood did not always go directly into the test bottles (about 20% of participants).

Cost-Effectiveness

We did not identify any studies reporting the cost-effectiveness of implementing the INSTI HIV-1/2 Antibody Self Test in Canada. Globally, HIV self-testing has been reported to be cost-effective.⁶

Future Developments

Several developments could have an impact on the implementation and uptake of the INSTI HIV-1/2 Antibody Self Test kit and HIV self-testing in Canada.

Oral HIV Self-Tests

In addition to blood-based HIV self-tests, oral saliva-based tests are available and used in other locations around the world. Examples of a saliva-based tests include OraQuick In-Home HIV Test (OraSure Technologies Inc., Bethlham, PA)²⁸ and Exacto Rapid HIV Self-Test (Novax Pharmaceuticals CC, Cape Town, South Africa).²⁹

Combination STI and HIV Rapid Tests

In the rapid, point-of-care testing space, combination tests for HIV and other sexually transmitted infections are also available and being studied around the world.³⁰⁻³⁶ Examples include INSTI Multiplex rapid HIV 1/HIV 2/Syphilis Antibody Test (bioLytical Laboratories, Inc.),³⁷ TruQuick HBsAg/HCV/HIV/Syp (Weldon Biotech Inc., New Delhi, India),³⁸ and The Multiplo TP/HIV test (MedMira Inc., Halifax, Nova Scotia).³⁹

The performance of the Multiplo TP/HIV test and the INSTI Multiplex rapid HIV1/HIV2/Syphilis Antibody test compared with standard HIV and syphilis testing in Alberta was published in 2023.⁴⁰ Further, CADTH has summarized evidence related to the bioLytical INSTI Multiplex HIV-1/2 Syphilis Antibody Test in a 2022 Horizon Scan.⁴¹

mHealth and Virtual Care

In July of 2022 UNAIDS and WHO released a policy brief to support the implementation of virtual (online and phone) solutions (including HIV self-testing) to help governments achieve their 95 to 95 to 95 targets by 2025.⁴²

In Canada, the development and use of a smartphone apps to support self-testers have also been evaluated^{21,22} HIVSmart! (Nitika Pant Pai Lab, Montreal)⁴³ is a multiplatform, confidential smartphone app designed to engage and proactively inform HIV self-test users through the testing process, store test results, and (rapidly) connect users to counselling and care. HIVSmart! is compatible with any HIV self-test and is intended to help address gaps in the self-testing process related to accurate detection, test interpretation, and connections to care. The feasibility of implementing HIVSmart! was evaluated with an identified gbMSM group in an unsupervised clinical setting in Montreal in 2018.²¹ The role the app might play in different HIV testing settings in South Africa and Montreal has also been explored.²²

Nucleic Amplification Testing Self-Test Devices

HIV self-testing devices that use more sensitive nucleic amplification testing technologies to identify HIV RNA from fingerstick blood samples are also being developed and may help overcome 1 limitation of current HIV antibody self-tests – the ability to detect HIV infection in the early weeks after exposure.⁴⁴

Additional Considerations

If HIV self-testing is implemented more widely across Canada it will be important to consider the following potential issues.

Targeting Populations

When implementing an HIV self-testing program, it will be important to ask what populations should be targeted?⁴ In considering this question, O’Byrne⁴ notes that Canada has a good sense of what groups account for the most HIV diagnoses (gbMSM, ACB persons, people who use injection drugs) and what groups are disproportionately affected by HIV (Indigenous people and trans people). However, surveillance data are based on diagnosis (i.e., people who access HIV testing) which is impacted by cost, accessibility of testing services, and perceptions of testing. Surveillance data are also based on “newly reported” cases, not “newly diagnosed.” This means known HIV infections may be reported as new when a person moves to a new location in Canada. To account for these known issues, target populations for HIV self-testing should be based on up-to-date local epidemiology (not necessarily pan-Canadian data or trends).

HIV self-testing also has the potential to change the way jurisdictions in Canada understand the epidemiology of HIV.⁴ Currently, HIV testing, performed in clinics, primary care practices, emergency departments, and other outreach and clinical settings, relies on a passive, self-selective approach that does not represent the population as a whole. Risk profiles collected from people seeking HIV testing are often incomplete, may not ask the right questions or may not word questions in ways that illicit responses with adequate accuracy (e.g., to understand if an infection is truly new), and people are lost to follow-up

further having an impact on our understanding of HIV in Canada. HIV self-testing might worsen the current shortcomings in HIV surveillance (i.e., people may not report test results) but could also improve surveillance data across the country (e.g., self-testers may be more truthful in what they report compared with what they share directly with health care providers).

Self-Testing Uptake

Assuming HIV self-testing programs select the right populations to target, O’Byrne suggests decision-makers ask if these groups will use HIV self-testing?⁴ Because HIV self-testing is not yet widely used in Canada, what is known about its uptake is limited to the studies in Canada and other locations. HIV self-testing appears to be acceptable to priority groups, and using HIV self-testing is linked to increased HIV testing, more HIV diagnoses than other existing testing options, and timely access to care.⁴

Cost is also a known barrier to self-testing uptake (it undermines willingness or ability to obtain self-tests). Still, literature suggests that when HIV self-tests are free, test positivity rates exceed those of tests provided elsewhere in the health care system (even if those tests are made available for free).⁴ The GetaKit program emerged in response to the licensing of INSTI HIV-1/2 Antibody Self Test, and its sale price of \$54 for 2 tests (including shipping) is a cost the program team believed to be prohibitive to many people affected by HIV; this could negate the benefits of self-testing by limiting who accessed testing.²⁶

Support for Testers

While tests are designed and intended to be done alone, additional supports are likely needed to ensure accurate HIV self-test use.²⁵ Additional supports could take many forms, including: real-time assistance by video, phone, or in-person appointments, additional information resources in a variety of format types (e.g., written or video) to help testers use the tests so they work the first time, or in-person self-testing spaces where testers could get help performing the test.^{7,25}

Data from Galli et al.⁷ supports the need for alternate testing locations. When asked about testing location preferences, 60% of testers said they would prefer to do the test at home and 40% said they would prefer to use the self-test in a clinic or other health care facility – suggested assisted and unassisted self-testing options are needed for real-world access and uptake.

Costs of Self-Testing Programs

While no Canadian studies have yet looked at the costs of operating an HIV self-testing program some considerations have been reported.

O’Byrne et al. (2022a)²⁰ noted invalid test results have implications for the costs of operating an HIV self-testing program because they lead to additional requests for tests kits. The authors found that the cost of invalid results in the GetaKit program was (40 per kit delivered) \$3,560. At a reported 8% invalid test rate, the authors noted that program costs could escalate quickly if the program expanded.

Successful adoption and integration of HIV self-testing into health care systems in Canada will likely require diverse public and private payment models (e.g., income-tested payment, low costs test).⁶ Because HIV self-

testing can increase demand for related services for people who test negative (e.g., access to PrEP, partner referrals, and partner notifications), those follow-up services will also require funding.⁶

Ethical Considerations

In a policy review and analysis published shortly after the INSTI HIV-1/2 Antibody Self Test was licensed for use in Canada O'Byrne discussed the individual- and population-level ethical considerations for implementing HIV self-testing.⁴

Individual Level Considerations

At the individual level, ethical issues were related to access to testing, consent, support, and access to follow-up prevention and treatment services.⁴

Access to Testing

Access to HIV testing is often limited by geography. Self-testing could help with this limitation, but existing testing inequity could be exacerbated (and self-testing could become a second opportunity for groups already well served by existing HIV testing programs) if the cost of HIV self-tests is left unconsidered.⁴

Restricting access (particularly if done for unsubstantiated reasons) may perpetuate the stigma and HIV exceptionalism. One example of an unintended access restriction self-testing cost. Many people who would benefit from HIV self-testing are in a position of socioeconomic and political disadvantage. Implementation of HIV self-testing will need to recognize this, and cost should be a consideration when implementing HIV self-testing if the potential population benefits of HIV self-testing are to be realized.⁴

Consent

Consent is an important ethical consideration as it relates to potential coercion. For HIV self-testing, consent is unlikely to be an issue if testing is free (i.e., offered in a way similar to current testing programs).⁴

Support

It is important that HIV self-testing programs include access (via phone, text, Internet, and so forth) to support, particularly to help manage issues of consent and to help testers interpret their test results and manage a positive HIV test result.⁴

Access to Follow-Up Services

Self-testing programs must include connections to wraparound services for people who test positive for HIV.⁴ These include psychological and emotional support and confirmatory testing, treatment, and PEP for partners. It will also be important to consider how peer and community support is incorporated into self-testing programs (to mitigate potential harms).⁴

Population Level

At the population level, the goal of HIV testing is to prevent additional infections. This goal is equal to an individual's right to autonomy to know their HIV status and their subsequent right to care. HIV self-testing is an additional way to allow people to learn their HIV status (when they are ready) and should not be considered by decision-makers as a new way of identifying "vectors of disease."⁴

Framing HIV self-testing as a new way to help people learn their HIV status may help shape communications that are focused on informing people of the impact an HIV diagnosis has on individuals' lives, the lives of their loved ones, and their community. Avoiding morality-based messaging would help avoid discrediting people who are not yet ready to learn their HIV status.⁴

Considerations for the INSTI HIV-1/2 Antibody Self Test

Potentially there is a need for regulators and policy-makers to look at combined performance metrics (true invalid results plus results users could not interpret) when authorizing and selecting self-tests for use.²⁰ Canadian research also shows some issues with the INSTI HIV-1/2 Antibody Self Test kit (e.g., blood collection) that could be addressed by additional insert instructions.⁷

Final Remarks

Self-testing for numerous infectious diseases has become recognizable to most people in Canada as 1 way to reduce the spread of infections. HIV screening through self-testing is new tool in a comprehensive Canadian HIV prevention strategy (e.g., PrEP and PEP) that could, through appropriate implementation, provide greater access to HIV testing, treatment, and prevention for priority groups living in Canada and help Canada achieve its commitments to end the HIV and AIDS epidemics by 2030. HIV self-test kits are available at a cost, or individuals may obtain them through programs like GetaKit for free. Studies conducted in Canada have found higher than expected rates of invalid test results (when the test does not produce a result and another test must be taken) – which increase the cost of testing whether paying out of pocket or through a free program.

While funds have been allocated to purchase test kits, there is a need to ensure that the tests are distributed equitably to those who require testing, that health care providers are aware of this testing option, that programs providing tests and follow-up care free of charge can continue to provide services, and that there is an effort to reduce the proportion of invalid test results. Should HIV self-testing become widespread in Canada, delivery models centred on self-testing will need to be developed.⁶ This will require collaboration between private providers, publicly funded clinics, community services, laboratories, and test manufacturers.⁶

Policies and guidelines related to HIV self-testing may require large-scale Canadian studies to understand cost-effectiveness and guide implementation.⁶ Should oral HIV self-tests be approved in Canada, their place in HIV testing will also present similar questions to decision-makers before adoption and implementation.

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