

Setting the Stage: Scaling-up testing technologies in Canada with pragmatic approaches to reach the undiagnosed with HIV, HCV and other STIs - and link people to the care they need

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MAP Centre for
Urban Health
Solutions

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Acknowledgement of Indigenous Traditional Territory



Colourful Headress
drawing by artist Jasmine Wemigwans, Toronto



Outline – Setting the Stage – Why are we here ??

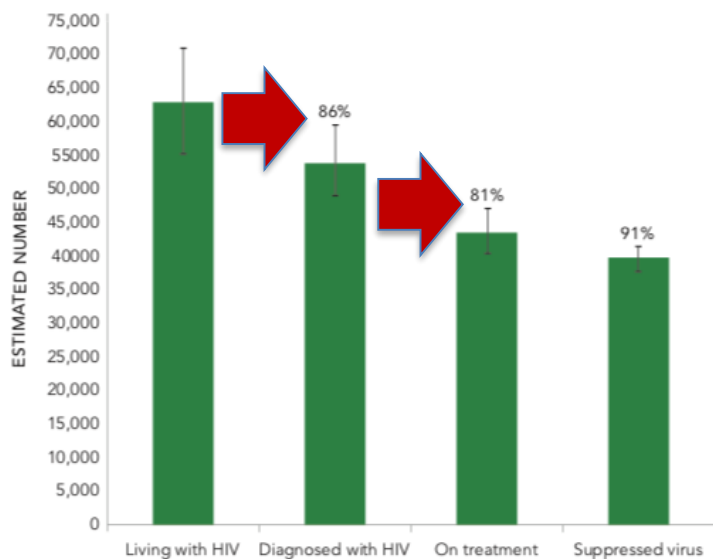
1. The context – **Reaching the undiagnosed*****
2. The Pan-Canadian STBBI Framework
3. What we already know – now time to adapt and apply
4. REACH 3.0 Bringing new STBBI tests to market in Canada
5. REACH 3.0 Testing-Linkage Program – Phase I
6. Community-based opportunities – “Bring the test to the people”
7. Testing scale-up, indicators, and monitoring / evaluation
8. Pragmatics of self-testing – delivery options, access and delivery, support, linkage to care, and monitoring/evaluation
9. HIV testing awareness campaigns and PSAs – need more visibility



CANADA'S PROGRESS ON MEETING THE 90-90-90 HIV TARGETS

In Canada at the end of 2016, 86% (plausible range 78–94%) of the estimated 63,110 (plausible range 55,500–70,720) persons living with HIV were diagnosed. Of those diagnosed, 81% were estimated to be on treatment (plausible range 75% to 87%) and an estimated 91% of persons on treatment had suppressed viral load (plausible range 87% to 95%) (Figure 1).

FIGURE 1: Estimated number and percentage of persons living with HIV, diagnosed, on treatment, and virally suppressed in Canada at the end of 2016 (vertical bars represent plausible ranges).



Estimated %	--	86%	81%	91%
Plausible range (%)	--	78–94%	75–87%	87–95%
Estimated #	63,110	54,020	43,680	39,960
Plausible range (n)	55,500–70,720	49,200–53,320	40,520–47,000	38,000–41,500

If we want to end the HIV epidemic in Canada, 90% will not be enough to get there –

Priorities:

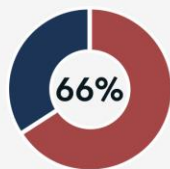
1. We will need >95%
2. Focus on 1st 2 bars



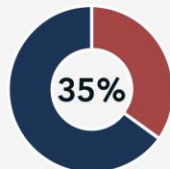
BLUEPRINT TO INFORM HEPATITIS C ELIMINATION EFFORTS IN CANADA

Estimated 250,000 infected – 44% who are undiagnosed

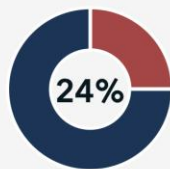
Figure 8. Hepatitis C virus (HCV) prevalence among Priority populations



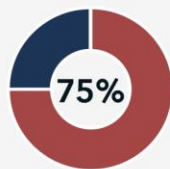
Up to 66% of people who inject drugs have past or current HCV infection.



Up to 35% of all HCV infections in Canada are among immigrants and newcomers, especially those from countries where HCV is common.

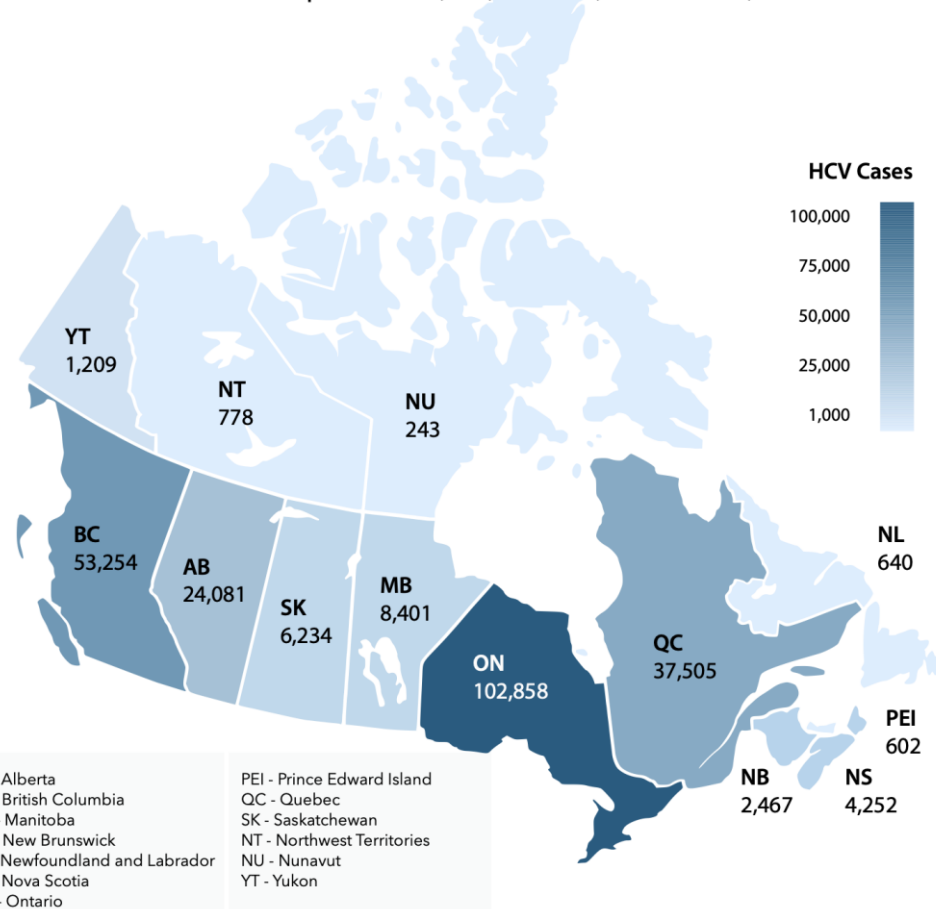


Nearly a quarter of prisoners in federal and provincial correctional facilities have a past or current HCV infection.



Up to 75% of all HCV infections in Canada are among people born between 1945-1975.

Figure 3. Provincial and territorial hepatitis C virus (HCV) estimates (total HCV cases)²⁸



AB - Alberta
 BC - British Columbia
 MB - Manitoba
 NB - New Brunswick
 NL - Newfoundland and Labrador
 NS - Nova Scotia
 ON - Ontario
 PEI - Prince Edward Island
 QC - Quebec
 SK - Saskatchewan
 NT - Northwest Territories
 NU - Nunavut
 YT - Yukon



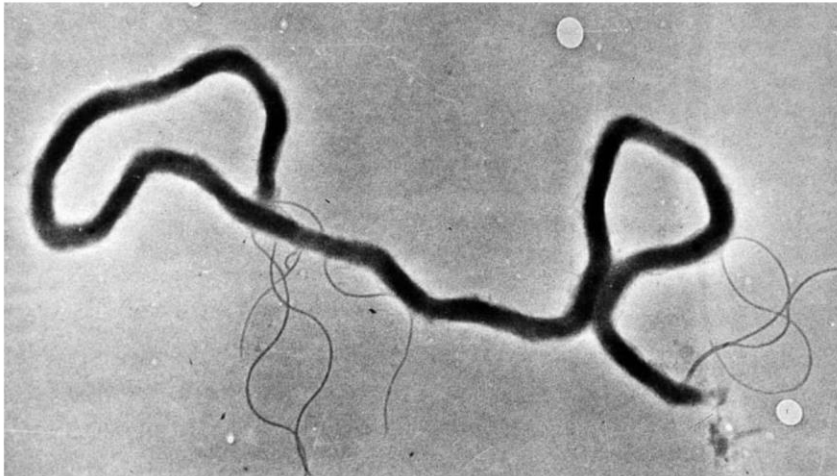
Edmonton

Number of syphilis cases in Alberta continues to rise during outbreak



Most of the new cases have been diagnosed in the Edmonton area

CBC News · Posted: Dec 09, 2019 12:52 PM MT | Last Updated: December 9



The organism treponema pallidum, which causes syphilis, is seen through an electron microscope in this 1944 file photo. (The Associated Press)

The number of syphilis cases in Alberta continues to rise, with the province in the midst of another outbreak.

Just one example:

In Alberta:

1,536 cases in 2018

1,753 cases already in 2019

In 2014 – only 160 cases in all of Alberta

Since 2014, there have been 61 cases of congenital syphilis, with 38 of those this year – and 31 in Edmonton.



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Context - Progress in other G7 Countries

nam aidsmap

HIV & AIDS - sharing knowledge, changing lives

News

About HIV

Epidemiology

Could UK HIV transmissions really go down to near-zero by 2030? The latest report suggests so

90% viral suppression rate reached in London; most people on ART now have lower death rate than the general population

Gus Cairns | 16 January 2020

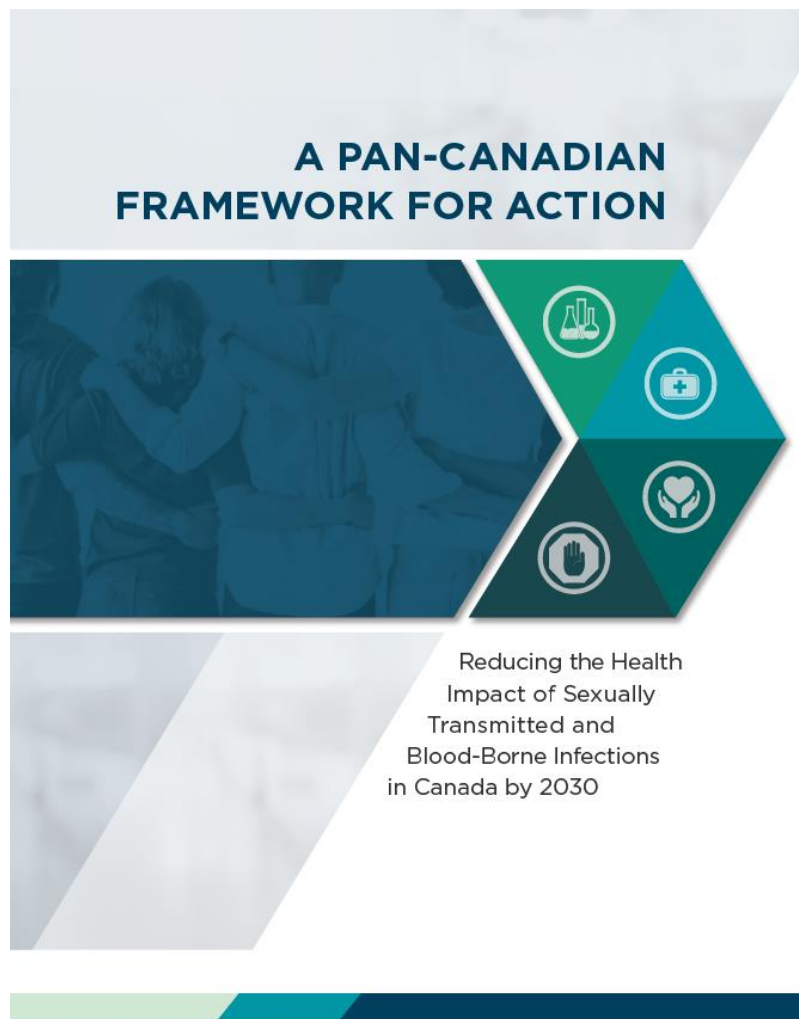
Incidence in
gbMSM fell 71%
from 2014 to 2018

Public Health England cites, as measures we must improve if we are to reach this goal:

- more testing in non-traditional settings such as A&E departments, prisons and via self-testing;
- more consistent testing of people who come to clinics with symptomatic STIs (over a third of STI attendees who fell within HIV testing criteria were not tested last year); and
- instituting routine commissioning of PrEP in England which, it says, may bring about a further “rapid fall in new HIV diagnoses in gay and bisexual STI clinic attendees from 2019 onwards”.



The Pan-Canadian STBBI Framework for Action



Vision

- STBBIs are rare
- People living with STBBI receive the care and support they need

Outcome

- Reduce health impact of STBBI in Canada by 2030

Strategic Goals

- Reduce incidence of STBBI
- Improve access to testing, treatment and ongoing care and support
- Reduce stigma and discrimination that create vulnerabilities to STBBI

CORE PILLARS



Comprised of four interconnected pillars that span the continuum of STBBI care:

1. **Prevention***
2. **Testing****
3. **Initiation of Care and Treatment***
4. Ongoing Care and Support

The four pillars are embedded within an enabling environment

Includes eight Guiding Principles

GUIDING PRINCIPLES

- › Meaningful engagement of people living with HIV and viral hepatitis and key populations
- › Moving towards truth and reconciliation
- › Integrated approach
- › Cultural relevance
- › Human rights
- › Health equity
- › Multi-sectoral approach
- › Evidence-based policy and programs

The STBBI Framework – Success Factors: People and Integration of Efforts

AN APPROACH TO ADDRESS STBBI IN CANADA

A Shared Responsibility

The success of the Pan-Canadian STBBI Framework for Action depends on the commitment of all partners and stakeholders working within their respective roles (Annex A). No one sector or government can reduce the health impact of STBBI alone—it will require collaboration to succeed.

It is expected that partners across Canada, in various sectors, can identify how and where they can best contribute to these collective efforts. Partners that should be included (among others) people living with STBBI, communities, civil society, academia and front-line providers.

The Pan-Canadian STBBI Framework for Action's core pillars are supported by a strong foundation of surveillance, research, knowledge mobilization, and monitoring and evaluation.

Surveillance systems provide key information about the epidemiology of STBBI in Canada. They also help identify key populations and locations where action is needed to reduce the public health impact of STBBI. Surveillance can also contribute to monitoring and evaluation of policies, programs, and interventions.

Research is essential to develop STBBI related policies, programs, and interventions. The development of innovative interventions and treatment methodologies is necessary to reduce the health impact of STBBI.

Knowledge mobilization enhances the integration of information and evidence into programs and policies to prevent and control STBBI. It also supports more effective health services and products to strengthen the healthcare system overall.

Monitoring and evaluation determines progress and identifies gaps or limitations of policies, programs, and interventions. All concrete actions identified as part of specific implementation plans must be regularly

1. Partnerships and collaborations**

2. Integration and alignment**

ENHANCED TESTING: OPPORTUNITIES FOR ACTION

1. Provide health professionals and front-line service providers with knowledge, skills and resources to implement **person-centred***, culturally-relevant, and integrated testing that respects patient privacy and rights.
2. **Ensure appropriate linkages** to prevention, treatment, and care resources are provided to individuals who have been diagnosed with, or at risk of, a STBBI.
3. Research, implement, and evaluate **innovative and emerging testing technologies, testing approaches**, and sustainable quality assurance systems.
4. **Improve availability of, and access to**, evidence-based testing technologies and approaches in a variety of settings.
5. **Normalize the offer of STBBI testing** among healthcare providers while individual rights to confidentiality, pre- and post- test counselling, and informed consent are respected.

*A person-centred approach means that health professionals and front-line service providers work together with people to ensure their services are tailored to individual needs



Ending the HIV Epidemic in Canada in Five Years It's Time to Act

"I have been impressed with the urgency of doing. Knowing is not enough; we must apply. Willing is not enough; we must do."

LEONARDO DA VINCI
(ARTIST AND SCIENTIST)

The Context

Unlike other G7 countries, Canada is not seeing a reduction in the number of new people being diagnosed with HIV, notwithstanding significant investments over the past many years.

Recent data from the Public Health Agency of Canada (PHAC) indicate that in 2016 an estimated 2,165 people became infected with HIV in Canada.¹ This is one new infection every four hours. Our numbers are almost 10% higher than in 2014.

Jurisdictions around the world have launched new, highly targeted initiatives to end HIV, including "Getting to Zero" and the UNAIDS strategy to end AIDS by 2030. Although Canada has endorsed the UNAIDS 90-90-90 target² (90% diagnosed, 90% of those on treatment and in care, and 90% of those who are suppressed), we lag behind others in reaching these targets. But with strategic interventions, we believe that in the next five years we can "bend the curve" and end the HIV epidemic in Canada. New cases of HIV will become rare.



How is Canada Doing?

It is estimated that there are 63,110 people living with HIV in Canada, but only 86% of those are diagnosed (1st 90 target) – this represents **9,090 individuals who have undiagnosed HIV infection across the country who are not adequately connected to our health care system.** While many G7 countries are seeing progressive declines in the numbers of those undiagnosed – we are not in Canada.

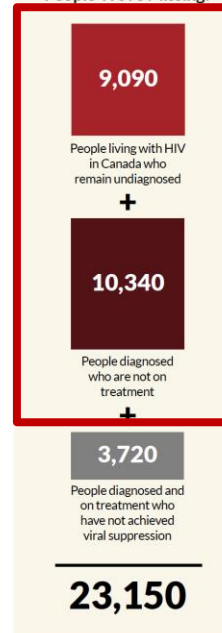
For those people diagnosed with HIV, 81% are now on antiretroviral treatment (2nd 90 target), and of those, 91% have suppressed viral load (3rd 90 target).

While we have reached one of three key UNAIDS targets, we cannot lose sight that there are **23,150 people who are still falling through the cracks along the cascade** (see chart on right)³. All of these people are not benefiting from appropriate prevention, treatment and ongoing care and supportive services to support their own health. And we can prevent the further transmission of HIV if our public health, community-based and health care systems can support these individuals to get tested, diagnosed, be on treatment and achieve viral suppression.

We have to change our approach.

In contrast to most other developed countries, we do not have the leadership in place or a national coordinated approach that is needed. But with targeted and pragmatic interventions for testing, reaching those who are undiagnosed, and supporting more people to manage and adhere to treatment, and achieve viral suppression, we can achieve (and exceed) Canada's UNAIDS commitment to all three of the 90-90-90 targets – and Canada can effectively end its HIV epidemic in the next five years.

Who Are the 23,150 People We're Missing?



Morbidity and Mortality Weekly Report

Vital Signs: HIV Transmission Along the Continuum of Care — United States, 2016

Zhao Li, PhD¹; David W. Poncelet, JD, PhD¹; Stephanie L. Sansom, PhD¹; Demorah Hayes, MA¹; H. Irene Hall, PhD¹

On March 18, 2019, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

Abstract

Background: In 2016, an estimated 1.1 million persons had human immunodeficiency virus (HIV) infection in the United States; 38,700 were new infections. Knowledge of HIV infection status, behavior change, and antiretroviral therapy (ART) all prevent HIV transmission. Persons who achieve and maintain viral suppression (achieved by most persons within 6 months of starting ART) can live long, healthy lives and pose effectively no risk of HIV transmission to their sexual partners.

Methods: A model was used to estimate transmission rates in 2016 along the HIV continuum of care. Data for sexual and needle-sharing behaviors were obtained from National HIV Behavioral Surveillance. Estimated HIV prevalence, incidence, receipt of care, and viral suppression were obtained from National HIV Surveillance System data.

Results: Overall, the HIV transmission rate was 3.5 per 100 person-years in 2016. Along the HIV continuum of care, the transmission rates from persons who were 1) acutely infected and unaware of their infection, 2) non-acutely infected and unaware, 3) aware of HIV infection but not in care, 4) receiving HIV care but not virally suppressed, and 5) taking ART and virally suppressed were 16.1, 8.4, 6.6, 6.1, and 0 per 100 person-years, respectively. The percentages of all transmissions generated by each group were 4.0%, 33.6%, 42.6%, 19.8%, and 0%, respectively.

Conclusions: Approximately 80% of new HIV transmissions are from persons who do not know they have HIV infection or are not receiving regular care. Going forward, increasing the percentage of persons with HIV infection who have achieved viral suppression and do not transmit HIV will be critical for ending the HIV epidemic in the United States.

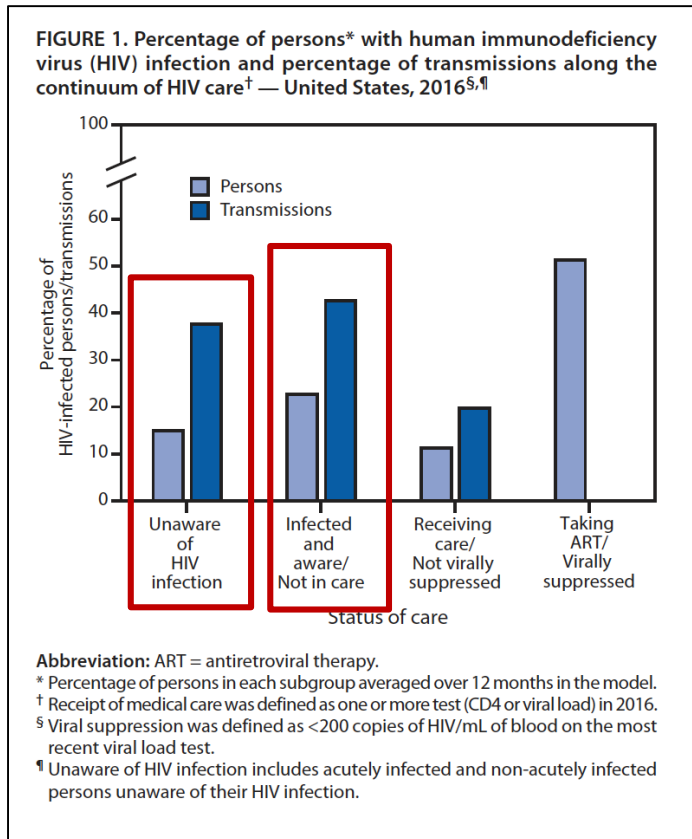
Introduction

Medical treatment has substantially improved the health, quality of life, and life expectancy of persons with HIV infection (1). The benefits of treatment are maximized with suppression of the virus (<200 copies of HIV/mL of blood on the most recent viral load test), which benefits health and decreases rates of transmission. Four recent studies found that viral suppression prevented sexual transmission of HIV (2–5). Together, these prospective studies found no HIV transmissions attributable to sex between HIV-discordant couples when the partner with HIV infection was on treatment and maintained viral suppression, despite documenting tens of thousands of acts of condomless sex in which the HIV-negative partner was not using preexposure prophylaxis. These findings indicate that HIV transmission can become a rare event if persons with infection can obtain treatment and achieve and maintain viral suppression. Today's treatment regimens are simpler than those prescribed in the past, sometimes requiring only single-tablet formulations, with fewer side effects; most persons with HIV infection can achieve viral suppression within 6 months of initiating treatment. These findings also provide an important scientific underpinning to the new federal initiative headed by the U.S. Department of Health and Human Services (HHS) to end the HIV epidemic in the United States within 10 years (6).

Despite the availability of effective treatment, many of the 1.1 million persons with HIV infection in the United States are not effectively treated (7,8). In 2015, among all persons with HIV infection, 14.5% did not have a diagnosis, 37.2% were not in care,[†] and 48.9% were not virally suppressed (7). In addition, sexual and injection-drug-associated risk behaviors varied with knowledge of HIV infection status and access to care (9,10). Lack of effective treatment results in worse outcomes for persons with HIV infection and higher rates of HIV transmission and was associated with 38,700 new HIV infections in 2016 (8). To focus national and local prevention efforts to eliminate HIV, CDC used a model to estimate the number of persons and HIV transmissions at each step along the continuum of care.

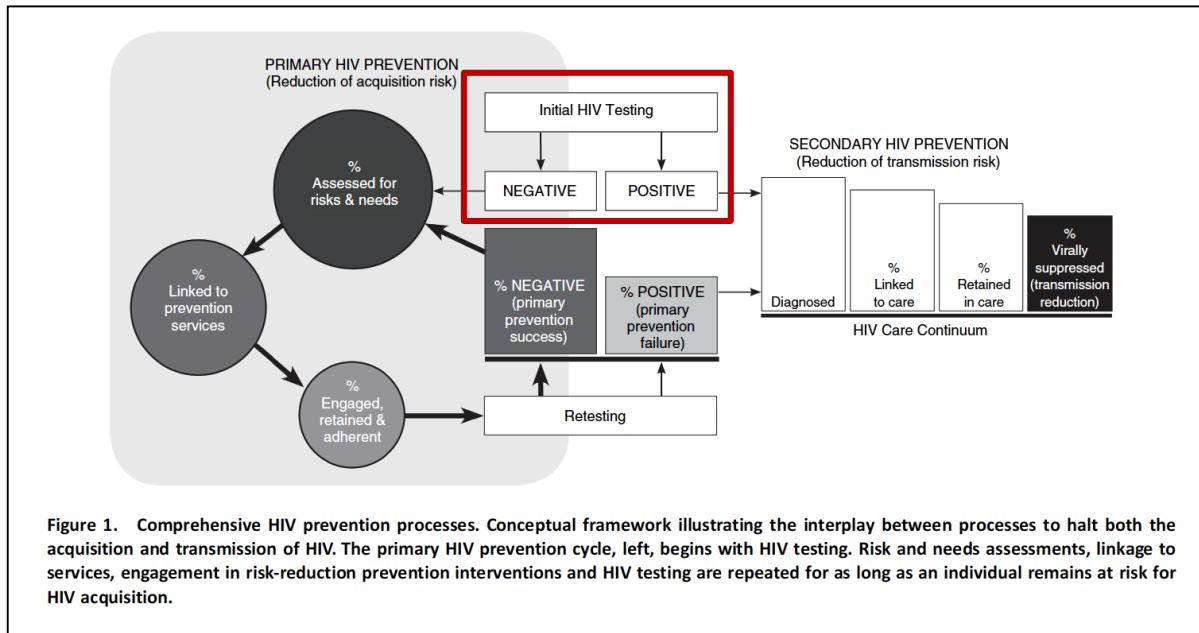
[†]Receipt of medical care is defined as one or more tests (CD4 or viral load) in the measurement year. The percentage of persons with HIV infection who are in care is obtained by multiplying the percentage with diagnosed infection by percentage in care among persons with diagnosed HIV infection.

US Department of Health and Human Services/Centers for Disease Control and Prevention MMWR / March 22, 2019 / Vol. 68 / No. 11 267



80% of new HIV transmissions arise from: (1) persons with HIV who have not yet received diagnosis (15% - who contributed 38%); or (2) those who have diagnosed infection that is not controlled (23% - who contributed 42%)





Herz T et al. *Journal of the International AIDS Society* 2016, 19(2):206
<http://onlinelibrary.wiley.com/doi/10.1002/jia2.22011> | <http://dx.doi.org/10.7446/IAS.19.2.206>

Commentary

Towards an integrated primary and secondary HIV prevention continuum for the United States: a cyclical process model

Tim Horn^{1,2}, Jennifer Sherwood^{3,4}, Robert H Remmen⁵, Dennis Nash⁶ and Judith D. Auerbach^{7,8}, for the Treatment Action Group and Foundation for AIDS Research HIV Prevention Continuum Working Group

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¹These authors have contributed equally to the work.

Abstract

Introduction: Every new HIV infection is preventable and every HIV-related death is avoidable. As many jurisdictions around the world endeavour to end HIV as an epidemic, missed HIV prevention and treatment opportunities must be regarded as public health emergencies, and efforts to quickly fill gaps in service provision for all people living with and vulnerable to HIV infection must be prioritized.

Discussion: We present a novel, comprehensive, primary and secondary HIV prevention continuum model for the United States as a conceptual framework to identify key steps in reducing HIV incidence and improving health outcomes among those vulnerable to, as well as those living with, HIV infection. We further discuss potential approaches to address gaps in data required for programme planning, implementation and evaluation across the elements of the HIV prevention continuum.

Conclusions: Our model conceptualizes opportunities to monitor and quantify primary HIV prevention efforts and, importantly, facilitates the interplay between an outcomes-oriented primary HIV prevention process and the HIV care continuum to move aggressively forward in reaching ambitious reductions in HIV incidence. To optimize the utility of this outcomes-oriented HIV prevention continuum, a key gap to be addressed includes the creation and increased contribution of data relevant to HIV prevention across sectors.

Keywords: HIV; prevention; continuum; PEP; process model; cyclic; testing.

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Introduction

The HIV care continuum has become a highly visible, accessible and reproducible model to improve health outcomes and minimize transmission risk among those living with the virus [1]. Viral load suppression is viewed not only as the continuum's central outcome to minimize individual morbidity and mortality, but also as a key intervention for secondary HIV prevention, given that viral suppression reduces the risk of HIV transmission [2]. Reducing the risk of HIV acquisition among those not already infected and vulnerable to HIV requires a cyclical process.

An HIV prevention continuum, like the care continuum, is potentially valuable to identify opportunities at key steps in an HIV incidence- and health outcomes-oriented process. Such a model affords the opportunity to: 1) define best biomedical, behavioural and ancillary support practices, including those that foster integration of HIV prevention with broader primary care, wellness promotion and sexual and reproductive health services; 2) further evaluate and refine the metrics of success; 3) identify gaps in provider/intervention access and utilization; 4) inform the allocation of human and financial resources; 5) establish implementation science priorities; and 6) generate and support advocacy for the highest impact HIV prevention activities.

Primary HIV prevention continua and similar heuristics have been developed by others. These include a generalised, population-based approach [3]; an infection cascade and prevention pathways model [4]; and pre-exposure prophylaxis (PrEP) and other intervention-specific cascades [5–7]. Proposed models are not without limitations, however. Most fundamentally, unlike engagement in specialized care and antiretroviral therapy after an HIV diagnosis, initiation of a particular intervention following an HIV-negative diagnosis is neither routine nor straightforward. HIV prevention needs and options are not universal or static because of individual and intra-population variability and temporal fluctuations in risk. Additionally, few proposed models address congruity with the HIV care continuum. A heuristic device illustrating the importance of both primary and secondary HIV prevention may prove useful in further influencing HIV incidence.

Recognising inherent challenges, we present a novel continuum model for the United States as a conceptual framework for addressing individualized primary HIV prevention needs to achieve population-level reductions in HIV acquisition risk and to illustrate the critical link between a comprehensive primary prevention process and the care continuum to further improve health outcomes and minimize transmission risk among those who are infected with HIV. To bolster stakeholder

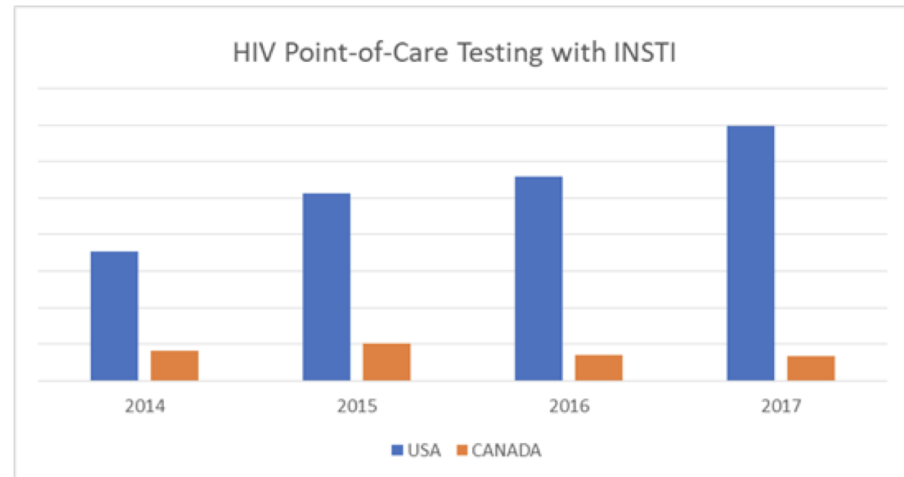
Community-based and health system collaboration and integration for testing and linkages is critical to reach the undiagnosed --> These need to intersect + overlap – not operate in parallel



INSTI HIV Test Kit Distribution in Canada and US, 2014-2017

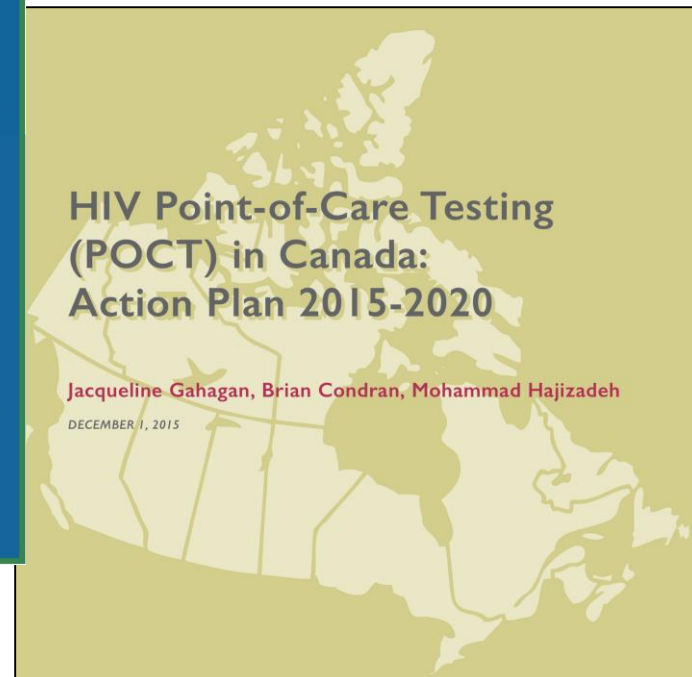
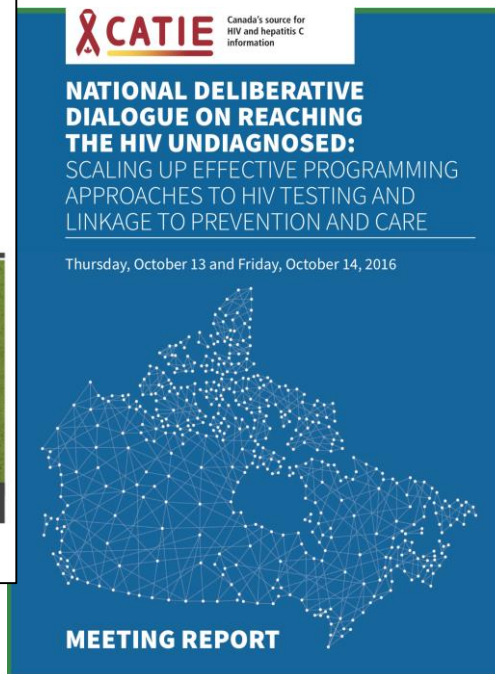
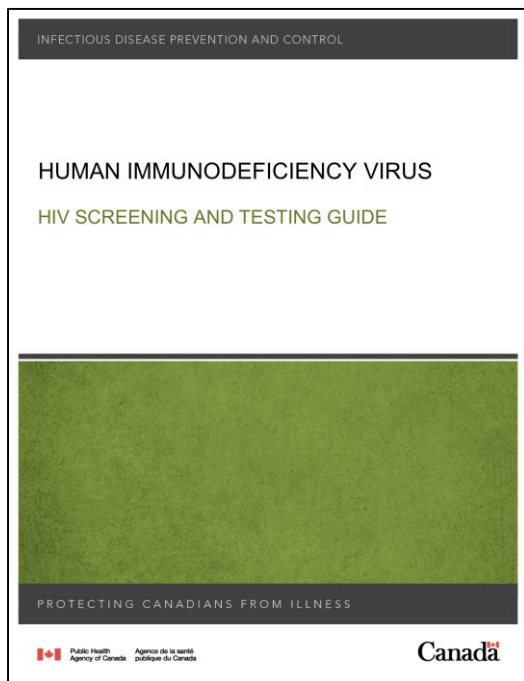
- In addition to INSTI The US has 6 FDA approved, CLIA waived HIV POC tests: **Determine HIV Ag/Ab Combo; Oraquick; Stat Pak, Sure-Check, DPP; Unigold.**
- In Canada, only INSTI is approved for POC testing with fingerstick blood
- Graph represents distribution in 100k increments

Canada purchased 59,000 INSTI POC test kits in 2018 – **33% reduction from 2011**



Source: bioLytical Laboratories





No one-size-fits-all model for testing



Reaching the right people, at the right time,
at the right place, with the most effective
programs



POCT with lay testers integrated in
community program



DBS in remote communities



POCT Duo Test in Gay men's Clinic



Self-testing at home

Courtesy of Geneviève Boily-Larouche, NCCID

Bringing New Testing Technologies to Market in Canada

REACH - Private-public partnerships with Industry Partners:

bioLytical Laboratories – HIV Self-Test, HIV-Syphilis multiplex, HCV POC:

1. INSTI HIV Self-Test – Study with 1,000 end-users to perform and interpret test results (Expect completion by March 2020)
2. HIV-Syphilis multiplex study – Treatment study in Edmonton and northern AB with 1,000 patients to address health crisis – Starting April 2020
3. HCV POC test – Assay validation work with BC-CDC underway, with clinical studies to begin in Canada in 2nd half of 2020, if needed.

OraSure – Oral fluid HIV and HCV self-tests

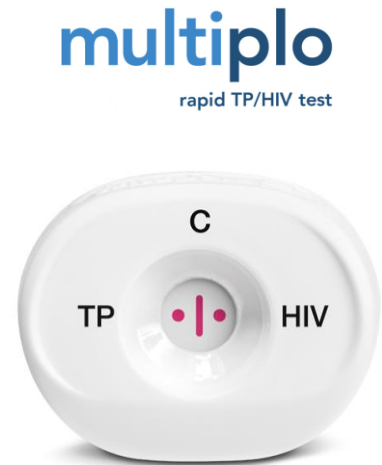
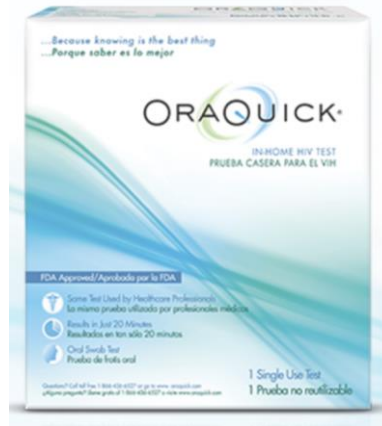
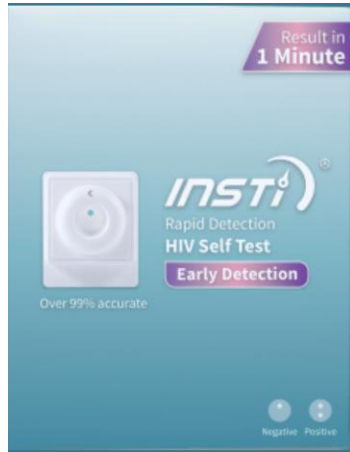
4. OraQuick HIV self-test – Have regulatory data requirements by Health Canada for studies needed – planning underway – 1st studies to start in Q2
5. OraQuick HCV self-test – Forming expert working group to discuss / make recommendations of need for HCV self-test in Canada.

MedMira – HIV-Syphilis multiplex - Multiplo

6. HIV-Syphilis multiplex study – Treatment study in Edmonton and northern AB with 1,000 patients to address health crisis – Starting April 2020.



Bringing New HIV, HCV and Multiplex Testing Technologies to Canada



New Testing Technologies to Market in Canada – Workplan / Timeline

	Expected Approval
1. bioLytical INSTI HIV Self-Test	2020 Q3
2. OraSure – OraQuick (oral fluid) HIV self-test	2020 Q4 / 2021 Q1
3. bioLytical HIV-Syphilis multiplex	2021
4. MedMira Multiplo HIV-Syphilis multiplex	2021
5. bioLytical HCV POC	2021
6. OraSure – OraQuick (oral fluid) HCV self-test	2021/2022



Building Private–Public Partnerships: REACH (CIHR) and CANFAR



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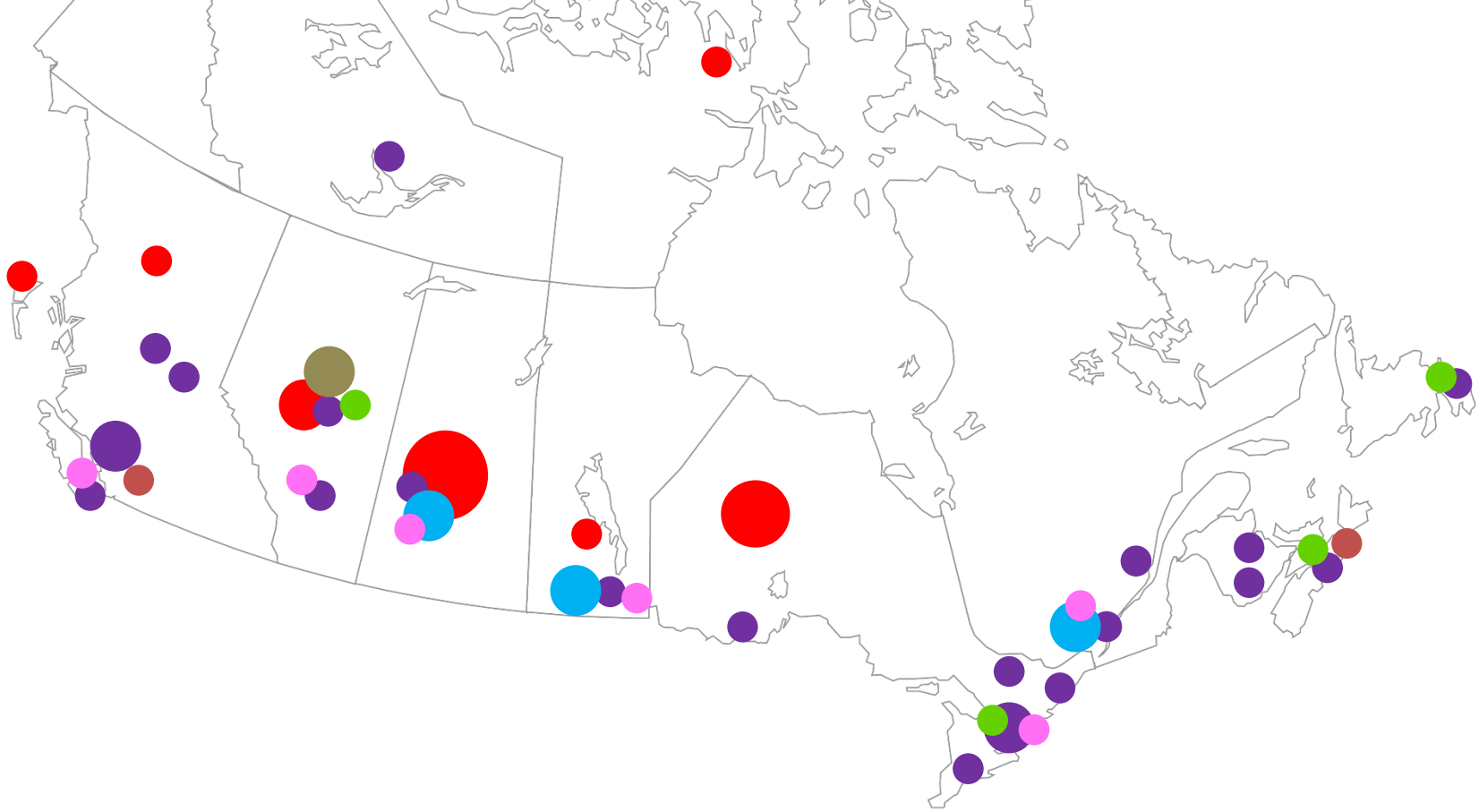
CANFAR is very pleased to support this first national HIV self-test study. This was a major recommendation of our national working group that put together the action plan ‘Ending the HIV epidemic in Canada in Five Years’. Additional HIV testing options will connect more people with HIV prevention, treatment and care efforts that can help them effectively manage their overall health – and contribute to ending the HIV epidemic in Canada.

Alex Filiatrault, CEO of CANFAR.



NATIONAL PROGRAM FOR REACHING THE UNDIAGNOSED WITH STBBIs – PHASE I

1. Indigenous-Led DBS Testing (2018-2019+) – National Lab (PHAC)
2. gbMSM: POC/Home Testing/DBS (2020-22) – CBRC/U.Vic/Advance Alliance
3. HIV/Syphilis Multiplex POC (2020-21) – Alberta Health Services/U.Alberta
4. HIV/HCV/Syphilis Multiplex POC (2020-22) – McGill Team
5. HIV self-testing and access to services using apps (2020-22) – McGill Team
6. Pharmacy-based Interventions with POC/DBS (2020-22) – Approach 2.0 Team
7. Rural/Remote HIV/HCV POC with Harm reduction (2020-21) – In Development



INSTI – Sept 29, 2019 Health Canada Approves for Lay Testers

Same Test.
New Possibilities. 



INSTI now available for expanded point-of-care use in Canada

The world's fastest HIV test is more accessible than ever before as Health Canada approves revised Intended Use statement.

RICHMOND, BC September 19 2019 /GLOBE NEWSWIRE/ – bioLytical Laboratories, a world leader in rapid diagnostic tests for infectious diseases, is pleased to announce that the [INSTI HIV-1 / HIV-2 Antibody Test](#) is being made more widely available in Canada. A recently approved amendment to INSTI's Intended Use statement means the test can now be used by HIV testers and healthcare providers in a significantly expanded variety of settings.

Known globally for its outstanding performance, INSTI uses innovative technology to deliver instant, accurate HIV test results from a one-minute procedure. The test's updated Intended Use statement makes it possible for an increased range of healthcare professionals to use INSTI, including HIV counsellors and peer testers. It also allows for INSTI to be performed in more point-of-care (POC) settings including outreach testing events. This is similar to the CLIA Waiver in the United States, which was granted to INSTI in 2012. The waiver certifies that INSTI is a "simple laboratory examination or procedure that has an insignificant risk of an erroneous result." This means the test can be performed by a variety of users in POC settings across the country.

This is important news for Canada's community-based organizations and HIV research community, who have been calling for better access to HIV POC test delivery for many years. "This is a watershed moment in Canada. With this increased delivery access of HIV POC testing, we will be able to significantly support the scaling up of community-based models to 'bring the test to the people.' It is only in this way that we will reach those who are undiagnosed with HIV and who need testing the most. Notably, their health, livelihood and survival depend on this increased access," said Dr. Sean B. Rouke, FCAHS, MAP Scientist and Director of CHRC Centre for REACH 3.0, St. Michael's Hospital.

INSTI was approved by Health Canada in 2005, making it the only POC HIV test of its kind in the country. At the time of its approval, the test was designated for use only in medical POC settings such as doctors' offices, clinics and laboratories according to the Intended Use statement. This also meant that only trained healthcare professionals such as doctors, nurses and laboratory technicians were permitted to perform the test. INSTI is successfully used in traditional and non-traditional testing models worldwide due to its fast, flexible procedure, accuracy and ability to detect HIV as early as 21-22 days post-infection.

Convenient, accessible HIV testing is increasingly important in Canada amid reports that HIV is on the rise. An estimated **14% of people living with HIV in Canada are undiagnosed**, which represents 9,090 individuals who are not aware of their status. Populations who may be most at-risk include people who live in remote communities, men who have sex with men, people of African and Caribbean background, Indigenous peoples (First Nations, Metis and Inuit), people who use intravenous drugs, and at-risk youth and women.

INSTI HIV POC Test: Opportunities for front-line community-based sector to “Bring the test to the people”



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Reaching the Undiagnosed with HIV: 9,000-10,000 People

TARGETED/STRATEGIC IMPLEMENTATION – BEYOND 95% 3-Year Plan to reach >95% Diagnosed: min 1.5M Tests Required

<u>Type of Testing</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>
Venous Blood Draw	1.5M	1.5M	1.5M
Dried Blood Spots	10K	10K	10K
Existing POC	60K	60K	60K
<u>Additional Tests Required</u>			
POC tests	80K	100K	250K
Self-test / home testing	20K	300K	750K
Multiplex POC testing*	2K	10K	50K
TOTAL	1.67M	1.97M	2.57M

(2019: Baseline 1.61 million/yr)

K=1,000; M=Million. *Multiplex POC (HIV/syphilis, HIV/HCV) – amount would lower single POC tests required



If you can not measure it,
you can not improve it.

Lord Kelvin

quotezfancy



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INDICATORS TO BE TRACKED FOR HIVST INCLUDE:

- Number of HIVST kits delivered and to whom
- Proportion of self-testers choosing different deliver and follow-up options
- Proportion of self-testers who are 1st time testers
- Change in proportion of key population members who have ever been tested for HIV
- Proportion of self-testers linked to confirmatory testing
- Proportion of self-testers enrolled in care
- Proportion of self-testers initiates on ART



Health economics of targeted and responsive testing in Canada

Conduct economic evaluation (including both cost-effectiveness and cost-utility analysis) of HIV testing strategies from the perspectives of Canada's health care system and society. Simulate the cost, value for money and affordability of innovative testing in Canada based on best-practice guidelines.

- 1. Micro-costing studies of innovative testing:** Estimate and compare unit cost (per individual) of each testing strategy (HIVST, DBS, POC and Pharmacy-based STBBI). Conduct empirical costing study from a societal perspective and estimate the start-up, scale-up and implementation costs (e.g., staff training level and time, travel costs) and estimating unit cost of each resource from diagnosis through to linkage to care / treatment initiation.
- 2. Economic evaluations:** Evaluate the potential impact of testing strategies on patterns of HIV, HCV, or STBBI, new diagnoses, and linkages to care.
- 3. Budget impact analyses:** Develop budget impact models to estimate costs of implementing each testing strategy.



Brazil – Reduced HIV undiagnosed: 31% to 14% in 3-4 years

The Ministry of Health in Brazil to distribute HIVST kits for free

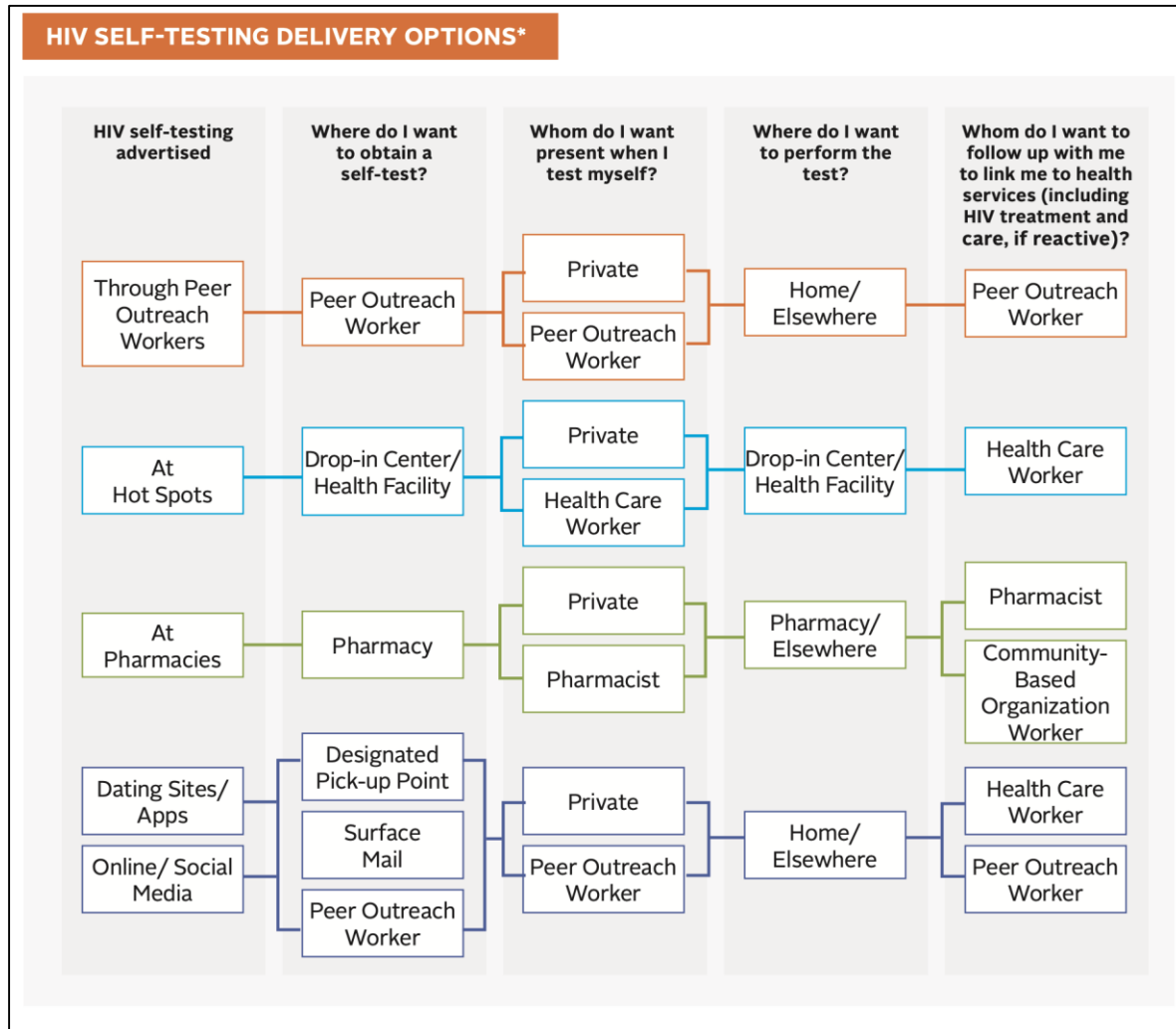
As of January 2019, the 'Sistema Unico de Saúde' (SUS) will offer, free of charge, a self-test for HIV diagnosis. Currently, the self-test is only sold in private pharmacies.

With the distribution in the public network, citizens will be able to take the self-test in the Basic Health Units (UBS), collect the sample itself (oral fluid or blood) and report their result. According to the Ministry of Health, the self-test will increase the autonomy of the individual, decentralize services and create demand for HIV testing among those not reached by the services or who need to be tested more frequently due to continuous exposure to risk.

More people will have access to diagnosis, increasing the reach of free treatment provision, as there will be 400 000 self-tests distributed.



The Pragmatics: HIV Self-Testing – Wide Range of Delivery Options



Courtesy of WHO



The Pragmatics: HIV Self-Testing – Support Tools

Table 2.3. Support tools for directly assisted and unassisted HIVST approaches

Support tools	Directly assisted	Unassisted
Brief in-person, one-on-one or group demonstrations on how to correctly use the kit and how to interpret the results	✓	
Internet-based, virtual or social media demonstrations on how to correctly use the kit and how to interpret the results	✓	✓
In-person assistance during self-testing procedure	✓	
Instructions for use: <ul style="list-style-type: none"> • Pictorial/written • Brochures or flyers that include information on local HIV services and contact details, for example, health clinic, 24hr hotline • Multimedia instructions 	✓	✓
Remote support via telephone, social media, text message, QR code, Internet-based or mobile messaging applications	✓	✓

Courtesy of WHO



HIV Self-Testing – Potential Linkage Strategies / M&E

Box 2.5. Summary of linkage strategies following HIV self-testing

Proactive, community-based follow-up by peer and/or outreach workers (in-person or via telephone/text message/social messaging platforms). Particularly in instances where trained community-based workers are responsible for HIV self-testing (HIVST) kit distribution, these workers can offer follow-up and additional post-test counselling, as well as assistance and/or accompanied referral to confirmatory testing services.

Home-based treatment assessment and initiation, with support and active follow-up through community-based networks. This approach has proven to be an effective way to support linkage to care in Malawi among the general population, including young people (10,60). The same approach has been used effectively among key populations in Viet Nam (55).

Brochures and flyers distributed together with HIVST kits, containing information on HIV testing services (HTS) and HIV prevention, treatment and care, as well as information on other diseases such as tuberculosis, bacterial sexually transmitted infections and viral hepatitis.

Telephone hotlines that users call before or after self-testing to obtain psychosocial and/or technical support can also provide referrals and linkage to HTS and other HIV services, as well as to nonmedical services such as legal support and violence support programmes.

Mobile phone text messages services can provide information, reminders, videos and messages that encourage linkage following HIVST.

Internet- and computer-based programmes and applications can provide linkage information in a variety of ways. Some approaches used to date have included live, online two-way text, audio or video counselling services and programmes that offer step-by-step instructions on what to do following a reactive self-test result.

Vouchers, coupons or rebates may facilitate linkage, particularly among populations facing structural barriers to accessing services, such as long distance and costly transportation.

Appointment cards and referral slips given to clients may facilitate linkage by including the day and time of an appointment or the name and phone number of a contact person and facility where services can be sought.

Couples and partner HIVST can promote linkage in the way demonstrated by a study in Kenya, where women delivered HIVST kits to their male partners, who then linked to care (18).

Box 2.6. Summary of monitoring and reporting tools

Monitoring and analysis of calls to HIV self-testing (HIVST) hotlines and text message services, including pictures of self-test results that are shared, which can be used to estimate the number of reactive test results and identify reports of test kit failures, adverse events or social harm.

Community-based surveillance systems and household/population-based surveys, health impact assessments and behavioural surveys can be modified to include HIVST, by collecting data not only on the uptake of HIV testing but also on the mode of testing in order to be able to assess what proportion of all diagnoses are identified through HIVST and record instances of social harm and adverse events.

Site-level and facility-level logbooks/testing registers can be modified to include HIVST, for example by noting if clients have self-tested before attending an HIV testing service facility and recording the reported self-test result. These registers can also be used to monitor linkage to prevention, treatment and care.

Internet and mobile phone surveys and tools can be used to encourage users to provide feedback on their experiences, including test kit failures and social harm or adverse events.

Existing post-market surveillance systems can be adapted to identify and report on problems related to the rapid diagnostic tests used for HIVST.

E-readers and mobile applications that assist users in interpreting self-test results can be linked to health information systems. Thereafter, test results or other patient information and health outcomes can be sent electronically to facilities that monitor the impact of the HIVST programme and the performance of HIVST kits used by self-testers.

Financial or in-kind incentives can be utilized to encourage users to report and share information about their HIV self-testing experience.

Courtesy of WHO



HIV Self-Testing – Countries authorized for use, sale and distribution



Canada – Listed as “Under Development”



Awareness Campaigns in US – Who should get tested? How often? Where?

Who Should Get Tested?

Learn About HIV Testing
The only way to know for sure whether you have HIV is to get tested. CDC recommends that everyone between the ages of 13 and 64 get tested for HIV at least once as part of routine health care.

KNOW YOUR STATUS
Knowing your HIV status helps you make decisions to prevent getting or transmitting HIV.

There are many places to get an HIV test
Find one near you: [Locator.HIV.gov](#)

Too Many People Living with HIV in the U.S. Don't Know It

Should You Get Tested for HIV?
Everyone between the ages of 13 and 64 should get tested for HIV at least once. If your behavior puts you at risk after you are tested, you should think about being tested again. Some people at higher risk should get tested more often.

Learn About HIV Testing

Where Can You Get Tested for HIV?

You can get an HIV test at many places:

- Your health care provider's office
- Health clinics or community health centers
- STD or sexual health clinics
- Your local health department
- Family planning clinics
- VA medical centers
- Substance abuse prevention or treatment programs

Many pharmacies and some community-based organizations also offer HIV testing.

HIV testing is covered by health insurance without a co-pay, as required by the Affordable Care Act. If you do not have health insurance, some testing sites may offer free tests.

These places can connect you to HIV care and treatment if you test positive or can discuss the best HIV prevention options for you if you test negative.

You can also buy a home testing kit at a pharmacy or online.

How Do I Find HIV Testing Sites Near Me?

Find an HIV test site near you by using the HIV.gov HIV services locator:

GET TESTED, FIND SERVICES.

Enter City, State/ZIP

For more information on this widget, please visit [HIV.gov](#)

SEARCH | SHARE | HELP

GET TESTED FOR HIV...
CDC recommends that everyone between the ages of 13 and 64 get tested at least once. People with certain risk factors should get tested more often.

MORE FROM HIV.GOV

THERE ARE MANY PLACES TO GET AN HIV TEST
Find one near you: [Locator.HIV.gov](#)

Too Many People Living with HIV in the U.S. Don't Know It

Secretary Azar Addresses CDC's National HIV Prevention Conference

GET TESTED FOR HIV...

CDC recommends that **everyone** between the ages of 13 and 64 get tested **at least once**.

People with certain risk factors should get tested more often.

Find an HIV testing site near you: [Locator.HIV.gov](#)

<https://click.get.hhs.gov/?qs=7b4fa4a56c7aa0a0108e7cb0a1b421bf51be7b1e0c37441b8deb96d70368c80d05e96b3d1d186091779a64c403f9b0823>

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