



National Collaborating Centre
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Point of Care Testing for Sexually Transmitted and Blood-Borne Infections

A CANADIAN REALIST REVIEW

November 2019

PREPARED BY:

Marc-André LeBlanc



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Contact us at:

National Collaborating Centre for Infectious Diseases

Rady Faculty of Health Sciences,

University of Manitoba

Tel: (204) 318-2591

Email: nccid@umanitoba.ca

www.nccid.ca

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ABSTRACT

Canada has endorsed global targets to eliminate sexually transmitted and blood-borne infections (STBBI) as public health threats by 2030. Despite these goals, STBBI – including HIV, hepatitis B (HBV) and hepatitis C (HCV), human papilloma virus (HPV), Chlamydia trachomatis, Neisseria gonorrhoeae, syphilis, and Trichomonas vaginalis – continue to be important public health concerns. Notably, reported rates of STBBI have been on the rise for the last decade in Canada and there is a resurgence of congenital syphilis. Furthermore, a significant number of people remain undiagnosed or unaware of their HIV and/or HCV status, as stigma prevents people from seeking medical care and healthcare practitioners may be reluctant to offer STBBI testing routinely.

As testing is the gateway to the continuum of prevention, care and treatment, elimination can only be achieved by reaching the undiagnosed through the implementation of new and innovative strategies that ensure timely and equitable access to quality care, diagnosis and treatment. Many accurate and reliable STBBI POCTs are licensed and used globally, but in Canada only two rapid tests are licensed currently and their availability varies across the country.

This realist review aims to contribute to a greater understanding of the usefulness of STBBI POCT in Canada by highlighting what we found in the literature in terms of the enablers and barriers to implementing STBBI point of care testing. It includes a summary of the evidence regarding feasibility, cost effectiveness, detection of positive cases and early diagnosis, linkage to care, user preference, acceptability and uptake (including traditional serology versus POCT; single versus multiplex tests).

The review first focusses on populations most affected by STBBI and then outlines key considerations when implementing POCT in different settings, from urban to rural, hospital to non-conventional testing sites. Each section considers the evidence in relation to Canada's complex health care and public health systems, its unique geography and many jurisdictions. Lastly, the review summarizes important strengths and weaknesses of POCT in comparison to traditional serology testing.

Point of care testing for HIV, HCV and syphilis has been shown to be feasible and effective, and generally has high acceptance among populations most affected by STBBI. However, the context for testing and treatment follow-up is important. There are also still barriers for specific populations, such as people with unstable housing, people who use drugs and people who face racism and other forms of stigma. Expanding the range of providers who can offer POCT (e.g., peers, counsellors) may increase uptake. Information and education for those testing and those being tested -- including to improve counselling and to address stigma -- are important components to consider for new POCT programs.

The review concludes with areas for further exploration, including potential research to address knowledge gaps. Careful planning of STBBI POCT is critical to success; the entire process from testing and linkage to care, through to treatment completion must be considered when planning an effective testing campaign or programme. Implementation based on meaningful community and stakeholder engagement, careful examination of available evidence, and new research will bring Canada a step closer to meeting the global targets aimed at eliminating STBBI as a public health threat by 2030.

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1. Background

Sexually Transmitted and Blood-borne Infections (STBBI) in Canada

Canada has endorsed global targets aimed at eliminating HIV, hepatitis C (HCV) and other sexually transmitted and blood-borne infections (STBBI) as public health threats by 2030. Despite these goals, STBBI – including HIV, hepatitis B (HBV) and HCV, human papilloma virus (HPV), *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, syphilis, and *Trichomonas vaginalis* – continue to be important public health concerns. Indeed, reported rates of sexually transmitted infections have been on the rise for the last decade in Canada, increasing by 49% for Chlamydia, 81% for gonorrhoea and 178% for infectious syphilis (1). There has been a resurgence of congenital syphilis in many provinces since 2017.¹ In addition, an estimated 63,110 Canadians were living with HIV in 2016, of whom 14% were undiagnosed (2), and an estimated 246,000 Canadians were living with HCV at the end of 2011, of whom 44% remained unaware of their status (3).

According to the Public Health Agency of Canada (PHAC), “rates of notifiable STIs have increased despite numerous public health interventions designed to increase awareness and to prevent, diagnose, and treat infection. There are various potential factors that may explain these observations, such as a true rise in incidence, the use of improved diagnostic methods, and more effective contact tracing and case detection” (4).

STBBI are particularly challenging to control due to stigma and discrimination associated with these types of infections, which may prevent people from seeking testing and treatment. As a result, there is a low rate of perceived risk and a low acceptance rate of STBBI testing among the general population, as well as a reluctance among healthcare providers to offer STBBI testing routinely. In Canada, infections are largely concentrated in young people and communities that face additional stigma, discrimination and structural factors that contribute to greater STBBI rates, including First Nations, Métis and Inuit populations, gay, bisexual and other men who have sex with men (GBMSM), people who inject drugs (PWID) and people in correctional facilities (2,4).

Left untreated, STBBI may have important consequences on the sexual and reproductive health of Canadians, and current evidence supports that complications disproportionately affect women. As testing is the gateway to the continuum of care and treatment, elimination can only be achieved by reaching the undiagnosed through the implementation of new and innovative strategies that ensure timely and equitable access to quality diagnosis, care, and treatment.

Point of Care Testing (POCT)

Diagnostic tests play a critical role in efforts to eliminate HIV, HCV and other STBBI as public health threats by 2030. Indeed, timely and accurate diagnosis of STBBI is essential for linking individuals to appropriate treatment and care, thus preventing adverse outcomes and limiting the spread of infection.

¹ <https://www.ctvnews.ca/health/n-l-syphilis-rates-up-first-cases-of-transmission-to-unborn-infants-1.4288806>; <https://www.cbc.ca/news/canada/edmonton/syphilis-alberta-health-outbreak-warning-1.5213851>; <https://www.cbc.ca/news/canada/manitoba/syphilis-manitoba-outbreak-infants-1.5032422>

POCT may be especially useful in reaching populations disproportionately affected by STBBI, notably those who are not currently using health services due to potential stigma and discrimination or geographic isolation. POCT has been shown to be generally acceptable – and often even preferable to conventional testing options – for many populations. This high acceptability and some of the specific characteristics of POCT (availability of rapid results, flexibility in the settings where it can be administered) can contribute to reaching first-time testers, to increasing testing frequency among current testers, to increasing the proportion of testers receiving their results, to expediting linkage to treatment and care, and to reducing loss to follow-up. POCT is also useful in outbreak settings to provide earlier access to testing results and treatment, thus decreasing the risk of onward transmission.

At the same time, POCT has limitations.

For example, current POCT technologies

do not provide comprehensive screening for all STBBI currently recommended for testing including chlamydia and gonorrhoea, which are early indicators of risk for HIV and other STBBI. Depending on the specific STBBI being tested, there may be longer window periods (the period of time to detect from the time of exposure) for POCT compared to conventional testing. Furthermore, the test may only have screening capability (i.e., detecting antibodies), thus requiring confirmatory testing through conventional methods to distinguish between an active infection and a previously treated infection (e.g., syphilis, HCV). POCT also requires immediate resources (including time spent with clients) to respond to a positive test. Despite some of these limitations, there are significant patient-centred and public health advantages to offering a range of STBBI testing options including POCT. Ultimately, it is important for patients, healthcare providers and policy makers to acknowledge, understand and weigh the relative advantages and disadvantages of conventional and POCT testing options in order to make informed decisions about their most appropriate use.

Many accurate and reliable STBBI point of care tests are licensed and used globally, while in Canada, only one HIV rapid test and one HCV rapid test are licensed for use at point of care (since 2005 and 2017 respectively). STBBI POCT availability varies greatly across Canada, with testing rates remaining quite low in Canada compared to the United States and European countries (5).

“Point-of-care testing (POCT) refers to diagnostic tests performed at or near the patient’s location by health care professional or other qualified personnel... POCT may be performed in a variety of settings, such as hospitals, clinics, physician’s offices, pharmacies, ambulances, nursing and long-term care facilities, or the patient’s residence. It may be advantageous compared with conventional testing, because it allows increased staff and patient mobility, portability across community and rural settings, and rapid turnaround time for test results. These factors may expedite decision-making and patient management and increase efficiency of care.”

Point-of-care testing. Ottawa: CADTH; 2017 Oct. (Environmental scan; no. 65).

[https://www.cadth.ca/sites/default/files/pdf/es0308_point_of_care_testing.pdf Accessed on 11 Oct 2019]

In *Accelerating Our Response: Government of Canada Five-Year Action Plan on Sexually Transmitted and Blood-Borne Infections*, the Government of Canada states that, “Deploying new technologies [such as POCT] in non-health settings must be part of strategies to reach the undiagnosed and link them to treatment. The Government of Canada is committed to playing its role in the development, regulatory approval and deployment of POCT and additional novel technologies, according to standardized methods that assure quality” (1).

Aim of this Realist Review

The National Collaborating Centre for Infectious Diseases (NCCID) commissioned this realist review on STBBI POCT as part of several projects that support national efforts to answer these questions:

- What are the enablers and barriers to implementing point of care STBBI testing for populations most affected?
- What works for who, when and under what circumstances?
- What can Canada learn from other countries that have integrated STBBI POCT more broadly?
- What can Canada learn for public health settings?

The purpose of this review of evidence is to describe patient-centre outcomes, feasibility, acceptability and potential consequences of POCT approaches that are relevant to the Canadian context, including the opportunities and challenges for their implementation in Canada. In order to support equitable approaches, it focusses on populations that are most affected by STBBI, as well as the context of rural and remote communities. [A previous review](#), published by NCCID in March 2018, summarized POC technologies and devices that are currently approved, available and used in Canada, or in the pipeline (5).

2. Methodology

This document uses realist review methods to synthesize and interpret a large body of evidence. Realist reviews provide context and practical considerations about the real-world interactions that affect the results of programs and interventions from site to site and population to population (6,7). Pawson et al. describe the realist review as a, “strategy for synthesizing research which has an explanatory rather than judgemental focus. It seeks to unpack the mechanism of how complex programmes work (or why they fail) in particular contexts and settings” (6).

Canada’s complex health care and public health systems, its unique geography and many jurisdictions, and the daily circumstances of the populations who may benefit from POCT and other interventions, mean that there will never be a single answer on the value of POCT. The aim of this realist review is to contribute to a deeper understanding of STBBI POCT and how it may work most effectively in different settings in Canada.

A comprehensive search of the literature was conducted July 25, 2018. PubMed, and Medline (via Ovid) were searched for MeSH terms related to Point of Care Systems, sexually transmitted infections, hepatitis B and C, AND terms related to point-of-care (see Supplementary material for complete search string). The search was limited to records published in English and French in the years 1946 through July 25, 2018.

Sociological Abstracts was searched using the terms ((sexually transmitted) OR (sexually transmitted infections) OR (sexually transmitted diseases) AND pd (>20020101)) AND (diagnostics OR diagnosis OR point-of-care OR (point-of-care testing)).

Duplicate records were removed using Rayyan QCRI software.

Eligibility Criteria

Titles and abstracts of all records identified through the process described above (n=2,713) were screened for eligibility.

Papers were included if they met the following inclusion criteria.

1. They describe POCT for HIV, hepatitis C, or syphilis. This could include testing for other STBBI (e.g., Chlamydia, gonorrhea, HBV, HPV), but only if they also included HIV, hepatitis C or syphilis.
2. They focus on at least one key population with STBBI risk relevant to Canada.
3. They include at least one key outcome measure relating one or more of:
 - a. patient-centred outcomes (e.g., patient preference, acceptability or satisfaction; POCT uptake);
 - b. feasibility outcomes for the program or strategy (e.g., ease or convenience; cost effectiveness); or,
 - c. impact outcomes (e.g., linkage to care and loss to follow-up; reaching first time testers; detecting new cases; early detection).

Papers were excluded if they met the following exclusion criteria:

1. The study is greater than 10 years old (i.e., published before January 2008).
2. A POCT is not physically used in the study.
3. The study is focussed on self-tests (versus point of care self-tests).
4. The paper is a systematic review.
5. The paper focusses on healthcare provider opinions of STBBI POCT (as opposed to patient opinions).
6. The study includes a stand-alone POCT for gonorrhoea, chlamydia, trichomonas, human papillomavirus or other STBBI, without also including HIV, hepatitis C or syphilis.

Final Selection of Articles and Abstracts

Using above criteria, articles were selected for inclusion in the final report based on their priority and relevance in the Canadian context. They were prioritized if they evaluated implementation of STBBI POCT strategies and policies in high income countries as well as strategies in key populations relevant to Canada. To keep the number of papers reviewed manageable, where there were several studies on a particular topic, a few of the most relevant studies were retained.

As a result, a total of 158 papers were included in this review, including 106 full articles and 52 abstracts and conference posters (for which full articles were unavailable or impossible to locate).

3. Key Considerations in Implementing STBBI Point of Care Testing

Each section below highlights what we found in the literature in terms of the enablers and barriers to implementing STBBI point of care testing, including a summary of the evidence regarding feasibility, cost effectiveness, detection of positive cases and early diagnosis, linkage to care, and user preference, acceptability and uptake (including traditional serology versus POCT; single versus multiplex tests). Where applicable, this includes a description of modes of delivery, including nurse-led and peer-led models. Each section highlights and compares evidence from Canada to the experience of other similar countries and contexts.

Finally, each section includes an analysis of how the evidence relates to the Canadian context, including considerations of our geography, policies, health systems and relevant populations. There is considerable overlap and repetition in these analyses, since similar findings apply to different populations and settings. These repetitions were nonetheless preserved to ensure that readers interested only in particular populations or settings were able to read the relevant considerations. The [Conclusion](#) constitutes an overall summary of these considerations.

3.1 Key Considerations According to Population

This section provides an overview of the evidence related to various populations of relevance for the Canadian context, including GBMSM, Indigenous communities, transgender populations, PWID, people in unstable housing situations, currently and recently incarcerated populations, immigrants and refugees, pregnant women, sex workers and their clients, and young people.

3.1.1 Gay, bisexual and other men having sex with men (GBMSM)

A large portion of the STBBI POCT literature concerns GBMSM, especially in terms of HIV testing. With consistently high rates of syphilis among GBMSM and increasing numbers of cases of HCV, studies have also begun to look at HCV and syphilis testing in this population.

Canada

Canadian studies on GBMSM largely focus on rates of HIV testing, particularly how to increase testing rates using rapid testing.

A Manitoba study of testing in inner-city populations showed that GBMSM and individuals with new partners were more likely to seek rapid HIV testing than conventional testing (8).

A study in Toronto that targeted GBMSM with an HIV testing campaign tested 1102 participants, 37% of whom were non-white. The awareness campaign increased testing by 20%. First time testers (13% of the cohort) and those who reported sex without condoms (72% of the cohort) had the highest positivity rates (9).

Two studies looked at HIV testing efforts in Montréal. One study found that offering free HIV POCT improved testing rates, with 10% of patients never having tested previously, and 29% not having been

tested within the past two years. Ninety-three percent (93%) reported they were more likely to undergo repeat screening because of rapid testing and 60% of those found to be positive (2% of those tested) cited the rapid test as the primary reason for undergoing screening. A much higher proportion of those found to be positive were in primary infection than the provincial average (10).

The other study looked at the demographics of an HIV service targeting GBMSM in Montreal's gay village. GBMSM tested at this site were more likely to inhale drugs, to have multiple partners, and to have used HIV Post Exposure Prophylaxis compared with a smaller group of heterosexual men and women who attended the clinic. All new detected cases (2.1%) were within this group (compared to heterosexual men or women who were tested) (11).

Australia

In an evaluation of peer-led mobile van HIV information and rapid testing units, a majority of participants (61.5% of 35) were GBMSM, with many stating a preference for testing in a non-clinical setting and identifying that they would test more frequently with rapid testing availability (12).

Another study looked at HIV testing of GBMSM in fixed community sites as compared to fast-track clinics in North Sydney. It found that fixed community sites were more likely to reach untested men, while fast-track clinics reached more infrequent testers. HIV/STI prevalence was similar across sites (13).

In a randomized control trial comparing rapid HIV testing (among 200 GBMSM) to conventional testing (among 196 GBMSM), rapid HIV testing increased the number of new testers by one-third compared to conventional HIV testing, but it did not significantly increase frequency of testing over time (14).

One study created a rapid HIV testing space that tested 1,226 individuals. Most users were young and return testers were more likely to have been born outside of Australia. The authors suggested that a range of STBBI tests may need to be offered to improve uptake in this space (15).

Lee et al. investigated rapid syphilis testing at two gay community events in Sydney. Of 183 tests, 48% of men surveyed never used condoms or used them inconsistently. Seven tests were reactive with one of those being current, untreated syphilis. GBMSM in this study preferred rapid syphilis testing to serology (16).

Europe

A study that looked at data across multiple European countries found particularly high HIV prevalence in transgender persons, male sex workers and GBMSM. Offering rapid HIV testing through community-based voluntary counselling and testing was effective in detecting new cases in these groups (17).

France. Preau and colleagues (2016) studied the experiences of 436 men (95% of whom identified as GBMSM) who received HIV POCT in two community "non-medicalized" testing programs in France. Satisfaction was related to the nature of the pre-test counselling and the relationship with the counsellor, as well as feeling understood (18).

A study of community-based HIV POCT by non-medical staff or trained peers in four French cities showed that 468 GBMSM with increased risk of HIV sought rapid testing for reassurance, routine testing, and recent risky sexual behaviour, and that this type of staffing was able to reach members of

this group who did not test frequently or recently. Fifteen tests were reactive for HIV and 12 clients were linked to care (19).

United Kingdom. A study from the UK showed that GBMSM were less likely to access rapid HIV testing in a general practice setting than through genito-urinary medical services, perhaps because GBMSM may be less willing to disclose their sexual orientation/behaviour to their general practitioner (20).

In another study, GBMSM liked the convenience of multiple rapid tests for HIV and STBBIs in Newcastle bathhouses and such testing was effective in reaching men who had not previously accessed sexual health services or been tested for STBBI (21).

A study of rapid HCV testing of GBMSM in HIV testing settings showed that it is feasible to combine the offer of testing and that this is an opportunity to detect new HCV cases as well as educate GBMSM on HCV risk behaviours. In 10 months, 64 HIV and HCV POCTs were completed and 1 test was reactive for HCV (22) .

Against a backdrop of increasing rates of syphilis among white GBMSM in the UK, particularly in the 25-34 age range, a retrospective analysis of rapid syphilis testing was shown to be an effective tool in settings without access to laboratory facilities onsite. Ninety-eight health records were included in the analysis: 20 had syphilis POCT due to genital ulceration or early infection, 8 tests had confirmed syphilis tests by serology, while 4 had reactive syphilis POCT and were treated on that day (23).

Spain. A retrospective study of testing rates in Spain from 2007-2012 showed that HIV POCT in non-clinical settings detected a significant portion of new diagnoses in GBMSM. 95,575 rapid tests for HIV POCTs were completed with 2,061 reactive tests (1582 in GBMSM). Rapid tests accounted for 3.4% of HIV tests in Spain in 2007, increasing to 11% in 2012 (24).

Between 2008 and 2011, 8,923 people were tested in outreach settings in Spain and compared to STBBI testing clinics and the national HIV surveillance system. Outreach programs were able to reach more GBMSM with 89.2% outreach testers being GBMSM. The authors recommended that outreach testing be located in areas that are frequented by GBMSM, as programme visibility was key to some GBMSM testing for the first time (25).

One study assessed mobile units offering rapid HIV testing in central locations between October 2006 to December 2007. Of 7,138 tests, 70 people had reactive tests with 3 indeterminate results with 83.6% having confirmatory serology. Mobile units reached mostly men, particularly immigrants and people who identified as males who have sex with men (MSM). The authors suggested that prevalence may have actually been higher in GBMSM (though it was already 2 out of 3 new cases of HIV infection) as their questionnaire asked about sexual orientation and not sexual behaviour (26).

Denmark. A Danish study demonstrated the ability of low barrier HIV POCT and STBBI testing in settings that target GBMSM to be successful in engaging individuals who would not otherwise test, particularly young GBMSM and those who engage with conventional healthcare settings at a lower rate. Of 3,012 HIV tests performed, 12% were new testers, 18% non-Danish. In total, 37 tests were reactive and accounted for 11% of positive HIV tests in Copenhagen for the period. A total of 76 men also received positive results for syphilis infection (27).

United States

A Seattle study compared oral, finger-stick and P24 antigen POCT, third generation serology and HIV nucleic acid amplification testing (NAAT) serology in a sample of men and trans persons who have sex with men. It was found that participants preferred the less invasive test experiences of POCT, but had more confidence in the results of conventional serology NAAT tests (with 49% of participants choosing this option as the one test they would select) in a population where knowledge and frequency of testing was high. One thousand testers were enrolled and 42 HIV infections identified of which 32 received rapid testing HIV reactive results. Six (6) individuals were identified to have HIV acute infections (28) .

In a study with GBMSM, Reynolds et al. found that education about rapid testing may increase acceptance with high-risk populations (29).

A New York study investigated the effects of HIV rapid testing using OraQuick Advance Rapid HIV-1/2 antibody test of GBMSM in bathhouse settings. HIV POCT was performed along with samples for pooled HIV viral load testing for negative POCT results. Of 493 men tested, 4% tested positive (19 individuals by HIV POCT, 1 individual by pooled HIV viral load testing), and 40% of these cases were new/acute (<170 days) infections. Bathhouses were shown to be a feasible location for testing GBMSM who use these services. They also theorized that stigma and cultural attitudes toward HIV may be a barrier to testing (30).

A Louisiana study implemented rapid syphilis testing at community-based organizations that served men and trans persons who have sex with men. Of 1,234 tests, 54 were positive with 30 confirmed positive by serology (10 were cases previously treated) and 20 of these were acute infections, cases that may not have otherwise been detected as this population's syphilis testing rate is low (31).

Within an HCV rapid testing study in Denver STD [sic] clinics, no individuals for whom GBMSM was the only risk factor tested positive for HCV. The authors concluded that despite the lower than expected positivity, fully integrating HCV screening into the STD clinic provides the opportunity for preventive counseling and education around HCV (32).

Latin America

A Peruvian study of HIV POCT with GBMSM suggests that high-risk samples tested with 3rd generation POCT should be screened with 4th generation HIV tests to avoid false negatives due to the window period. Forty of 172 tests were positive by HIV POCT compared with 45 of 172 for 4th generation serology (33).

A Columbian study demonstrated the feasibility of using respondent driven sampling as a recruitment strategy to reach high-risk populations for rapid testing (34).

Gay, Bisexual and Other Men Having Sex with Men (GBMSM)

Considerations for the Canadian context

- Given high rates of HIV, syphilis and HCV among GBMSM, POCT may be an important strategy to increase STBBI testing rates.
- POCT testing is feasible and acceptable among GBMSM. In fact, GBMSM often express a preference to access to rapid POCT (for HIV, syphilis and other STBBI) over conventional serology and may be more likely to seek it out. However, they have more confidence in conventional tests.
- POCT can be an effective way to reach first time testers, to increase testing frequency, to achieve earlier detection, and to reach GBMSM who are young, who are racialized, who have multiple partners and who use drugs. However, offering a combination of testing options may be required to reach first-time GBMSM testers and to increase testing frequency. These options may include non-clinical (outreach) settings, fixed-site settings, and fast-track clinical settings.
- POCT can be an effective way to reach GBMSM when offered by trained peers and non-medical staff (perhaps due to concerns over disclosing sexual behaviours), and when multiple tests can be conducted (HIV, syphilis, HCV and other STBBI).
- Targeted testing campaigns and creative outreach seem to be effective ways of reaching GBMSM in general as well as specific sub-communities (e.g., racialized GBMSM, GBMSM living with HIV, GBMSM who use substances). Indeed, offering STBBI POCT in outreach setting such as bathhouses and community-based organizations is feasible and acceptable to GBMSM. It can also be an effective strategy to use in outbreak settings.
- Education about the reliability of STBBI POCT compared to conventional testing and considerations around testing window periods should be taken into account when implementing POCT programs.

3.1.2 Indigenous communities

We found no Canadian studies in the past 10 years that focus exclusively on rapid testing with First Nations, Métis or Inuit populations. However, studies from Brazil and Australia have results that may apply to Canadian Indigenous peoples in rural and remote geographies.

Australia

In an Australian study of rapid syphilis testing in response to an outbreak in two remote Indigenous communities, of 326 persons tested, 30 were positive, with 24 of these confirmed through subsequent serology testing. These individuals were able to be treated immediately; something that may not have been possible without the availability of rapid testing. This pairing with treatment was considered important, as linkage to care would likely have been a barrier, post-testing. The authors recommended retesting after three months, depending on the sensitivity of the rapid test selected, as 5 tests were later found to be false negatives (35).

Brazil

Brazilian research has led to government policy to use rapid tests for HIV and syphilis with quality assurance in remote regions of the country (36). One Brazilian study in particular highlighted the importance of planning and training in developing testing and treatment projects to service remote Indigenous communities (37). Such projects seem more feasible than transporting individuals to larger centres for testing and treatment (38). Ruffinen and colleagues also found that language was an important factor in engaging Indigenous communities, especially during pre- and post-test counselling and in communicating positive results, as well as culturally sensitive education materials and delivery. In the Brazilian examples, non-Indigenous nursing staff had a high turnover rate, compared to Indigenous health workers (37).

Indigenous communities

Considerations for the Canadian context

- It is feasible to deliver POCT in rural and remote communities – including Indigenous communities – that may otherwise face barriers to access STBBI testing. This approach may be more feasible than transporting individuals to larger centres for testing and treatment.
- POCT can detect significant numbers of positive cases, including in communities facing STBBI outbreaks.
- Offering testing and treatment services in tandem could remove access barriers, facilitate linkage to care, and reduce loss to follow-up.
- Confirmatory serological testing should be offered as part of this package when screening for syphilis and hepatitis C.
- Hiring and training Indigenous healthcare staff could reduce turn-over rates and facilitate the delivery of culturally and linguistically appropriate education and counselling.

3.1.3 Transgender populations

No Canadian studies focus on transgender populations. Many studies from the US, Europe and Latin America report high rates of HIV among transgender populations within their studies (17,39–42).

A study from the United States (US) investigated cost and effectiveness of rapid testing in transgender communities, finding that costs varied widely, depending on the rate of diagnosis at different sites. In New York, 195 tested identified 35 positive HIV infections and averaged \$3,563 per diagnosis. In San Francisco, 106 transgender people were tested with 8 positive HIV infections and averaged \$8,284 per diagnosis (42).

Two studies from Latin America and one study from the US used trained peer facilitators to recruit and provide rapid HIV and/or syphilis testing to transgender individuals. They demonstrated the feasibility of this approach to detect infections, with relatively high positivity rates (31,34,40).

The authors of a 2014-15 Brazilian study showed that introduction of oral HIV rapid testing conducted by non-governmental organization staff who had been trained by the ministry of health improved access to testing for key populations. 29,723 oral tests were performed resulting in 791 positive HIV infections. Transgender people had the highest positivity rate. The authors stated that people accepted this testing strategy in part because they were not exposed to possible discrimination experienced when visiting traditional health services (40).

The authors of one American study using POCT to assess HIV prevalence among transgender populations suggested rapid testing facilitates outreach by community-based organizations in locations frequented by transgender populations (41).

Transgender populations

Considerations for the Canadian context

- Offering STBBI POCT to transgender populations is feasible; offering it through trained peer facilitators may facilitate acceptability and uptake.
- POCT can facilitate outreach by community-based organizations in locations frequented by transgender populations.

3.1.4 People who use drugs

There is considerable overlap in the literature for people who use drugs and people who are in unstable living conditions such as being homeless or street involved ([see section 3.1.5](#)), as there are high rates of substance use in this population.

Canada

Several Canadian studies have explored POCT among people who use drugs, mostly in Vancouver. Multiple studies looked at the feasibility and acceptability of community pop-up clinics (CPCs) in Vancouver's downtown east side. These CPCs offered a combination of HIV and HCV POCT, multidisciplinary care, and early treatment and referral. Engagement by people who inject drugs was high, and many new cases of HCV and HIV were detected (43–49).

Vancouver's downtown east side has a high prevalence of HCV. In one study, 33% of participants tested positive for HCV. While 45% were unaware that HCV is curable, most (80%) would consider treatment if offered (44).

In another Vancouver study, 51.8% of PWID tested positive for HCV, one fifth being new diagnoses. Only 37.1% were aware of curable treatment being available for HCV infection, and 53.7% would consider treatment for it where it was offered. There was a gap in transmission knowledge in the population, but a high willingness to engage in treatment with low barrier care options (45).

Another study demonstrated that offering a combination of POCT, increased social support and specialist consultation engaged people who injected drugs who did not normally engage with medical care, despite knowing their HIV/HCV-positive status (48).

A large project aimed at testing 5,000 inner city residents in Vancouver demonstrated that peer HIV testing is feasible with support from nurses and that community events are opportunities to link patients to care. This was achieved through a comprehensive social marketing campaign to encourage testing and increase community awareness of treatment as prevention and by offering a \$5 incentive for participating (49).

Another study offered immediate and facilitated engagement in care for participants testing HIV and/or HCV positive. Though there is extensive testing in the downtown east side of Vancouver, this study (like others described here) still identified a number of people who were previously unaware of their status or not engaged with care. Clients were interested in care when it was offered and convenient (46).

A study in Ottawa demonstrated the feasibility of delivering community-based peer-administered HIV POCT by testing people who reported injecting drugs or smoking crack cocaine, of whom 16.2% had never been tested (50).

Australia

A study in Melbourne demonstrated the feasibility and acceptability of offering HCV POCT through needle exchange programs (NSPs) based in community clinics. The project trained staff, including nurses, community health workers and NSP workers, and—importantly—offered both POCT HCV antibody and RNA testing as a confirmatory test. Despite very high acceptability, participants still found the two-hour wait for confirmatory results to be too long. However, a large proportion (74%) did return for results within 11 days, which can facilitate linkage to care (51).

Another Australian study found that targeted HCV screening based on risk factors offered in emergency departments successfully detected new cases among people who inject drugs (52).

Europe

A study in the UK found that using trained community workers (“champions”) was more effective than nurse-led testing efforts at reaching participants who use drugs for HCV POCT and linking them to care (53).

In another UK randomized study, offering of mouth swab versus blood-based testing for HBV, HCV, and HIV increased acceptability among young people who use drugs (54).

Similarly, a Spanish study demonstrated feasibility and high acceptability of oral HIV and HCV POCT among people who use drugs. The tests were offered through mobile and facility-based harm reduction programs and were able to detect new infections. However, only about two-thirds (68.6%) of HCV reactive tests could be confirmed (55).

Studies in Germany and Italy demonstrated the feasibility and acceptability of offering HIV and/or HCV POCT in community-based low-threshold drug services, whether facility-based or through mobile units (56,57). Unlike the previously mentioned Spanish HCV study, the Italian study was able to provide confirmatory HIV testing. However, the authors highlight the need to improve rates of linkage to care among people who use drugs (57).

Against the backdrop of a significant proportion of PWID having issues with blood access for conventional testing (almost 20%), a study in France compared the acceptability, specificity and sensitivity of HCV POCT and conventional testing among people who use drugs. With similar rates of specificity and sensitivity, POCT was found to detect more cases and was more acceptable. However, half the participants (48%) developed a major anxiety symptom during the 15 minutes of waiting for the test results and needed help and medical assistance (58). Similarly, a study in the US found that being a person who currently or formerly injected drugs, having lower educational achievement, and having impulsivity were associated with higher stress when undergoing POCT (59).

United States

One American study demonstrated the feasibility and acceptability of offering HCV POCT within syringe exchange programs, particularly when they were offered in tandem with already existing HIV testing (60).

Implementing HIV testing within substance use treatment programs was feasible and highly acceptable to clients in two American studies (61,62). The authors of the first study suggested four tasks for setting up successful POCT programs within such a service: 1) securing funding; 2) hiring and/or training staff; 3) developing new procedures as required, and: 4) complying with local regulations. Additionally, a champion within an organization may be necessary. Funding should include pilot project funding with flexibility to adjust to what works before a permanent program is established (61).

A study in New York City compared two models of HIV POCT within a methadone maintenance treatment program: 1) targeted HIV POCT upon request by a patient or upon referral by a counsellor, along with pre- and post-test counselling and an incentive (i.e., transportation voucher); 2) routine offer of opt-in HIV POCT upon admission and then annually, without test counselling or incentives. The study found that routine offer of HIV POCT increased the testing rate; 34% of patients were tested, compared

to 14% with a targeted approach, despite the lack of incentive. Additionally, patients were more likely to receive confirmatory test results and to follow up with treatment when routine testing was conducted (62).

A study of HCV POCT in community-based organizations serving high-risk populations successfully detected new cases among people with a history of substance use (10% of participants tested positive, of which 90% had a history of substance use). Only 13% were previously aware of their status, despite a large proportion of them having a primary care provider. None were engaged in HIV-related medical care. The authors conclude that, “Community based testing and linkage to care programs serving high risk individuals have the potential to engage individuals in subspecialty care, where the standard health care system may have failed to do so” (63).

One American study compared HIV and HCV POCT to conventional laboratory-based testing (LBT) among people who use drugs within a substance use treatment centre by measuring the proportion of test results delivered. Twice as many participants received test results in the POCT arm of the study (96%) compared to the LBT arm (51%). Additionally, Black participants had a lower rate of results delivery (64).

In another American study with 2,031 participants, people attending drug treatment programs, needle exchange programs, and other community based agencies serving people who use drugs were more likely to choose standard HIV testing when bundled with hepatitis and other STBBI tests over rapid HIV testing, but less likely to return (within seven days) for results (29).

Another American study conducted HCV POCT in urban community centres and alcohol and drug treatment centres. It detected a significant number of new cases, many of which were among people who reported a history of injecting drugs. Some patients refused confirmation testing and treatment, which may be related to stigma, denial, lack of health insurance, or lack of specific coverage for HCV treatment. As a result, uptake and coverage of HCV therapy in this largely poor, underserved, publicly-funded cohort remained low despite robust outreach, testing, and linkage to care (65,66).

A project in New York City demonstrated the feasibility of offering HCV POCT to people who inject drugs through community health centres and syringe exchange programs. The project detected a significant number of new cases, many of which were confirmed through blood draw. However, there were lower rates of confirmatory testing through the syringe exchange programs compared to the community health clinics, possibly due to the more transient nature of the SEP clients and their greater mistrust of the medical community (i.e., they tend to be more marginally connected to healthcare and therefore less used to encountering healthcare professionals at syringe exchange programs than the clients who used the community health clinics). Most participants attended at least one follow-up medical visit, which was facilitated through patient navigation services (67).

A similar study demonstrated the feasibility of detecting new HCV infections through HCV POCT offered at SEPs and other harm reduction services (68).

Asia

A study from Hong Kong demonstrated the feasibility and acceptability of offering HCV POCT to people who formerly injected drugs through rehabilitation centres. While positivity rates were quite high (56%),

only half the participants who tested positive (53%) attended follow-up hospital visits, and only one in five (20%) received treatment. The authors point to the need for an improved referral system and that interferon-free treatment regimens would improve treatment rates (69).

People who use drugs

Considerations for the Canadian context

- Several studies have demonstrated the feasibility and acceptability of HIV and HCV POCT among people who use drugs. This includes a variety of settings, including community outreach settings such as pop-up clinics, mobile units, outreach in parks, or embedding testing programs within needle and syringe exchange programs and substance use treatment programs. However, it may be necessary to address resistance among some providers to implement procedures that are outside their usual scope of practice.
- POCT may be especially valuable for PWID who experience difficulty accessing veins for blood draws.
- Even in settings with considerable HCV testing programs in place aimed at people who use drugs, high positivity rates are still detected.
- Using trained peers to reach people who use drugs to offer STBBI POCT and related counselling can be effective, including through partnerships with nurses and community health workers.
- Some studies found low rates of knowledge of effective treatments that can cure HCV among people who use drugs, perhaps due to the timing of when the studies were conducted. When informed, participants have high rates of acceptance of treatment if there are low-barrier care options.
- Many studies found relatively low rates of confirmatory testing—possibly due to the transient nature of this population and the timing requirements for receiving confirmatory test results, mistrust of the medical community, or the need for a blood draw. Achieving higher rates of confirmatory testing requires careful planning (such as offering immediate on-site blood draw in case of antibody-positive POCT results) and more concerted health navigation efforts.
- Many studies also found relatively low rates of engagement in care and treatment. Likewise, improving this situation requires more concerted efforts, including through better patient education of current treatment options and enhanced health navigation through the use of trained peers and community workers.

(continued)

People who use drugs (continued)

Considerations for the Canadian context

- Models that seem to work best offer testing where people are and embed them within a range of other services, such as health system navigation and on-site access to medical care and treatment.
- Some studies found that people who use drugs experience considerable levels of anxiety related to waiting for results of HIV and HCV POCT, sometimes requiring medical attention. This should be taken into account when planning POCT programs for this population. This might be a reason why some people who use drugs prefer conventional testing options. Factors related to anxiety and low rates of return for test results (including confirmatory testing) should be weighed.

3.1.5 People in unstable housing

There is considerable overlap in the literature for people who use drugs ([see section 3.1.4](#)) and people who are in unstable living conditions such as being homeless or street involved, as there are high rates of substance use in this population.

Persons who are homeless or street-involved are some of the most difficult individuals to reach and may struggle to access conventional testing services (70). Of the 10 studies focusing on people in unstable housing conditions, eight reported detecting new, previously undiagnosed cases of HIV, HCV, and syphilis that may have gone undetected if individuals did not have access to rapid testing (71–78).

Through an audit of treatment outcomes and qualitative interviews, the Dublin HepCheck study showed that rapid testing allows for more individuals to be aware of their status without requiring them to return for follow-up appointments, something that may be difficult or impossible for persons who are currently using drugs, who have chaotic lives or unstable living situations. The researchers suggested a new paradigm of community based “shared care” treatment as 90% of people with positive tests were not engaged in care (73).

When implementing routine nurse-initiated HIV POCT testing in high prevalence primary care settings for US Veterans, it was found that for homeless and street-involved populations, linkage to care is a barrier, including willingness to access care when it is made available, and lack of follow-up by and with participants (71,73,75).

Lack of symptoms (74) and fear of treatment and related procedures such as biopsy (73) for HCV are also related to lack of follow-up for treatment.

A study in Nova Scotia looked at POCT in two fixed and two mobile outreach services, and in this case 67 of 305 clients expressed interest in testing. Many participants were interested in HCV rapid testing as

opposed to HIV testing alone, which may speak to a need for multiple rapid testing availability in a single visit to meet the needs of persons who are street-involved and using injection drugs (79).

One strategy is to embed STBBI POCT within other services relevant to people in unstable housing situations. For example, in a study in British Columbia that offered free rapid HIV testing along with immunization services, 90% of clients said they would not have sought testing otherwise (70).

A study from Winnipeg showed that it was feasible to train community paramedics who could be embedded in shelters and detoxification centres allowing not just access to rapid HIV testing, but also rapid linkage to treatment, removing the barrier to accessing post-test care that relied on individuals going to a different service and perhaps having to make and keep an appointment (78).

Rapid testing can be easily incorporated into locations and services already in place to support persons who are homeless, whether at fixed or mobile outreach locations (70,79), often led by nurses or outreach workers (80), or by training peers (77) to recruit and counsel potential test clients. Familiar spaces and service providers make it more acceptable for some individuals to consider and agree to testing. Developing collaborations with other services and organizations such as food banks, churches and mobile outreach sites could increase access to testing (70).

People in unstable housing

Considerations for the Canadian context

- POCT can be an effective strategy to address STBBI testing barriers and low rates of linkage to care among people in unstable housing situations. Several studies have shown the feasibility of this strategy and its ability to detect new cases of infection.
- POCT can be incorporated into existing services used by people in unstable housing situations, whether in fixed locations such as shelters, food banks and churches, or through mobile and outreach services. Incorporating healthcare professionals such as community paramedics or nurses into testing programs can facilitate rapid linkage to care and treatment.
- Pairing STBBI POCT with other medical services such as immunizations can improve uptake, reaching participants who may not otherwise have accessed testing.
- The combination of STBBI tests being offered should be carefully considered. For example, people in unstable housing situations (many of whom use drugs) may prefer HCV testing to be included rather than a stand-alone HIV test.
- Using trained peers, nurses and outreach workers to reach people in unstable housing situations may improve acceptability by building on existing trust and familiarity, especially when conducted in familiar settings such as existing services.

3.1.6 Currently and recently incarcerated populations

Much of the literature related to STBBI POCT of incarcerated populations is from the US, and most studies focus on HIV.

There are no Canadian studies looking at testing exclusively among incarcerated populations, though one study offered testing to 635 men and women in two correctional facilities in Alberta, of which 508 accepted rapid HIV and syphilis testing. Acceptance of testing was high amongst incarcerated participants (80%), many of whom reported substance use and sex work behaviours. Rapid testing was determined to be feasible in terms of the number of people who consented to testing, reliability of the tests, and detection of new infections that were linked to care (80).

In one American study oral HIV POCT acceptance rates were very high among detainees (98%) and qualitative data showed that corrections staff perceived improved processing compared to phlebotomy. According to the authors, “delivering negative rapid HIV test results in real-time during the jail intake process remained a challenge but completion of confirmatory testing among those with reactive rapid tests was possible” (81).

An Irish study found that testing of inmates was feasible and had high acceptance. The study partnered with prison services, Irish Red Cross, and inmate volunteers to provide education and HIV POCT to 741 inmates. Only one positive result was confirmed. The study mentioned that a number of inmates declined testing, but emphasized the importance of education to decrease stigma related to testing, and supports the North American studies that promote peer-led interventions, such as with homeless and street-involved populations (82).

Young Offenders

An English study looked at the acceptability of oral HCV POCT in a young offender institution. There was high uptake of oral swab testing, and participants indicated a preference for oral testing over a finger prick. However, given this particular test’s relatively lower sensitivity and specificity compared to conventional testing, the authors caution its use might best be restricted to inmates who are unlikely to return for results, or who refuse blood testing (83).

Jails

In several American studies in jails, rapid testing for HIV and HCV were generally feasible and highly accepted by inmates (84–86) and provided early detection where individuals would likely have otherwise been diagnosed in later stages of infection (84,85,87). However, problems arose in linkage to care as individuals in jails are often incarcerated for relatively brief periods, and may not complete early treatment while in jail or may not be able to access treatment in the community upon release (85,88).

One study focussed on partnerships between jails, public health and academic medical centres found that these partnerships can be important in linking individuals released from jail with treatment services (89).

Probation and Parole Populations

An American study showed that HCV POCT of community supervision populations is feasible and may reach a population with otherwise low testing rates and potentially high-risk behaviour. Linkage to care was low in this study, despite the offer of a financial incentive (90).

A second American study compared offering probationers and parolees HIV POCT with referral to free testing at an independent location. Participants were more likely to agree to the rapid testing at their community supervision office rather than to go to an external location. The study suggests that it is feasible and beneficial to embed POCT testing in community supervision offices and to build partnerships with HIV care organizations in the community (91).

Currently and recently incarcerated populations

Considerations for the Canadian context

- STBBI POCT for currently or recently incarcerated populations is feasible, acceptable, detects new cases of STBBI, can detect earlier cases, and can successfully link people to care and treatment.
- Testing programs that involve peers can improve acceptability and address stigma related to STBBI testing among incarcerated populations.
- Linkage to care can be challenging in the context of jails, where inmates are incarcerated for shorter periods of time. Having partnerships with healthcare services within the community can facilitate linkage to treatment for recently released individuals.
- Offering STBBI POCT on-site at community supervision offices may improve testing uptake and linkage to care among probationers and parolees, compared to referrals to external services.

3.1.7 Immigrants and refugees

Most of the research on immigrants and refugees comes from European countries, with very little from Canada.

Canada

In a Quebec study, investigators contacted individuals who identified as immigrants who were tested at a Montreal clinic that specializes in STBBI treatment. Most participants chose this site because they wanted rapid results at an accessible location. Some of the feedback received was that it took longer than expected and that the participants would have preferred a wider range of operating hours. Discomfort with disclosing sexual behaviour may have been a barrier; more information was obtained from immigrant GBMSM by using iPads than in face-to-face interviews (92).

Europe

In a study from Belgium, Asian immigrants were tested for HBV and HCV, comparing POCT with conventional testing. POCT was shown to be more economical, and there was a significantly higher rate of linkage to care. The conventional test results were sent to participants 20-45 days after testing, whereas POCT results were delivered and linkage to care was arranged in the same visit (93).

A second Belgian study looked at testing in a low threshold HIV and STI testing centre targeting high risk groups. The study found a high prevalence of HIV in MSM (2.9%) and immigrant clients (3%), with high acceptability and uptake of HIV POCT overall (94).

Approximately one-third of participants (35.4%) from a Spanish study looking at HIV POCT among vulnerable populations included immigrants. Many were tested for the first time. The authors attribute the high uptake of testing by participants to the work of cultural mediators, who helped with outreach and to overcome linguistic barriers (95).

In another Spanish study, which used mobile vans in public squares in four cities to offer HIV POCT, approximately one-quarter of men and women who participated were born outside Spain. The authors found that, "street-based mobile units offering rapid HIV testing in selected sites, may diagnose HIV at an earlier stage of infection than clinic-based sites, and have a low rate of false-positives" (26).

Three Italian HIV studies focused on or included data about immigrants and refugees. One study showed that POCT had a higher rate of acceptability among immigrants, with a higher rate of delivering tests results to participants, and earlier detection of HIV infection than conventional testing (96).

A second study demonstrated the feasibility and high acceptability of HIV POCT among immigrants, with more than half the participants (59.8%) testing for the first time. The authors found that transcultural mediators were important in engaging immigrant participants (97).

Another Italian study included a component of HIV POCT offered to migrant populations through partnerships with non-governmental organizations and primary care services for migrants. There was a high rate of acceptability and uptake of POCT among migrants, two-thirds of whom (66.1%) had never been tested before. Most participants who tested positive (4 out of 5, or 80%) were linked to care (57).

Immigrants and refugees

Considerations for the Canadian context

- Several studies have demonstrated the feasibility of offering STBBI POCT to immigrants and refugees, with high rates of acceptability, first-time testers, receiving test results, early detection and linkage to care. In many cases, POCT outperforms conventional testing on several of these measures.
- Using cultural mediators can help with outreach and overcome linguistic barriers for immigrants and refugees.
- Uptake can be improved by offering testing programs in locations where immigrants and refugees can be found, including through mobile units and fixed sites such as organizations and health services for migrants.
- Strategies for overcoming discomfort discussing sexual behaviour should be explored, including the use of electronic questionnaires. However, language barriers should be considered when using these tools.

3.1.8 Pregnant women

Against the backdrop of a surge in congenital STBBI cases in Canada recently, point of care testing can be an important tool to prevent mother to child transmission, including in late pregnancy and especially in pregnant women who are presenting with limited or no prenatal care. However, there is little Canadian research that focuses on this particular population.²

Canada

One Canadian study looked at the use of HIV POCT for pregnant mothers in perinatal care as an emergency program to prevent perinatal HIV transmission. Of 114 women tested, one was confirmed positive and one false positive was detected; no infants tested positive. Sixty-three percent of the women tested had multiple risk factors including injection drug use. Among the women who were in the seroconversion window at the time of delivery, 25% of these women and 52% of their infants received prophylactic drug treatment. POCT detected a new HIV infection that was able to be treated immediately, thus ensuring the woman's health and preventing perinatal transmission (98).

² While there was a significant amount of research regarding this population in low-income countries, we did not include these studies because they did not meet the inclusion criteria.

We note that a more thorough gender-based analysis of the evidence reviewed was not feasible within our timeframes for this realist review.

A study in Winnipeg found that HIV POCT in obstetrical triage can be used to identify women with unknown HIV status and inform treatment decisions and follow-up for mother and infant (99).

United States

A study from the US explored recommendations in national guidelines to test pregnant women for HIV, with retesting in late pregnancy. The study found high acceptability of HIV POCT during natal care in the third trimester (95% of pregnant women), and the test was perceived to be less stressful than conventional tests by 91% of women tested (100).

A second American study embedded HIV counsellors and testing within obstetrical departments in New Jersey, a state with high HIV rates in women and children. In four years, the convenient, patient-centred program increased testing rates from 60% to 100%, in compliance with US Centre for Disease Control (CDC) guidelines. This coordinated, patient-centered approach helped to identify HIV-positive pregnant patients in the first/second trimesters and immediately connect them to prenatal and HIV care to minimize vertical HIV transmission (101).

Latin America

In Colombia, a study tested 1,048 pregnant women in antenatal care who had never previously been tested for HIV or syphilis. Patients were assigned to either one of two rapid testing groups: two separate tests for HIV and syphilis or one combined test. Acceptability was very high for both testing options (99.6% and 99.8%, respectively). There was no difference in efficacy between the single or combined tests, and all positive cases allowed for timely treatment. However, some healthcare providers (26.5%) did not consider the POCT results to be sufficient to prescribe treatment to prevent congenital syphilis, in the absence of confirmatory testing (102).

Pregnant women

Considerations for the Canadian context

- STBBI testing for pregnant women is standard offer (opt out) across Canada. However, STBBI POCT can be particularly important for pregnant women who have not received prenatal care. It can be an effective and highly acceptable strategy for ensuring the health of pregnant women and preventing perinatal transmission. For example, it can serve as a gateway to treating STBBI and to providing exposure prophylaxis.
- While pregnant women may find POCT to be at least as acceptable as conventional testing, some healthcare providers might not consider the POCT results to be sufficient to prescribe treatment to prevent congenital syphilis, in the absence of confirmatory testing. Ultimately, it is important for pregnant women and their healthcare providers to acknowledge, understand, and weight the relative advantages and disadvantages of conventional and POCT testing options in order to make informed decisions about their most appropriate use.

(continued)

Pregnant women (continued)

Considerations for the Canadian context

- Embedding STBBI testing within obstetrical services through a coordinated, patient-centered approach can be an effective strategy to identify pregnant patients with STBBI early in their pregnancy and to connect them immediately to prenatal STBBI care to minimize perinatal transmission.

A Peruvian study looking at HIV and syphilis POCT as part of regular care for pregnant women showed POCT to be feasible, acceptable, and cost effective. By the end of the project, it had become national policy in Peru to include HIV and syphilis POCT as part of regular care for pregnant women (103,104).

3.1.9 Sex workers and their clients

There is little literature on STBBI POCT among sex workers and their clients, especially in Canada.

Canada

A BC study focussed on the indoor commercial sex industry, where there is a high number of immigrant women, primarily Asian. Women in this context did not feel comfortable seeking STBBI testing through their primary care provider. The study demonstrated the feasibility and acceptability of providing HIV POCT and STBBI self-swab techniques to sex workers and their clients at indoor commercial sex venues, when offered through a partnership between community health workers (with current or previous sex work experience) and health practitioners. The authors emphasized the need to forge partnerships between outreach programs and existing clinical services in order to offer the full spectrum of care to promote women's sexual health, including confirmatory testing and linkage to care (105).

Europe

A Spanish study comparing program outcomes from HIV POCT use in HIV/STBBI clinics to national surveillance showed that use of HIV POCT was more successful in testing high-risk populations less likely to test in conventional settings. Female sex workers accounted for 23% of the new HIV diagnoses (106).

Another Spanish study demonstrated the feasibility of reaching previously untested male sex workers by offering HIV POCT through street outreach. Among overall participants, 31% were male sex workers, with over half (56.1%) having never undergone an HIV test before (107).

Research from Switzerland demonstrated the feasibility and high acceptability of offering HIV POCT to clients of sex workers in a street outreach setting, with more than 40% being first time testers (108).

Brazil

Sabido et al. investigated POCT for syphilis in an STI clinic in a red-light district in the Amazon region of Brazil. POCT was feasible and highly accepted by female sex workers and male clients though staff had concerns about the test's inability to distinguish between past, treated syphilis infections and active cases; however, this model did allow for same-day results and immediate treatment (109).

China

A study from China investigated syphilis POCT with female sex workers at several STI clinics in two regions. Rates of successful referral to treatment for positive cases among female sex workers varied considerably between clinics. This was found to be related to levels of trust for the testing teams (110).

Sex workers and their clients

Considerations for the Canadian context

- Studies have demonstrated the feasibility and high acceptability of offering STBBI POCT to male and female sex workers and their clients, as well as the ability of STBBI POCT to reach high proportions of first-time testers.
- It is feasible to offer POCT to female sex workers through commercial sex venues or STI clinics. In fact, some sex workers may prefer accessing testing through these venues rather than through conventional settings or their primary care providers.
- In the case of POCT through street outreach or in commercial sex venues, partnerships with clinical services facilitate linkage to confirmatory testing and treatment.
- Community health workers contribute to POCT acceptability among sex workers and may help to build sex workers' trust of clinical testing teams when they work in partnership.
- The inability of some point of care tests (e.g., syphilis) to distinguish between past, treated infections and active cases should be weighed against the ability to offer same-day results and immediate treatment to sex workers and their clients, especially in cases where is likely to be loss to follow-up.

3.1.10 Young people

There is very limited research focussed on STBBI POCT among young people other than as part of cohorts for other populations mentioned previously, especially in the Canadian context.

In one American study, HCV POCT was associated with a subsequent decrease in high-risk behaviors among young people who use drugs, which was sustained for several months. While HCV POCT was not

associated with an uptake in healthcare utilization, there was a higher likelihood of accepting HIV POCT in addition to the HCV test (111).

Another American HIV POCT program offering testing through homeless shelters, schools and college health centres as well as at community events (e.g., health fairs, social events for teens, church functions) managed to reach a high proportion of high-risk youth and to detect new infections among them (112).

Another American study compared HIV testing practices among three types of homeless youth in New York City (service-involved, street youth, and “nomads”, or chronic travellers). It found very high rates of HIV testing in their lifetime (92%) and in the last year (82%), particularly among those who were connected to services. However, the rate of referral and linkage to care was relatively low (44.4%). Referrals/linkages were slightly more likely to happen following a conventional test (35%) than following a rapid test (26%) (113).

Young people

Considerations for the Canadian context

- STBBI POCT programs can successfully reach young people at risk, such as young people who use drugs or homeless youth, and they can achieve relatively high lifetime and annual testing rates. However, linkage to treatment and related services (e.g., mental health, substance use) remains a significant challenge.

3.2 Key Considerations According to Setting

This section provides an overview of the evidence related to various settings, including outreach settings such as mobile street clinics, primary care facilities such as emergency departments and hospitals, community and sexual health clinics, pharmacies and dental clinics.

Each section highlights and compares evidence from Canada to the experience of other similar countries and contexts. Finally, each section includes an analysis of how the evidence relates to the Canadian context, including considerations of our geography, policies, health systems and relevant populations.

3.2.1 Outreach settings

The literature related to point of care testing in outreach settings often overlaps with the data on populations relevant to the Canadian context, as many outreach projects are designed to reach specific populations at increased risk of STBBI that are hard to reach through more conventional testing approaches. As such, several sections above include summaries of the evidence for outreach approaches to reach populations such as people who use drugs, GBMSM, people in unstable housing situations, and sex workers and their clients.

Supplemental evidence on outreach settings is presented below, none of which is from Canada.

United Kingdom

A study from the UK looked at the feasibility and acceptability of HIV testing in non-traditional sites (e.g., church hall, community centre, bathhouse, colposcopy, male partners of pregnant women attending antenatal care), and found a prevalence rate of 8% among 5,967 women and men tested, with 44% of people tested having never been tested previously (114).

A similar study from the UK looked at tailoring HIV testing to specific communities outside of sexual health settings (at a church hall and community centre). Testing was accepted by 75% of patients (40 women and 72 men), who were predominantly from Black African communities, 50% of whom had never previously been tested (115).

A London study of heterosexual Black men found the greatest barrier was in developing partnerships with community organizations where HIV testing could occur. However, of those who accepted testing, 44.4% had never previously been tested, so targeted outreach was seen to be effective (116).

Another study found that language and cultural barriers prevented many persons from getting tested for HIV. They found that trained peers/community members were able to reach at-risk populations and to link them to care at higher rates than traditional testing in conventional sites (117).

Dunkley and colleagues (2018) showed that in London, hard-to-reach communities were mobilized more by community outreach services (testing offered in-person at an HIV organization) than by online HIV initiatives. Likewise, Black African heterosexual men were less likely to access HIV testing at sexual health services, and were more likely to be tested at such community sites for the first time (118).

In another study from the UK, community rapid HIV testing aimed at reaching GBMSM (testing offered in social venues, community centres, for example) detected HIV at earlier stages than through conventional healthcare clinical settings (average of 468 CD4 count versus 387). The authors comment that robust care pathways, which are culturally appropriate, must be integral to the design of community HIV testing services (119).

Roberts and colleagues (2014) set up a mobile testing site for HIV, hepatitis, syphilis, chlamydia and gonorrhoea at a UK adult lifestyle event, Erotica. Of 180 screens (44% female, 56% male), only 5% said they had tested previously, reinforcing the importance of non-traditional testing sites to reach at-risk populations outside of large urban areas (120).

Spain

In Spain, a study looked at rapid HIV testing in a mobile unit, testing 7,138 individuals, with 54 confirmed positive tests. The project attracted a large percentage of GBMSM and immigrants (women and men, mostly from Latin America). This programme attracted many low-risk group members as well as high-risk, hard to reach populations (26).

Another Spanish study used a highly visible mobile HIV testing programme to test 7,552 persons, 47% of which were first-time testers. GBMSM who were least involved in gay communities and persons with lower education, as well as men and women under the age of 30 were more likely to be first time testers

(107). The visibility of the program was considered a decisive factor for attracting almost two thirds of the people who had not been tested before.

In another Spanish study, non-governmental and non-traditional sites were more highly valued by survey respondents. Mobile HIV rapid testing attracted participants who tended to be young, GBMSM, and who had high sexual risk exposure (121).

United States

A study out of Atlanta looked at a programme designed to test high-risk youth for HIV using POCT and to link them to care. The specially designed testing and motivational interviewing program tested 435 participants (85% men, 91% Black) in non-conventional venues (e.g., nightclubs, college campus, street testing, private parties, malls, fairs, shelters) and found 49 cases of HIV. This approach had higher rates of HIV detection and linkage to care than conventional testing and referral programs (122).

A project in North Carolina used trained student volunteers to recruit youth online and to offer rapid HIV tests, with results provided during the same visit 90% of the time, to high-risk populations, particularly GBMSM. The program was successful in detecting new HIV infections and linking participants to care (123).

A Pennsylvania study of rapid HCV testing in community spaces compared baby boomers with young adults. Young adults who were tested in community settings had higher prevalence of HCV than baby boomers (23.7% vs 14.8%) but were less likely to be linked to care and to start treatment (124).

Linkage to care remains an issue, especially for outreach events, according to a study in Birmingham, Alabama, where higher linkage to care success was seen in testing sites that included or had close connections to HIV care options, especially on-site (125), which supports the studies of linkage to care barriers in other hard-to-reach, high-risk populations, as described in previous sections.

A study in seven US cities provided HIV POCT in outreach and community settings, including public parks, homeless shelters, and bars. This approach was found to be feasible, acceptable and effective at detecting new cases. A large proportion of participants were from racial/ethnic minority groups, GBMSM, people who used drugs or homeless. Venues with the highest HIV positive results and highest rates of participants receiving confirmatory results were bathhouses, social service organizations and needle exchange services. The lowest were parks, street corners and community events. However, there were challenges in reaching PWID. A low proportion of all tests were conducted at needle-exchange programs and drug treatment facilities, and only 11% of people with newly diagnosed HIV infection reported intravenous drug use in the past year (126).

Outreach settings

Considerations for the Canadian context

- Offering POCT through outreach efforts is feasible, acceptable and can be an effective way to reach specific populations at increased risk of STBBI. POCT offered through outreach efforts can detect high rates of positive tests, first-time testers, and individuals who would not normally be reached through conventional approaches to testing.
- Using peers is an effective way of identifying appropriate outreach venues, which should be tailored to reach each specific population, according to local context. For example: reaching African communities through churches and community centres; reaching at-risk youth through nightclubs, malls, campuses, street outreach, shelters and online; and, reaching GBMSM through bars and bathhouses.
- Through training, peers can also provide essential complementary services such as linguistic and cultural translation that can facilitate pre- and post-test counselling as well as referral towards treatment, care and prevention services.
- Embedding POCT services within outreach venues can help overcome the stigma associated with seeking out specific STBBI services, such as HIV testing.
- Building strong commitments and partnerships with local organizations will facilitate buy-in and linkage to related prevention and support services.
- Ensuring linkage to treatment and care can be a challenge when offering POCT at outreach venues. Programs should be designed to mitigate loss to follow-up through partnerships with local treatment services and/or offering testing and treatment services in tandem onsite. In some studies, trained peers or community members can achieve higher rates of linkage to care than through traditional testing in conventional sites.

3.2.2 Community and STI clinics

Canada

A study from Manitoba demonstrated the feasibility of offering HIV POCT in community health centres. The testing program reached a high proportion of first-time testers (68.8%) and detected new diagnoses. There was no difference in time to linkage to care or to viral load suppression between the POCT and standard screening cohorts (99).

United States

An American study showed that offering HIV POCT can be cost effective or even cost saving in sexual health clinics, though offering brief risk reduction counselling significantly increased costs compared to

not offering counselling. However, this increased cost must be weighed against some of the advantages of POCT, including potentially less staff time spent doing follow-up of positive cases when patients do not return for conventional test results. In addition, depending on current clinical practice, the cost of risk reduction counselling may already exist for conventional HIV testing; therefore, including it for POCT does not represent an added cost (127).

A Baltimore study showed that in STBBI clinics, those at the highest risk for HIV also had the highest acceptance of HIV POCT (128).

Community and STI clinics

Considerations for the Canadian context

- Offering STBBI POCT in community health centres and STBBI clinics is feasible and can be effective at reaching first-time testers and detecting new infections.
- Depending on current clinical practice (in particular offering risk reduction counselling as part of testing), integrating STBBI POCT can range from cost saving to cost effective to representing additional costs.
- There is some indication that those at the highest risk for HIV also had the highest acceptance of HIV POCT and that patients who use POCT have rates of linkage to care and viral suppression that are at least comparable to conventional testing.

3.2.3 Emergency departments

Almost all studies related to STBBI POCT in emergency departments focus on HIV, with only a handful on HCV. None addresses other STBBI. There is little Canadian research in this area.

Canada

A study from Winnipeg demonstrated the feasibility and acceptability of HIV POCT in a hospital emergency care setting. Most of the 501 patients tested were under 40 years of age, and about half were women (48.5%), Indigenous (53%), and had not previously been tested for HIV (50.9%). Prevalence was higher than other North American studies, at 1.4%. All participants confirmed to be positive were linked to specialized HIV care within 24 hours (129,130). An earlier study from Alberta showed that HIV POCT in acute care hospitals provided a practical option for HIV screening in a time sensitive context (131).

Europe

In France, one study showed little buy-in for routine HIV POCT from physicians in an emergency department (ED) setting, which resulted in 401 rapid HIV tests being performed out of 16,024 patient visits. Arguments advanced by physicians to explain this included: lack of time, reluctance to obtain

inform consent, and questions about the interest of routine HIV screening in emergency departments (132).

In comparison, a study that used nurses to target-screen patients in a French ED resulted in 2,818 HIV tests being performed out of 17,727 participants (133), suggesting that ED staff buy-in, including for routine vs targeted screening, and appropriate staffing are important in successful POCT in EDs.

A study from the UK demonstrated the feasibility of offering HCV RNA POCT in an inner-city ED setting to detect current HCV infection. The study also sought to assess the impact of offering concomitant HIV and HCV POCT on acceptability and uptake. They found a significant decreased uptake when HIV POCT was offered concomitantly with HCV testing, compared to HCV POCT testing alone. The authors hypothesized this might be due to HIV-related stigma in a relatively low incidence community that was predominantly white and economically deprived, and suggested further research to assess whether a similar effect would be seen in a more diverse population with higher HIV and HCV incidence (134).

United States

An American study demonstrated the feasibility and acceptability of offering opt-in HIV POCT in an urban ED, with 93% of patients consenting to the test and 50% having not been previously tested (135).

Similarly, another American study demonstrated the feasibility and acceptability of offering routine HIV POCT in an ED setting, where background HIV prevalence is greater than 0.1%, as per US CDC recommendations. Almost all patients (98.7%) received the results of their preliminary HIV test, including 100% of those who tested positive (12 out of 1000 patients tested). About a third of patients who tested negative had never been tested (136,137).

A California study in an emergency department that sees low-income, predominantly Latino patients offered non-targeted opt-out HIV POCT. The program detected 25 new cases of infection, and 174 previously diagnosed cases (47 of which were out of care). By having an HIV specialist meet with all out-of-care patients in the ED and schedule follow-up appointments, the program successfully linked 90% of newly diagnosed and 78% of previously diagnosed patients to care (138).

Hsieh and colleagues (2011) compared three models of HIV POCT in EDs, using staff indigenous to the department, staff who were exogenous to the department, and a mix of the two. The exogenous staff group tested the most patients and therefore identified the most patients with unidentified HIV infection, but the indigenous staff group detected a higher positivity rate and had the best rate of linkage to care (100% vs 60%). Likewise, the exogenous group had the lowest cost per patient tested, but the indigenous group had the lowest cost associated with linkage to care per individual (139).

A retrospective study from California found that adding targeted HIV testing (focused on a defined subpopulation thought to have a higher risk of infection than the general population) to clinician-initiated diagnostic testing (based on clinical signs or symptoms) increased the number of tests conducted monthly and the median number of new infections diagnosed monthly. Over 90% of newly diagnosed and out-of-care HIV-infected patients were linked to care (140).

A study from New York showed that moving from counsellor-initiated testing to routine HIV POCT in an ED led to a seven-fold increase in testing volume. Patients who tested HIV positive were more likely to

be male, uninsured, and non-White, and the authors comment on the value of having free and routine HIV testing in the EDs of large urban hospital centres (141).

A retrospective study from New Orleans explored the impact of HIV POCT offered at an urban ED. Among the 99 patients who were newly diagnosed, half met the clinical definition for AIDS at diagnosis (49%). These patients were mostly male (59%) and African American (79%). The majority had presented for healthcare previously within the past five years (58%), indicating missed opportunities for earlier diagnosis. In fact, 27% had presented three or more times. While the majority (86%) were referred to specialized care, only 60% were linked to care within a year of diagnosis (142).

Similarly, a study from Chicago illustrated the importance of offering targeted HIV screening for patients waiting for admission in EDs. Three quarters of patients testing positive (76%) met the clinical definition for AIDS at diagnosis and on average they had three previous visits to the ED without testing in the previous two years. Almost all patients were non-white: 64% Black and 33% Hispanic (143).

A study from the Bronx demonstrated the feasibility and acceptability of using HIV counselling videos to support HIV POCT in a high-volume inner-city ED. While most patients testing positive were linked to care (84.2%), it should be noted that—once again—most patients (34.6% of whom were Hispanic, 37.9% African American) were diagnosed late in their illness and that they had an average of 8.9 healthcare visits prior to their diagnosis (144).

A study compared targeted opt-out HCV POCT screening offered by triage nurses based on risk profile (i.e., age cohort and injection drug use) to diagnostic testing ordered by clinicians at their discretion, in an ED setting. While diagnostic testing yielded a higher positivity rate, targeted screening detected the larger number of cases (70%). However, the study found considerable challenges in ensuring confirmatory testing was conducted (67% of positive cases), test results were delivered (51% overall; 33% disclosed during the ED visit) and linkage to care (22%). This might be due to the indication in the study description that “rapid tests were processed in the hospital laboratory” (145).

Asia

A Hong Kong study within a low-prevalence semi-rural hospital showed that patients find HIV POCT in the ED acceptable but have a preference for testing with their primary care physician. However, not all ED patients have a primary care doctor and therefore the authors suggest this may be a site that is useful for reaching uninsured, lower income persons (146).

Emergency departments

Considerations for the Canadian context

- Offering HIV POCT in emergency departments (EDs) is feasible and acceptable to patients. However, ED staff buy-in and capacity may impact implementation levels. In addition, using staff indigenous to the department, staff who were exogenous to the department, and a mix of the two can influence overall testing rates, rates of seropositivity, rates of linkage to care, and per-patient cost. Using validated videos as support for test-related education and counselling may reduce staff burden in high-volume ED settings.

(continued)

Emergency departments (continued)

Considerations for the Canadian context

- HIV POCT in EDs can achieve high absolute numbers of patients tested, high rates of first-time testers and high rates of receiving test results. It can detect new infections and successfully link patients to care, whether newly diagnosed or previously diagnosed and out-of-care.
- A high proportion of patients diagnosed through HIV POCT in EDs meet the clinical definition of AIDS at diagnosis and many of them had several previous encounters with the healthcare system (including previous ED visits), indicating missed opportunities for earlier diagnosis. This is especially true of patients from racialized (Black and Latino) communities. This may be due to testing policies and practice—whether routine offer (op-in or opt-out), based on risk profile or based on clinical indications—and suggests screening offered through EDs can reach communities that otherwise might be missed, including uninsured, low income and racialized communities.
- The combination of STBBI tests offered in EDs (for example, HCV alone or combined HCV/HIV tests) can influence acceptability and uptake, especially in contexts of high HIV-related stigma.

3.2.4 Hospitals (other than emergency departments)

Europe

A UK study found high uptake of HIV POCT (76%) among patients of an inner city polyclinic within a London hospital, with 75% of these participants never having been previously tested, despite 85% of them having a primary care physician (147).

Another UK study explored the impact of expanded testing in a hospital setting as a means to address potential missed opportunities for earlier diagnosis among patients who were diagnosed late. Offering opt-out HIV POCT in outpatient departments was feasible and led to a high rate of positivity. Rates of late HIV diagnosis decreased significantly (148).

A qualitative study from the UK exploring the experience of people testing positive through HIV POCT used in primary care settings reports that POCT is deemed to be acceptable, possibly linked to its “normalised” use in these settings, although patients may require additional support (149).

United States

An American study found that offering HIV POCT in an adolescent/young adult clinic within a hospital was feasible, acceptable and led to an increase in testing, in first-time testers and in patients receiving their test results. Same-visit results removed a gap where patients might not return to receive results at a second appointment (150).

Likewise, a study of nurse-led programmes in primary care clinics in American veterans' hospitals found that HIV POCT improved result delivery compared to traditional testing in a nurse-led programme (151).

Peru

A study from Peru offered simultaneous HIV/syphilis POCTs in the consultation room of a hospital in a marginalized zone of Lima. There was high acceptability and satisfaction with the simultaneous screening process among patients (152).

Hospitals (other than emergency departments)

Considerations for the Canadian context

- Offering STBBI POCT within hospital settings, particularly when embedded within “normalised” care, may be an effective and acceptable way to reach patients who have not previously been tested and to address otherwise missed opportunities for diagnosis.
- STBBI POCT in hospital settings can achieve higher rates of patients receiving their test results than conventional testing.

3.2.5 Pharmacies

Canada

A study from British Columbia demonstrated the feasibility of offering HIV POCT in pharmacies in an attempt to reach individuals who may not seek out or access testing in more conventional spaces. The pilot study offered HIV POCT in four pharmacies in BC. In Vancouver, three quarters of participants (74%) had not been tested previously and 60% were Asian (153).

Europe

Two UK studies demonstrated the feasibility and acceptability of offering STBBI POCT in pharmacies in geographically isolated and sparsely populated areas. First, a study found that HCV POCT in pharmacies on the Isle of Wight reached 186 individuals, 68 of which reported injection drug use, and 17 of which tested positive for HCV (154).

Second, in a study offering a combined HIV and syphilis POCT in pharmacies in Cumbria, Phillips and colleagues (2018) found that most participants (81.9%) stated ease of access as the reason for choosing to be tested in a pharmacy. Nearly half the participants (44%) had never tested for HIV before. Though there were no positive HIV and only one positive syphilis test result, numbers of tests increased on a monthly basis as education and awareness continued (155).

A Spanish study evaluated a pharmacy-based HIV POCT programme offered in a low HIV prevalence region of Spain. In total, 2,168 people were tested in 16 pharmacies in 10 cities with low HIV prevalence. There were 23 positive tests: 60.9% among GBMSM, 34.8% among heterosexual men and 4.3% among women. Fifty per cent (50%) of GBMSM and 75% of heterosexual men testing positive were previously untested (156).

United States

Four US studies demonstrated the feasibility of using pharmacies as sites for either HCV POCT (157,158) or HIV POCT (159,160).

The first pilot study (in California) demonstrated the feasibility of incorporating HCV POCT into their routine pharmacy work, despite some concern about whether non-customers would see the pharmacy as a testing option, and that it might sometimes be difficult for a pharmacist to balance the time it takes for counselling with regular pharmacy duties. One participant was found to be HCV positive (157).

The second pilot study (in Michigan) also found one HCV positive case. It assessed the time and cost per patient and found that on average pharmacists and technicians spent a total of 22 minutes with each patient and that the cost was US\$14. This small study suggests that testing in pharmacies is feasible. The authors suggest that costs might be offset through partnering with public health and other organizations, particularly to acquire test kits and education materials (158).

A third pilot study involved 21 community pharmacies and retail clinics offering HIV POCT, with once again one confirmed new diagnosis (out of 1,540 tests). However, a large proportion of confirmatory test results were not reported back to the pharmacy. Average time spent with the participants was 4 minutes pre-test and 3 minutes post-test, with 23 minutes wait time for results (160).

Finally, a fourth study was carried out in pharmacies in NYC neighbourhoods with high HIV prevalence, high rates of poverty and predominantly minority populations (53.8% Hispanic and 43.3% Black). Using trained peer public health advocates (PHAs) to recruit, counsel and test clients, the program was able to detect new HIV diagnoses. Linkage to care was high for those who tested positive (83%) and the average time between positive test result and seeing an HIV specialist was less than one hour. This study suggests that pharmacy-based testing is an important addition to other community testing programs, and an additional way to reach persons who would not likely seek or access testing in other more conventional locations (159).

Pharmacies

Considerations for the Canadian context

- STBBI POCT offered in pharmacies is feasible and acceptable and can reach a significant proportion of first-time testers, including in remote regions, regions with low prevalence, as well as in urban settings with high prevalence.

(continued)

Pharmacies (continued)

Considerations for the Canadian context

- Offering STBBI POCT in pharmacies can reach individuals who may not seek out or access testing in more conventional spaces, either due to stigma or geographic isolation.
- STBBI POCT can be delivered in pharmacies through pharmacists or trained community workers. It can be incorporated into routine pharmacy work while allowing pharmacists to balance the time required for testing with regular pharmacy duties. Partnering with public health and local community partners could offset costs such as by acquiring testing kits and educational materials as well as by reducing staff time required for counselling and linkage to care. Such partnerships may be important in order to ensure confirmatory testing is conducted and to ensure successful linkage to care.

3.2.6 Non-conventional testing sites

Dental clinics

A study in Florida looked at the feasibility and acceptability of HIV POCT in dental offices in communities with high HIV rates. Oral rapid tests were performed on 600 patients. Though no positive cases were detected, the study suggests that patients are comfortable talking to their dental professionals about HIV, and that this may be a useful site for education, prevention and testing in high-risk communities (161).

Assisted living facilities

An American study demonstrated the feasibility and acceptability of offering HIV POCT to veterans who had mental health and substance use disorder diagnoses residing in assisted living facilities. The tests were provided by nurses known to the participants, which likely contributed to the remarkably high acceptance rate (98%). HIV prevalence was 3.1% among 64 participants, very few of which had been tested in the previous five years (17%) (162).

Infectious disease clinics

A North Carolina study offered HIV POCT to persons accompanying HIV-positive patients to infectious diseases clinics, detecting 16 new positive cases out of 450 persons tested (3.6% prevalence). Of this high rate of positive clients, three had never been tested. Most patients who tested positive (86.4%) had confirmatory testing and immediately entered into HIV care at the clinic. This study showed that it was possible to reach high-risk populations who may not have intended to test but found themselves in a low-barrier, convenient testing situation, and that it was possible to detect new cases and immediately link people to care (163).

Non-conventional testing sites

Considerations for the Canadian context

- HIV POCT offered in carefully selected non-conventional sites such as dental clinics can be highly acceptable to groups at high risk, could reach people who have not often (or never) been tested, detect a high proportion of new infections, and successfully link patients to care. High acceptability is likely linked to patient trust of healthcare professionals in settings they already use.

3.3 General Considerations Related to STBBI Point of Care Testing

This section provides an overview of the evidence related to STBBI point of care testing in general, not already covered in previous sections.

Comparing POCT to conventional testing. A study comparing blood-based HCV testing to HCV POCT found that the testing modalities complemented each other. Patients tested with POCT were more likely to be co-infected with HIV and POCT had a higher rate of finding new infections (164).

Another study comparing HCV POCT to conventional testing offered through mobile medical clinics in Connecticut found almost equal rates of preference for one form of testing over the other (47.7% POCT; 52.3% standard testing) and no difference in HCV prevalence. However, those who chose HCV POCT were significantly more likely to be linked to care after 30 days than those who chose standard testing (93.8 vs. 18.2%) (165).

A German study compared HIV POCT to conventional testing and did not demonstrate that POCT was able to reach populations that could not be reached through conventional testing. Furthermore, POCT was not as efficient at detecting very early HIV infections (166).

Introduction of rapid HIV testing was shown in Brazil to increase the rate of timely diagnoses of HIV, and to decrease the rate of late and very late diagnoses (167).

Alternative testing modalities. A Dutch study demonstrated the feasibility of adding HIV-RNA rapid testing to routine serological testing among GBMSM in a sexual health clinic, in order to identify acute HIV infections, to provide same day results and to start immediate treatment (168).

In a study from California, two (or more) rapid tests were used to confirm initial positives. The positive predictive value (PPV) of using a second (different) rapid HIV test was 100% compared to 86.4% with a single test. Clients received confirmatory results the same day (as opposed to an average of 8 days later with conventional laboratory confirmatory testing), they were referred to care within 90 days, and costs were lower than laboratory confirmation tests. The authors found this study demonstrated the benefits of an improved PPV and immediate referral to HIV care (169).

General Considerations

Considerations for the Canadian context

- Conventional venous testing and POCT are complementary testing modalities. In many cases, POCT can be more acceptable, improve rates of receiving test results, early detection and linkage to care. However, for some populations and some specific STBBI (e.g., HIV in GBMSM), conventional testing can detect very early infections and is still needed for confirmatory testing. Combining two (or more) rapid tests can also be used to confirm initial positives.

4. Conclusion

Overall, point of care testing for HIV, hepatitis C and syphilis has been shown to be feasible and effective, generally with high acceptance among populations most affected by STBBI. However, the context within which testing is being employed is an important consideration.

High acceptability rates for POCT may be in part due to its less invasive nature than conventional venous blood draws. Offering a broader range of testing modalities may contribute to greater acceptability as well. For example, oral swab tests for HIV and HCV could be seen as less invasive than a finger prick test that draws blood. In addition, offering multiplex testing options may be preferable for some individuals. The rapidity with which results can be obtained through POCT contributes greatly to its acceptability and flexibility (e.g., ability to use it in outreach settings or for women presenting in late pregnancy or for delivery). However, as some research suggests, conventional testing is still needed to confirm a positive rapid test result, to distinguish between an active untreated infection and an old treated infection (HCV and syphilis), or to detect HIV cases within a shorter window period.

The literature demonstrates that STBBI POCT can play an important role in reaching first-time testers, detecting new infections, ensuring test results are delivered and expediting linkage to care. However, there are still barriers for many specific populations, such as people with less stable living conditions, people who use drugs or people from racialized communities. Minimizing the time it takes to get HIV, HCV and syphilis test results increases the likelihood that individuals, particularly with chaotic lives, will be willing and able to access care. Housing testing and treatment services together on site and using trained peers can help overcome these barriers for a range of populations (e.g., people in unstable housing situations, people transiting through short-term correctional facilities) and for outreach settings where loss to follow-up is more likely. Embedding POCT within services and organizations that specific populations already use (e.g., shelters, needle exchange or immunization programs, bathhouses) can improve acceptability and uptake by building on trust, familiarity and convenience. Enhanced (ideally peer-driven) health navigation services may be required for some populations.

Careful planning of STBBI POCT is critical to success; the entire process from testing and linkage to care through to completed treatment needs to be considered when planning an effective testing campaign, project or programme, including knowing the specific populations to be reached. A combination of approaches may be needed, such as: testing programs designed to reach populations most affected by STBBI in general (e.g., GBMSM); targeted testing campaigns and creative outreach to reach specific sub-communities (e.g., racialized GBMSM, GBMSM living with HIV, GBMSM who use substances); and, general testing programs such as routine offer of testing in emergency departments, which can reach significant numbers of people that might not otherwise access testing.

STBBI testing offered through conventional healthcare settings (e.g., emergency departments, community health and STBBI clinics) and non-conventional settings (e.g., pharmacies, dental clinics) can be effective. In the case of conventional healthcare settings, there is considerable evidence that there are several missed opportunities for testing individuals at risk of STBBI when they interact with the healthcare system—especially individuals from racialized communities. This should be considered when designing testing programs and policies. Potential strategies to improve the cost-effectiveness of testing

programs in non-conventional settings include the development of external partnerships with local public health, healthcare facilities and community organizations. Such partnerships could provide test kits, facilitate linkage to care or even support existing on-site staff by conducting some of the test-related education and counselling. Planning testing programs in either type of setting requires careful consideration of potential barriers such as workloads and staff attitudes toward rapid testing.

Peers and cultural mediators were found to be useful, particularly with populations that may not access medical services, or may not be comfortable in doing so. In addition, they can facilitate the delivery of culturally and linguistically appropriate education and counselling.

Expanding the range of healthcare providers that can offer POCT, such as nurses and pharmacists, may increase uptake. Where regulations allow, using community workers and peers to conduct testing, whether alone or in partnership with healthcare providers, can be beneficial as well.

Information, education and communication are important elements to consider in testing campaigns. This includes information about the testing programme, point of care testing itself and STBBI in general, as well as ensuring appropriate pre- and post-test counselling and risk-behaviour counselling. Specific themes that should be addressed include HIV stigma, lack of knowledge about HCV treatability, and the efficacy and reliability of POCT. This should include information about the relative benefits and drawbacks of both POCT and conventional testing such as considerations around ease of use, time needed to obtain results, window periods, and the potential need for confirmatory testing.

Innovative technological approaches should be explored to reach particularly isolated and marginalized populations, such as: using tablets to collect sensitive risk behaviour data; providing validated videos to patients as a way to complement education and counselling efforts in high-volume settings; and, using tele-health to reach individuals living in rural and remote communities.

Ultimately, conventional serology and point-of-care testing are complementary modalities. Making the most appropriate and strategic use of these powerful tools requires:

- meaningful collaboration and engagement from all relevant stakeholders, including policy-makers, public health officials, healthcare providers and the communities most affected by STBBI in Canada, such as GBMSM, transgender populations, Indigenous communities, people who use drugs, people in unstable housing situations, currently and recently incarcerated populations, immigrants and refugees, pregnant women, sex workers and their clients, and young people;
- carefully examining the available evidence, including the contents of this report as well as other key resources, such as NCCID's [previous review of evidence](#): *Reaching Underserved Populations: Leveraging Point-of-Care Tests for Sexually Transmitted and Blood-Borne Infections to Explore New Program Options in Canada* (5);
- urgently supporting new Canadian-specific research to fill the evidence gaps ([see section 5](#));
- acknowledging, understanding and weighing the relative advantages and disadvantages of conventional and point-of-care testing options, including their potential role in meeting Canada's commitment to meeting global targets aimed at eliminating HIV, hepatitis C and other STBBI as public health threats by 2030.

5. Areas for Further Exploration

For many specific populations, there seems to be a lack of Canadian research relating to STBBI point of care testing. In fact, in some instances, there is limited international research as well.

- There is a lack of Canadian research among GBMSM beyond HIV POCT (i.e., for HCV, syphilis, other STBBI).
- There is a lack of Canadian data (and little international data) on STBBI POCT among transgender populations.
- We found no Canadian studies in the past 10 years that focus exclusively on STBBI POCT with Indigenous populations.
- There is a lack of research among people who use drugs for STBBI other than HIV and HCV.
- There is information on STBBI POCT among currently and recently incarcerated populations, but the evidence for appropriate follow up and evidence from Canada is limited.
- There is limited Canadian research on STBBI POCT among immigrants and refugees.
- There is limited research on STBBI POCT among sex workers and their clients, especially from Canada.
- There is very limited research focussed on STBBI POCT among young people other than as part of cohorts for other key populations, especially in the Canadian context.

In some instances, it is possible to learn from research taking place in similar contexts. For example, some of the studies among Indigenous persons in Australia and Brazil might provide useful insights that may be applicable to Indigenous populations in Canada, though our geography may present unique challenges not present in other countries, such as reaching Inuit communities in the far North.

Much of the Canadian research is based in our larger urban areas, while rural and remote populations, Indigenous and otherwise, may have little or no access to testing and care, even in a country with a largely public funded healthcare system. Perhaps drawing from more studies conducted within low-resource settings could be informative for designing Canadian implementation research and pilot testing in these hard-to-reach areas.

More research is needed to clarify whether there is a preference in different populations for multiple individual tests for different infections or whether there would be uptake for multiplex tests that use one sample for multiple test results. The studies that do look at multiple tests do not seem to clearly show a preference. In some studies, using multiplex tests is acceptable because it is more convenient to have everything done in one visit, while in others, participants may have preferred bundled tests without HIV. Yet other studies show that some persons only want individual testing, especially if they have recently tested for one or more infection, if they don't want to know results, or if stigma (often HIV-related) is a barrier in some contexts.

POCT has been shown to contribute to earlier detection of STBBI, though few studies provide enough specific information (such as CD4 counts in the case of HIV) to determine the extent to which this is true.

As a matter of public health urgency, policymakers, public health officials, healthcare providers and the communities most affected by STBBI in Canada should urgently support new Canadian-specific research to fill these evidence gaps.

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