



National Collaborating Centre
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Commentary

Point of care technologies for HIV/STBBI: an analysis of contextual factors impeding implementation in Canada

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Expert Opinion

Summary

As Canada gears up to achieving the UNAIDS 90-90-90 targets for HIV/AIDS, an underlying obstacle remains: detecting HIV in the 20% of individuals who remain unaware of their HIV sero-status. In this commentary, we make a case for a greater use of point-of-care technologies (POCTs) , their versatility of use across Canada, and potential for decentralized deployment, which will increase access and improve detection rates, and thus help achieve UNAIDS 90-90-90 targets.

Further, to effectively control HIV/STBBI syndemics, we call for the following: i) increased funding for combined POCT initiatives, ii) scale-up of successful POCT pilots into provincial screening programs, iii) approval of POCTs to increase choice, availability, reduce costs, iv) training/certification of professionals on POCTs, and finally, v) making POCTs widely available nationwide for expanded access and health equity.

Introduction

The Public Health Agency of Canada estimates that about 65,040 (range: 53,980 to 76,100) people were living with HIV (including AIDS) by 2014 and about 20% of these were unaware of their infection, due, in part, to lack of accessibility for testing and diagnosis.¹ Besides accessibility, increasing test uptake in communities also depends on risk perception, community awareness and knowledge, as well as stigma and discrimination. Traditionally disadvantaged communities are also impacted by an ever-increasing HIV and related HCV/syphilis disease burden. Besides offsetting limitations of access and equity, point-of-care technology (POCT)-based screening services can also help catalyze the first steps of engagement into primary care. For example, in rural northern communities where fewer healthcare professionals are available to meet the screening needs of the populations, delays in receipt of laboratory test are inevitable. Real life issues of sample conservation in cold environments and timely shipment of samples impact the availability and receipt of test results. Diagnostic delays potentially lead to late presentation for key health problems, while delayed engagement in care and treatment precipitates losses to follow-up, translating into increased healthcare costs. Transmission of these infections continues unabated, as has been observed in Saskatchewan.¹

POCTs are near patient care technologies, intended to be used at the point of clinical care, in various contexts and settings. These tests are available to screen for HIV, HCV, HBV, syphilis, trichomonas, HPV, and many other co-infections. POCTs therefore, can serve as first line screening/triage tools that aid in expanding access to screening services in rural/small urban areas, improve engagement of marginalized populations in health behaviours, expedite screening and linkages to care, control infections and thereby, promote health equity.² POCT-based screening programs offer an alternative, decentralized, complementary testing model to the standard laboratory-based testing model. POCT programs circumvent service delivery barriers faced with standard testing models, such as: a) lack of timely access and absence of 24/7 testing services; b) delay in the receipt of test results; c) delay in implementing linkages to counselling and treatment; d) stigma; e) cultural insensitivity; f) delayed diagnosis/clinical care; g) losses to follow-up; and h) failure of infection control in communities.²

In 2017, Canada stands to benefit from a successful integration of POCT for HIV and related infections, with established laboratory services across provinces and settings, primarily for communities in small urban, rural, remote and underserved areas. For such communities, a lab-integrated POCT based screening program could provide accessible results on site, improved integration of linkages to lab confirmed test results and integrated linkages to clinical care pathways. This set up could potentially increase a rapid diagnosis and treatment outcome, for the patient, that will in turn translate to cost savings and thereby improve equity in health care.

POCT programs/initiatives are not new to the Canadian context; many pilot programs/research studies in provinces and territories have successfully explored their benefits.³⁻⁸ Of note: 1. Hassle Free Clinic, ON; this clinic has trained frontline healthcare professionals to successfully offer POCT on site for many years. 2. CIHR funded SPOT-HIV Testing Project in Montreal, Quebec, offered a successful free anonymous, rapid HIV testing service to gay men, aided by community health workers.⁹ 3. The Stop HIV/AIDS Project by the BC CDC offered a province-wide free HIV POCT for First Nations health agencies.

Success with POCT has also been reported in research studies across Canada.^{8,10-15} Studies funded by CIHR and provincial agencies have been conducted in many distinct sub populations; from men who have sex with men,¹⁶ previously untested users,¹⁷ multiplex testing in injection drug users,⁸ multiplex testing in Nova Scotia,⁵ and in several non-urban settings.^{6,7,17} These studies prove that a health system integrated rapid POCT-based program can be set up in different provinces.

However, many proven strategies do not get scaled from a pilot project nor get past their successful initial implementation into successful A-base funding or sustainable programs to influence service delivery over time.¹⁸ Recently, this issue of limited availability of POCT in Canada has been systematically explored and an action plan for implementation of POCTs has been proposed.¹ In this report, the authors documented that POCTs do not get scaled in Canada because of three factors: a) inability of the health system to purchase POCT based test kits, b) lack of a billing code in many provinces, and c) inability to cover the cost of test kits.¹

Analysis of contextual macro factors

While cost-related issues do not seem insurmountable, the issue of limited uptake of POCT merits a *macro analysis* of the contextual diagnostic ecosystem and factors that potentially impede availability and scale up of POCT.

Some of these contextual macro factors are analyzed below:

1. Diagnostic Ecosystem/Landscape

Canada has a well-funded public healthcare system, with an efficient network of central and provincial laboratories. Although testing occurs in the communities, tests need to be shipped to a Central or Provincial Lab, often adding costs and increasing time to receipt of test results to the provider and patient, with the risk of failing to deliver test results to the patient. Thus, there are limited opportunities to obtain testing outside of the labs (except in the major provinces of Ontario and Quebec, where they are available in private settings).

2. Market Size

Anecdotal reports reveal that Canada lacks a substantial market size for POCT to be profitable; a lack of a sizeable market deters companies from selling POCT. Additionally, approvals for POCT require expensive and time consuming clinical trials. With a lack of substantial market, small companies are unwilling to invest time and money to approve and market their devices in Canada. Limited choice and market size translates to a high unit cost of a POCT device that is widely and cheaply available in other countries. To date, only two approved POCT are available for Canadians: one each for HIV (INSTI Rapid HIV testTM) and HCV (Oraquick® HCV test). Limited choice and availability prevents the use of POCT devices in public screening initiatives. Besides, a lack of co-ordination between provinces and territories on deployment of POCT results in a fragmented market. Improved provincial and regional co-ordination and collaborative efforts will certainly help make the case to improve markets size in Canada. This in turn would increase choice and availability of different POCTs for public screening initiatives. This inertia translates to a reduced availability of POCT devices including HIV self-tests and STBBI multiplex tests for the Canadian market.

3. Regulatory Approvals

As of 2017, in Canada there are limited approved POCTs for HIV, HCV, HPV, HBV, Syphilis, self-tests and multiplexed tests available for use by communities. Communities have often raised the need for POCTs; to increase choice and availability for them, we need expedited regulatory approvals of FDA/WHO PQ approved POCTs in Canada. Their approvals will stimulate competition; this will in turn lower unit costs, facilitating programmatic scale up and the restructuring of provincial POCT friendly policies. This domino effect process will benefit many Canadian populations.

4. Screening Policies

For POCTs to be impactful and cost effective, they need to be used in settings with an undetected and/or high disease burden. Screening by itself is ineffective unless linkages to confirmatory testing and treatment are in place in settings of use. For that, policies must be set to enable their integration in clinical decision making. However, there are currently no federal nor provincial Canadian POCT guidelines that call for an integration of POCTs. These guidelines will be very useful for health care professionals who may consider a greater use of POCTs in expediting their clinical and diagnostic decision making. Without an immediate impact on clinical decisions and care pathways, the advantage of rapid POCT testing is lost. In sum, a successful deployment of POCT calls for integration and for that, a greater cooperation and collaboration amongst healthcare professionals, provincial and federal policy makers, and community organizations is necessary.

5. Cost Savings

Given the inability of POCTs to batch (many results at one time, compared to laboratories), a POCT strategy/program often is considered to be labour intensive, with a high initial cost of deployment. In the Canadian context although a high unit cost, labour and set-up costs will inflate implementation in the short term, it stands to offer cost savings in the long term.¹⁹⁻²¹

In the United States for example, POCTs are found to be cost effective because of their potential for early detections, establishment of rapid linkages to care and potential role in control of HIV transmission; these metrics outweigh initial set-up costs over time.²² Almost always, the last few cases detected will be more expensive than the first ones because of the expenses involved in extensive case finding in communities.

Regarding cost savings, in Ontario, some agencies pay to screen low-income populations, and labour costs are shared for sustainability. For a maximum uptake, a reasonable unit cost of a POCT device is essential. Companies market their devices in North America and Europe, where private vs. public mark up for profitability and market volume drive their businesses. A reduced mark up could increase availability of affordable devices for our community based and public health screening initiatives. Reduced mark up, cost sharing and device availability will facilitate a maximum uptake of POCT in screening initiatives.

6. Training/Certification, Education Webinars and Workshops on POCT

For POCTs to be effective, both quality control (QC) and quality assurance (QA) are essential to maintaining their quality. For that, an ongoing proficiency training program and certification is essential. The NCCID, CATIE, and REACH 2.0. National HIV&STBBI Working Group regularly offer training programs, webinars, conferences, and workshops that cover many different related aspects of POCT.²³ These training programs prevent or foresee concerns that are raised by laboratories on POCT test quality.

7. Supply Chain/Integration of POCT

Maintenance of a supply chain is crucial to keeping quality on POCT programs. A risk of introduction of poor quality POCTs, due to lapses in supply chain management, is a critical concern to their large scale implementation. Lapses in supply chain management impact quality of POCTs, impacting quality of testing. Sometimes, in health care settings, the volumes of POCT tests are not enough, so test kits reach their expiry date and have to be thrown away, resulting in higher cost per test. This adds to the higher cost of QC/QA. Further, critical to quality is the need for appropriateness and consistency in test storage, conduct, interpretation and communication of test results to influence practice. An efficient supply chain management system – workflow integration within clinics for rapid clinical management decisions – and

deployment of web-connected solutions for community-based outreach are also essential to sustainability.

Finally, a cost-effective implementation of POCTs entails a smarter use of available resources and co-operation and collaboration to establish and maintain quality assured POCT programs. In Quebec, enhanced cooperation between community clinics (private/public) and provincial laboratories for quality assurance and collaboration for post-marketing surveillance of post approval of POCTs is already made available. In such conditions, it is easy to introduce high quality and high sensitive POCTs in some provinces.

8. Novel POCT Strategies: Self-testing and Multiplexed Testing

HIV self-testing is viewed as a strategy of engagement, proactivity, and expanded access. Recent WHO guidelines recommend innovative HIV self-testing as a supplement to facility-based HIV testing, for the first 90 of the UNAIDS 90-90-90.²⁴ Approvals of self-tests in US, UK, and France and self-test friendly guidelines in over 40 countries, offer a precedent for Canada, where there are currently no approved self-tests. Availability of both oral and blood-based HIV self-tests in Canada will catalyze the set up of many innovative provincial programs. Since self-tests are to be administered by patients, besides their rapid approvals, establishing rapid linkages to counselling and referrals to treatment will be essential to their successful deployment.

Multiplexed POC devices/platforms (i.e. biomarker/molecular based) simultaneously screen for many infections (i.e. HIV, HCV, HBV, syphilis) in small samples of blood in one patient visit.¹³ Simultaneous preliminary screening and triage within a rapid turnaround time for a syndromic or disease specific management increases their popularity. Barring few research studies,⁸ research evidence at scale is needed in Canada, to address both the demand from communities and the need for policy guidance for policy makers.¹

9. Sustainable POCT Programs for Community Engagement

Marginalized populations in rural and peri-urban areas have limited screening choices but they do have a substantial burden of undetected HIV/STIs. To improve detection and linkage to care, we need engagement. Engaging the community of end users is also a first essential key step to introducing POCT based screening strategies. Availability of HIV POCTs and self-tests can catalyze/ increase community engagement. Community engagement is essential to setting up sustainable POCT-based programs that are envisioned to benefit many marginalized populations across Canada.

10. Innovations and Implementation Research

Research data are sparse and much needed.²⁵ Implementation research with POC based technologies will generate evidence for policy. Research evidence, improved quality assurance, surveillance and linkage programs will spell success for POCT. Innovations that plug gaps in access, linkage seeking,²⁶ and notification/surveillance are needed. Innovations in POCT (from development to deployment) will change the implementation landscape.¹ Finally, an investment in POCT strategies/programs for populations/provinces, grounded in evidence, sparked by innovations, will catalyze their uptake.

Conclusion

In conclusion, POCT based strategies/programs offer many promising health equity benefits to Canadian populations at large, from rapid, early and timely screening, enhanced community engagement, expanded access to cost savings. Their efficient and rapid deployment in rural, small urban, and marginalized communities will improve the quality and efficiency of screening services to enhance control of HIV/STBBI in Canada. With expedited linkages to treatment and retention, with the support of community based organizations and linked community and outreach clinics, their deployment could possibly help reduce transmission in communities.

However, understanding restrictions to their deployment within the Canadian diagnostic landscape and brainstorming potential solutions, is a necessary starting point towards drafting a POCT based deployment strategy. For that, an ongoing dialogue between various stakeholders is being conducted through three agencies- a) *The CIHR Centre for REACH 2.0 National HIV&STBBI Working Group*, b) *NCCID* and c) *CATIE*. These discussions and dialogues and ongoing collaborations for research and policy are paving the way for a mixed use of POCT based strategies/programs in many provinces.

Finally, an open pan-Canadian mindset, greater inter-provincial collaborations and enhanced cooperation between laboratories and key stakeholders is needed. Stakeholders across the spectrum from policy makers, practitioners, researchers, community advocates and manufacturers, funding agencies, implementation agencies, community based organizations, all need to be actively engaged in this process. Besides, an increased funding for implementation research followed by a sustainable scale up of POCT programs will help realize the full potential of POCT in Canada.

Currently, POCTs are excluded from our lab-based screening strategies, and we are struggling to reach the UNAIDS 90-90-90 screening and treatment targets to end the HIV epidemic. The addition of POCT based strategies for HIV and STBBIs will aid us with expanded access and expedited screening linkages to care and prevention. Finally, as a last mile solution, it could potentially increase our chance of meeting the UNAIDS 90-90-90 targets for HIV elimination by 2030.

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