ONTARIO HIV TREATMENT NETWORK

HIV self-testing in high-income settings:

Acceptability, potential benefits and harms, issues related to linkage to care, interventions to increase HIV self-testing

Questions

- What is the current evidence in high-income settings on HIV self-testing related to acceptability, potential benefits and harms, issues related to the linkage to care after a positive test, and interventions to increase HIV self-testing?

Key Take-Home Messages

- HIV self-testing has the potential to increase rates of HIV testing and is acceptable to a range of populations in a variety of contexts (1).
- HIV self-testing is believed to produce public health benefits by increasing the number of people who test, the frequency of testing, the number of people who know their status, and the number of people linked to treatment and care – all of which contribute to decreasing HIV transmission (2).
- There is little evidence of harms related to HIV self-testing, but concerns remain about the reliability of currently available test kits (especially in the early stages of HIV infection) and whether people who have a reactive HIV self test are linked to care for confirmatory testing (1).
- Although there is some evidence that linkage to care rates after positive HIV self-testing are no worse than after facility-based testing, this is one area that would benefit from further empirical research (2).

The Issue and Why it's Important

Self-testing is not a new concept; it is used in the diagnosis and management of other health conditions, such as pregnancy and diabetes, as well as colon cancer (3). Since its introduction, HIV self-testing has been subject to scrutiny by regulatory agencies, researchers, and users because of potential ethical, legal, and social issues (4, 5).

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Despite the increasing availability of HIV self-tests around the world, there are concerns about the lack of pre- and post-test counseling, the need for those who test positive to be linked quickly to care, the need for confirmatory testing, and the "window period" during which a person very recently infected may test negative on any HIV antibody test (4).

Advocates and public health officials have expressed concerns about HIV self-tests being done without counselling and linkage-to-care outcomes for HIV-positive individuals (6). A recent survey of 183 stakeholders (clinical providers, public health professionals, researchers) engaged in HIV testing initiatives in Canada identified the concerns, opportunities and challenges to implementing HIV self-testing in Canada (7). A majority (71%) felt that self-testing was a necessary investment to reach the undiagnosed, and 65% felt that self-tests should be made available to their clients (7). While stakeholders saw the benefits of the option of HIV self-testing in reaching undiagnosed individuals, they felt it was important to address issues, such as the cost and accuracy of self-tests, expedited linkages to counselling, and integration of self-testing within prevailing HIV testing models, before implementing self-testing widely (7).

Because of the likelihood that Health Canada will approve an HIV self-test in the near future, it is important for Ontario organizations to have updated evidence on the limitations, strengths, acceptability, feasibility, and effectiveness of HIV self-testing in high-income settings comparable to Canada. The aim of this review is to assess current evidence around HIV self-testing in high-income settings including: its acceptability, potential benefits and harms; issues related to linkage to care after a positive test; and interventions to increase HIV self-testing.

What We Found

HIV self-testing: General concepts and facts

There are two approaches to self-care in the context of HIV testing: self-sampling and self-testing (8):

- Self-sampling consists of ordering test kits online that contain a fingerstick device and a tube for self-collection. The person collects a blood sample and mails it to a certified laboratory for testing (9). Note: companies providing self-sampling kits have not received FDA review for the procedure in the U.S. (9). In the UK, the National HIV self-sampling service provides HIV test kits to anyone living in England over the age of 16 (10, 11). A blood sample taken at home is mailed to a laboratory where it is tested using 4th or 5th generation assay (10, 11) and results are communicated within several days (10, 11).

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- Self-testing, which is defined by the World Health Organization (WHO) as "a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts" (3). This approach differs from self-sampling in that the person conducting the test receives and interprets the results themselves within minutes of testing (8). HIV self-testing does not provide a definitive HIV-positive diagnosis because, as with all HIV testing, a single reactive rapid diagnostic test is not sufficient to make an HIV-positive diagnosis (3). HIV self-testing is an initial screening test: individuals who have a reactive test result are required to seek confirmatory testing from a trained tester using a validated national testing technology (3). In jurisdictions where HIV self-test kits have been approved for use, they can be purchased in pharmacies and ordered online. Note: HIV self-testing kits have been approved by local regulatory authorities and are legally available in the U.S., UK, and France, as well as other jurisdictions (3). HIV self-testing was introduced in the U.S. in 2012 when the FDA approved the oral self-test: OraQuick® In-Home HIV Test (12). The first legally approved HIV self-testing kit went on sale in the UK in 2015 (13, 14). Currently, BioSURE HIV Self Test (by BioSure (UK) Ltd) (15) and INSTI® HIV Self Test (by a Canadian company bioLytical Laboratories Inc.) are available in the UK and several other European counties (16).

- As of November 2019, no HIV self-test has yet been approved for use in Canada.

This review focuses on self-testing, rather than self-sampling.

HIV self-tests and their accuracy

OraQuick® uses an oral fluid collection technique that is painless and preferred by many over finger-stick whole blood methods (17). The OraQuick® self-implemented HIV test is composed of three core components: specimen collection and testing, and interpretation of results; the use of OraSure's consumer support center for counseling; and referrals for confirmatory testing and linkage to care in the individual's geographic area (18). In addition, OraSure seeks to implement self-testing with good fidelity by training consumers appropriately using package instructions and an online video (18). Currently the OraQuick® In-home HIV Test is the only home HIV test available in the U.S. (19). The Home Access HIV-1 Test System, a home collection kit for finger stick blood specimens, was available for purchase through December 2018 but has been discontinued (19).

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BioSURE HIV Self Test and INSTI® HIV Self Test use a small amount of blood from a finger-prick sample to detect the presence of HIV antibodies and offers a result within minutes. Both of these tests can be purchased at pharmacies in the UK and they can also be purchased online in the UK and throughout Europe (15, 16). Autotest VIH® (manufactured by AAZ–LMB) is available for sale online and in pharmacies across France (20).

There are substantial differences in sensitivity and specificity between oral fluid and blood-based self-test methods. Sensitivity and specificity are higher for blood-based than oral fluid rapid diagnostic tests (21). Up to one in 12 infected people may test false-negative with the oral fluid OraQuick® In-Home HIV Test (22), whereas INSTI® HIV Self Test has a very high diagnostic accuracy, with sensitivity and specificity of 99.8–100% and 99.5–99.8% respectively, in fingerstick blood (23).

Most invalid results and errors in performance relate to user errors and manufacturing defects (21). These invalid results and errors can be mitigated with better instructions for use because the complexity of the procedure or the instructions increase the risk of problems with test performance and interpretation of a result (21). Product labelling should clearly state that people with reactive or invalid test results should seek further testing at a health facility (21). The labelling should also include information on test limitations in detecting HIV infection: during the window period, for people taking pre-exposure prophylaxis, and in people with a suppressed immune response, such as people on antiretroviral drugs (21). This is a crucial issue because people with HIV on antiretroviral therapy might be using HIV self-tests to check and reconfirm their HIV status, and could obtain a false-negative result (21).

Acceptability, feasibility and utility of HIV self-testing

Much of the published literature both before and after approval of HIV home-tests has focused on feasibility and acceptability (1, 4, 17, 24–26).

HIV home-testing has been found to be acceptable in a large number of studies among men who have sex with men (27–37) and other high-risk communities such as transgender women (38). The acceptability of HIV self-testing in other key populations, such as prisoners, is unclear due to limited research (9). Perceptions of and attitudes towards self-testing are positive across the studies (4).

A recent qualitative systematic review found that self-testing was preferred to facility-based testing because of its increased convenience and confidentiality, especially among stigmatized populations (39). HIV self-testing decreased test-associated stigma compared to facility-based testing, and generally empowered

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people because it provided greater control over individual testing needs (39). Individuals hesitant to test for HIV in a healthcare facility may be ideal candidates for the provision of HIV self-testing. Interestingly, there is some evidence suggesting high acceptability of HIV self-testing among migrant men who have sex with men. A study conducted among migrants living in the UK, France and the Netherlands found that HIV self-testing among migrants was relatively low, but higher among migrant men who had sex with men (40): among 477 migrants, HIV self-test usage in the preceding 12 months was 1.89% (n=9), and all of these nine users were men who had sex with men (40).

Across a number of studies and populations, participants prefer oral fluid to blood-based HIV self-testing methods (24, 29, 41), likely because the oral fluid method is perceived to be less painful and easier to perform (24). A study exploring testing preferences among men who have sex with men with a high risk profile found a greater likelihood of them using an oral swab over a blood-based test (42).

Benefits and harms

The most common benefits of self-testing reported in the literature were:

- The process was easy, convenient, and private (4).
- Ordering self-test kits online offers greater anonymity and convenience than clinic-based testing, and is acceptable and feasible (43).
- Most people could usually properly perform home tests, obtain accurate results, and interpret them, yielding high correlations with laboratory and health-professional performed tests (44).
- People generally understood the need to confirm positive test results (44).
- HIV home-testing has the ability to reach more people and the potential to leverage technology-based solutions to link persons to care (9).

The most common limitations of self-testing reported were concerns over pre- and post-test counseling, accuracy of the results, and cost of the test (4).

Impact on testing frequency

The Frequency of Oral Rapid Testing at Home (FORTH) study, a randomised controlled trial conducted in Australia, assessed

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the effectiveness of HIV self-testing in increasing HIV testing frequency among higher risk men who have sex with men (45, 46). It found that free HIV self-testing (in combination with facility-based testing) resulted in gay and bisexual men at high risk of infection testing twice as often with non-recent testers testing four times more often than with facility-based testing only (i.e. standard care), without reducing the frequency of facility-based HIV testing (46). The authors recommended wider availability of HIV self-testing to help increase testing and earlier diagnosis (46). The study also found that, among men who have sex with men, confidence in their perceived ability to undertake various aspects of HIV self-testing (self-efficacy) was associated with higher HIV testing frequency and perceived likelihood to self-test (47).

A study from Seattle, which also evaluated the implementation of self-testing, demonstrated that access to HIV self-testing at no cost increased testing frequency among high-risk men who have sex with men (48). Men randomized to self-testing reported significantly more HIV tests during follow-up (mean=5.3) than those randomized to testing as usual (mean=3.6), representing an average increase of 1.7 tests per participant over 15 months (48).

Ability to attract first-time testers

HIV home-testing can be an effective way to reach first-time testers, under-tested individuals, and individuals who otherwise would not test for HIV (9):

- Among gay and bisexual men in Australia, under-tested individuals are twice as likely as the general population to use an HIV home-test (49).
- The "Scaling Up HIV Testing among African American and Hispanic Men Who Have Sex with Other Men: The MSM Testing Initiative (MTI)" in the U.S., which recruited testers online and distributed test kits by mail, found that home testing was nearly five times more likely to reach first-time testers than clinic-based testing (50).
- In an online French survey of 5,908 HIV-negative men who have sex with men who were unaware of being able to order an HIV self-test online, 86.5% expressed interest in accessing the kits online, indicating convenience and ability to conduct tests at home as the primary reasons (51). Interest in accessing HIV self-testing online was associated with not having been previously tested and not having been tested in the last year (51).

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Ability to detect prevalent infections and reduce the time between infection and diagnosis

In a randomized clinical trial of 2,665 U.S. participants (eSTAMP – Evaluation of Rapid HIV Self-testing Among MSM Project), more participants in the arm that was mailed HIV self-tests (two oral fluid and two fingerstick whole blood tests each) reported testing for HIV three or more times compared with control participants (52). A total of 12 infections were identified in the self-testing arm in the first three months compared with two infections in the control arm (52). Participants who shared the study self-tests with others reported 34 infections among their social network members (52). The study results suggested that providing free HIV self-tests helped increase awareness of infection among men who have sex with men and their social network members (52).

The currently ongoing SELPHI randomized-controlled trial (An HIV Self-Testing Public Health Intervention) in the UK will attempt to answer questions about both the ability of HIV self-testing to detect prevalent infections and to reduce the time between infection and diagnosis. This study aims to recruit men who have sex with men in England and Wales (1, 53) and focuses on the rates of HIV diagnosis as determined through confirmatory testing and linkage to care as the primary outcome (1, 53). This trial will provide more evidence for future policy-makers in high-income settings and those working with key populations on the efficacy and cost-effectiveness of HIV self-testing in order to increase rates of HIV diagnoses (1).

Strategies to increase HIV self-testing

In 2016, the WHO recommended that "HIV self-testing should be offered as an additional approach to HIV testing services" (3), and it provides detailed guidelines on HIV self-testing implementation (3).

Although HIV self-testing is accurate, feasible, and safe – and recommended by the WHO – it is still not widely available. New approaches are needed, including the use of vending machines, online promotion and purchasing, and mail delivery, all of which have shown favourable outcomes and good linkage to care (6, 18). Social media has also served as a platform for delivering services such as HIV self-testing kits, HIV self-sampling, or home-based HIV testing (54).

Several studies examined strategies to increase HIV self-testing among men who have sex with men:

- In a study from Los Angeles, community based organizations distributed vouchers redeemable for HIV self-tests from a participating national pharmacy (Walgreens) (55). Of those who tested and completed

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a survey, 30% had not tested in the past year and 6.1% tested positive (55). While this sample of mostly African-Americans was not exclusively men who have sex with men, they did account for the majority (66%) of the sample (55).

- A study in San Francisco distributed self-testing kits to patrons of a local bathhouse (56). A quarter of those accepting the kits had not tested in the previous year and 7% had never tested (56).

- In New York, 27 men who have sex with men distributed test kits to their sex partners and acquaintances (28). Of 101 kits distributed, 10 tested positive, six of whom were not aware of their status (28).

- Other studies in Los Angeles offered HIV self-tests to men who have sex with men through online social network sites (Facebook) (57) or Grindr banner ads (58). The study using social network sites, mailed out 36 kits (57). Just under half (48%) of requesters had not tested in the previous six months, and 11% had not tested in the previous three years (57). In the study using banner ads, of the 333 men who requested tests, 29% had last tested over a year ago and 9% had never tested (58).

Other venues and methods have been used to increase HIV self-testing. For example, distributing HIV self-testing kits in bathhouses has been shown to reach a population of men who have sex with men most in need of improved access to HIV testing (56). Uptake of self-tests was significantly higher at a Brighton, UK sex-on-premises venue (sauna) when the tests were distributed through vending machines rather than by community workers in the same venue (59). A Los Angeles study also found that machines and HIV self-test kits in commercial sex venues was acceptable, feasible, used by the venue patrons and could help identify new HIV cases (60): over 18 months, 1,398 kits were dispensed, and 110 patrons completed the survey (response rate=7.9%) (60). Among those who reported that they used the test kit (n=96), 17 (17.7%) reported a first-time reactive HIV result (60).

Offering HIV self-testing in healthcare settings, such as emergency departments (ED), appears to empower and engage patients in testing (13, 17). Evaluation of an opt-in program in an inner-city academic emergency department in Baltimore, which looked at the impact of a kiosk-based HIV self-testing program as standard of care on 332 patients (61), found that approximately half chose to test themselves (61). An earlier study at the same ED department used a tablet-based approach that proved to be highly feasible, acceptable, and accurate; however, rates of engagement were moderate (62). That department also provided home HIV self-testing kits for patients who declined testing in the emergency department and this approach significantly improved engagement of HIV testing

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among those who declined testing in the ED (63).

Post-test counseling and linkage to care

To ensure that people who test HIV-positive receive the care they need (including counselling and antiretroviral therapy), they must be linked to care as soon as possible after diagnosis. One of the key concerns about self-testing is whether people who test positive are linked to care as quickly and effectively as they are through facility-based testing. It is important to compare linkage and retention experiences based on type of testing (64).

In the context of HIV self-testing, pre-test information and post-test counselling can be provided in a number of ways, including a directly assisted approach (e.g., in-person demonstration and explanation by a trained provider or peer) or an unassisted approach (e.g., use of manufacturer provided instructions), as well as a number of other support tools, such as brochures, links to Internet or computer-based programs or videos, telephone hotlines, mobile phone applications or text message services (3).

Whether samples are collected and processed by the user or mailed-in to a laboratory, priming people for linkage to care is a vital part of a successful HIV self-testing program (9). Without facilitation, users testing positive are less likely to link to care (9). Testing options that require people to mail specimens to a central laboratory to process can ensure that health care workers have the opportunity to follow-up with individuals who test positive (9). However, in practice, some users find the wait for results required by mail-in testing to be unacceptable (9). For tests that people complete and interpret at home, call lines offer assistance with test interpretation and troubleshooting as well as the option to discuss results immediately after the test and to be linked to care (9). Test manufacturers' websites can also provide video responses to common testing questions and a range of counseling resources including, for example, automated multimedia reminders for those using HIV home-testing that provide instructions on how to proceed following specimen collection (9).

Post-test counseling for home-testing often occurs through information provided in the testing kits themselves (9). OraQuick® instructions provide a support number testers can call to help them locate a health care provider for a confirmatory test (9, 65). Kit package inserts also provide explanations for how false positives and false negatives occur (9, 65).

Clinic-based testing allows offering linkage to care upon delivery of positive results, whereas for HIV self-testing, the timing (when), targeting (whom), and format (video, audio, text) of providing linkage to care is less clear (9). An individual who uses home-based self-tests has more power to determine the nature of their engagement

59. Vera JH, Soni S, Pollard A, Llewellyn C, Peralta C, Rodriguez L, et al. Acceptability and feasibility of using digital vending machines to deliver HIV self-tests to men who have sex with men. Sexually Transmitted Infections. 2019. [Epub ahead of print].

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61. Hsieh YH, Beck KJ, Rothman RE, Gauvey-Kern M, Woodfield A, Peterson S, et al. Factors associated with patients who prefer HIV self-testing over health professional testing in an emergency department-based rapid HIV screening program. International Journal of STD & AIDS. 2017;28(11):1124–9.

62. Gaydos CA, Solis M, Hsieh YH, Jett-Goheen M, Nour S, Rothman RE. Use of tablet-based kiosks in the emergency department to guide patient HIV self-testing with a point-of-care oral fluid test. International Journal of STD & AIDS. 2013;24(9):716–21.

63. Patel AV, Abrams SM, Gaydos CA, Jett-Goheen M, Latkin CA, Rothman RE, et al. Increasing HIV testing engagement through provision of home HIV self-testing kits for patients who decline testing in the emergency department: A pilot randomisation study. Sexually Transmitted Infections. 2019;95(5):358–60.

64. Tucker JD, Wei C, Pendse R, Lo YR. HIV self-testing among key populations: An implementation science approach to evaluating self-testing. Journal of Virus Eradication. 2015;1(1):38–42.

65. OraSure Technologies Inc. OraQuick® package insert. Available from: https://www.fda.gov/media/83607/download Accessed November 18,2019.

with linkage to care services (9), and there is some indication that people who self-test do link to care relatively quickly:

- In a study conducted in New York City that examined reactions to receiving HIV positive results through self-testing among men who have sex with men, subjects appeared to be strongly motivated to ensure linkage to care after a partner tested positive using a self-test (66).

- Another New York study assessed the time it took men who have sex with men to seek confirmatory testing after a self-test and linkage to care (67). Higher proportions of self-tested (91%) than non–self-tested persons (81%) linked to care within three months of diagnosis (67). In addition, significantly more persons who self-tested positive (89%, 39 of 44) than persons who self-tested negative (39%, 14 of 36) sought a laboratory-based HIV test within one month of their last self-test (67). The study authors suggest that men who have sex with men sought timely HIV confirmatory testing and linkage to care (67). However, the cost of self-test kit may be an important barrier to its wide adoption across sociodemographic groups (67).

- The pharmacy voucher program for OraQuick® in Los Angeles (described above) also found that self-testing identified more new cases of HIV infection and there were high rates of linkage to care (55).

- A longitudinal study assessed 896 participants who collected specimens and sent them to a central laboratory for testing and then used a call line to receive the results. People who had tested positive were connected to a trained HIV counselor (68). Among the 25 who tested positive, 14 (56%) were linked to care (68). This highlights a unique advantage of blood-based HIV self-testing where testers are incentivized to call hotlines to receive their results, which offers a built-in opportunity for linkage (9, 68). This option is not possible for oral fluid HIV self-testing (9).

- A small (n=10) study explored the acceptability and usability of a smartphone app for high-risk men who have sex with men that uses data from light sensors on Bluetooth low energy beacons to monitor when HIV self-testing kits are opened (69). Health care providers then call the users to provide timely follow-up contact (eTEST) (69). Initial results showed that this approach was feasible and acceptable to high-risk men who have sex with men (69).

- A study of an app–optimized HIV self-testing program in Montreal found that all of the participants who self-tested positive and were lab-confirmed positive (0.7% of all

66. Martinez O, Carballo-Dieguez A, Ibitoye M, Frasca T, Brown W, Balan I. Anticipated and actual reactions to receiving HIV positive results through self-testing among gay and bisexual men. AIDS & Behavior. 2014;18(12):2485–95.

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68. Ricca AV, Hall EW, Khosropour CM, Sullivan PS. Factors associated with returning at-home specimen collection kits for HIV testing among internet-using men who have sex with men. Journal of the International Association of Providers of AIDS Care (JIAPAC). 2016;15(6):463–9.

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70. Pant Pai N, Smallwood M, Desjardins L, Goyette A, Birkas KG, Vassal AF, et al. An unsupervised smart app-optimized HIV self-testing program in Montreal, Canada: Cross-sectional study. Journal of Medical Internet Research. 2018;20(11):e10258.

71. Wood BR, Ballenger C, Stekler JD. Arguments for and against HIV self-testing. HIV/AIDS Research and Palliative Care. 2014;6:117–26.

72. Hurt CB, Powers KA. Self-testing for HIV and its impact on public health. Sexually Transmitted Diseases. 2014;41(1):10–2.

participants, 3 of 451) were linked to a physician within the same day (70). The HIVSmart! app-optimized strategy was feasible, accepted, and preferred by educated, urban men who have sex with men in Montreal (70).

- The currently ongoing SELPHI randomized controlled trial in the UK (described above) will add to the currently limited body of evidence from high-income settings on linkage rates after HIV self-testing (1, 53).

Public health implications of HIV self-testing

There are numerous arguments both for and against HIV self-testing that must be considered in efforts to implement effective programs (71, 72).

The case in support of HIV self-testing contends that:

- The modality is highly acceptable, especially among individuals most at risk (71).
- Self-testing empowers users and helps to normalize testing (71).
- HIV self-testing is associated with increased uptake and frequency of testing (43), particularly among those at risk who may not otherwise test, which means it will likely identify more HIV-positive individuals than standard testing services alone (43).
- Mutual partner testing has the potential to increase awareness of risk and avert condomless sex between discordant partners (71).

An Australian modelling study estimated that, at a population level, if access to HIV self-testing led to men supplementing their usual sexual health check-ups (involving a laboratory HIV immunoassay) with one or more self-tests at home, or self-tests led to untested gay and bisexual men having an HIV test for the first time, there would be a public health benefit (73). Additional public health benefits include a reduction in the period of undiagnosed infection, which is known to be a period of relatively high infectiousness (73).

Arguments against HIV self-testing include the following:

- Cost may limit access to those who need testing most (71).
- False-negative results, especially during the window period, may lead to false reassurance and could promote sex between discordant partners at times of highest infectivity (71).

73. Guy RJ, Prestage GP, Grulich A, Holt M, Conway DP, Jamil MS, et al. Potential public health benefits of HIV testing occurring at home in Australia. Medical Journal of Australia. 2015;202(10):529–31.

74. Ontario HIV Treatment Network, Rapid Response Service. The risk of coercion in the context of HIV self-testing. September 2019. Available from: http://www.ohtn.on.ca/rapid-response-the-risk-of-coercion-in-the-context-of-hiv-self-testing/ Accessed November 18, 2019.

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76. Greacen T, Kersaudy-Rahib D, Le Gall JM, Lydie N, Ghosn J, Champenois K. Comparing the information and support needs of different population groups in preparation for 2015 government approval for HIV self-testing in France. PLoS ONE. 2016;11(3):e0152567.

- Opportunities for counseling, linkage to care, and diagnosis of other sexually transmitted infections may be missed (71).

- Self-testing may lead to potential for coercion between partners (71). In high-income settings, HIV self-testing may be less challenging in this respect because existing systems ensure proper regulation, access to health care, and protection from abuse (74).

There is, however, very little evidence to suggest that self-testing kits will cause significant harm (1, 2, 5, 13, 75), and some authors propose that the only way to properly evaluate their impact is to carefully assess their use once they are widely available (13). Right before introducing HIV self-testing in France in 2015, 72 experts were surveyed and they identified eight important information and support needs (76): communicating at both national and community levels about self-test arrival (24% of all recommendations); providing information adapted to the needs of different community groups (23%); providing counselling on self-test use and access to care (15%); making self-tests available to all in terms of accessibility and cost (13%); preparing community health care and screening systems for the arrival of the self-test (11%); approving only high quality self-tests (6%); defending self-test users' legal rights (5%); and evaluating self-test use (3%) (76).

Factors That May Impact Local Applicability

Only studies and data from high-income settings have been included in this review. The availability of HIV oral fluid or blood self-tests and their approval by regulatory authorities varies across countries and settings. The sensitivity and specificity of HIV self-tests as well as their price also varies across manufacturers and products. The body of the available evidence may not be directly applicable to Ontario's and Canada's health care or legal systems and the findings may not be generalizable.

What We Did

We searched Medline (including Epub Ahead of Print, In-Process & Other Non-Indexed Citations) using a combination of text term HIV and (text terms self test* or home test*). Searches were conducted on October 15, 2019 and results limited to English articles published since 2010. Reference lists of identified review articles were also searched. Google searches using various combinations of the above listed terms were also conducted. The search yielded 477 references from which 76 were included.

Rapid Response: Evidence into Action

The OHTN Rapid Response Service offers quick access to research evidence to help inform decision making, service delivery and advocacy. In response to a question from the field, the Rapid Response Team reviews the scientific and grey literature, consults with experts, and prepares a review summarizing the current evidence and its implications for policy and practice.

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