# IX INTERNATIONAL WORKSHOP

**HIV Self-Testing** 

Brasilia, DF, BRAZIL September 3, 2019

Sean B. Rourke, Ph.D., FCAHS Scientist, Centre for Urban Health Solutions Li Ka Shing Knowledge Institute of St. Michael's Hospital Professor of Psychiatry, University of Toronto Director, CIHR Centre for REACH in HIV 3.0 and CIHR CBR Collaborative Centre

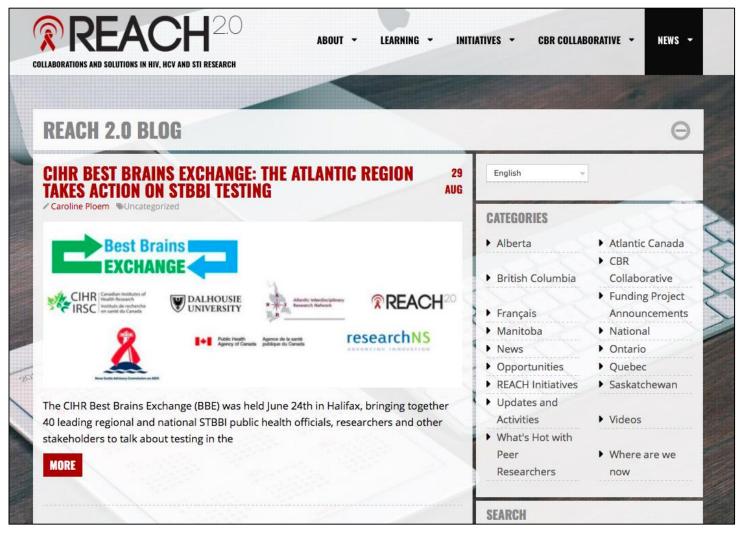


St. Michael's

Inspired Care. Inspiring Science.

**Centre for Urban Health Solutions** 

## CIHR Centre for REACH 3.0 – National Network / Pragmatic Solutions for HIV





# **CANFAR National Working Group**





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

(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 target" (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 events.

#### How is Canada Doing?

It is estimated that there are 63,110 people living with HIV in Canada,¹ but only 86% of those are diagnosed (1"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 ( $2^{nd}$  90 target), and of those, 91% have suppressed viral load ( $3^{nd}$  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)\*. All of these people are not benefitting 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?



People living with HIV in Canada who remain undiagnosed



People diagnosed who are not on treatment



3,720

People diagnosed and on treatment who have not achieved viral suppression

23,150

Page 2 | Ending the HIV Epidemic in Canada in Five Years



## Ending HIV Epidemic in Canada – Main actions



#### Goal I - Increase Prevention

#### Within Five Years, Dramatically Reduce New HIV Infections

from > 2,100 to < 500 per annum

This would be a major step in ending the HIV epidemic in Canada, where new cases would be rare events.

#### The Challenges

Certain populations continue to have unacceptably high incidence rates of HIV (and many of these populations intersect with one another, or can have multiple factors of risk).

It is concerning that Indigenous people have incidence rates four times higher than non-Indigenous people; black people of African and Caribbean background living in Canada have incidence rates six times higher than non-black people; men who have sex with men have rates 131 times higher than been there men; and people who inject drugs have rates 59 times higher than people who do not inject drugs. We know that we need more testing and prevention efforts, and we need to eliminate the structural barriers that prevent access to the information, tools and supports people need to manage their health.

Despite great advances in testing technology, including the development of highly reliable self-testing options, the rates of HIV testing have not changed appreciably for all priority populations in recent years. We do not have point-of-care testing widely accessible throughout Canada, nor is self-testing yet available.

Our prevention messages and strategies have not kept pace with new scientific evidence (e.g. PrEP, PEP, U=U, TasP) and they do not reach all of those who are at risk, or the general public. Compared to other countries, Canada has not made it easy for people at "high risk" for HIV to access PrEP and PEP.

#### The Solutions

- Engage affected communities and the general public about new prevention science and technologies – everyone should know enough about HIV to keep them from acquiring the virus;
- Increase health promotion messages and campaigns to promote U=U and TasP, and empower people living with HIV to play a major lead role in these prevention efforts;
- Implement and scale-up evidence-based combination prevention efforts (including PrEP and PEP) that support sexual health and well-being, and that are tailored to support different priority populations' needs and risks;
- Ensure that there is 100% coverage and access to antiretroviral medications for prevention (PrEP and PEP) and treatment.
- Increase access to harm reduction supplies and services including condoms and sterile drug use equipment;
- Address structural barriers to health and wellness, such as poverty, unstable housing, mental health and addiction issues, and racism, as well as other forms of discrimination, that can put people at risk of acquiring HIV.

#### Definitions

#### PrEP

#### (Pre-Exposure Prophylaxis)

Involves an oral pill of antiretroviral medications that, when used correctly (consistently or on demand) by someone who is HIV-negative, works as a highly effective strategy for reducing the possibility of HIV transmission.

#### PEP

#### (Post-Exposure Prophylaxis)

Involves starting a 28-day regime of oral pills within 72 hours of potential exposure to HIV, to prevent HIV from taking root and spreading throughout the body.

#### U=U

Undetectable = untransmittable.

#### TasP

#### (Treatment as Prevention)

Refers to the use of antiretroviral medications, specifically their ability to achieve and maintain an undetectable viral load, as a transmission prevention method.



#### Goal II - Increase Testing

Within Five Years, Increase the Proportion of People Living with HIV Who Are Diagnosed to > 95%

#### The Challenges

Over 9,000 people in Canada do not know they are infected with HIV, representing 14% of the people in Canada living with HIV.<sup>1</sup>

To reach or exceed the UNAIDS target of 90% of people living with HIV diagnosed, we must dramatically expand our testing efforts to reach as early as possible those who are infected, and reduce number of undiagnosed to less than 5%. Currently, there are few local, regional or national campaigns to raise awareness about HIV risk, or the significant health benefits of testing and antiretroviral treatment for care and for prevention.

#### The Solutions

- Normalize HIV testing with other sexually transmitted and bloodborne infections (STBBI) testing;
- Increase awareness and use of culturally safe, trauma-informed, and sex-positive social media and other promotional technologies and campaigns to increase access to (and benefits of) HIV testing;
- Increase availability and access to HIV point-of-care testing by trained health care and community providers at no out-of-pocket cost - in health care centres, community health centres, communitybased organizations, and pharmacies; and make the tests available where people live and can access them to support their sexual health and well-being;
- Provide wide-spread and easy access to accurate and affordable self-testing options sold in pharmacies;
- Work with public health officials, front-line providers and priority
  populations to expand client-centred HIV testing options and
  approaches that are innovative, pragmatic and evidence-based, and
  which includes peer-led programs where appropriate;
- Work with public health officials and leaders from priority
  populations to establish and implement appropriate, evidencebased targets for testing frequency that are responsive to
  individual need and sexual risk:
- 7. Implement evidence-based, culturally safe and equity-informed interventions to quickly link those who are newly diagnosed to care.





- 86% Current
- 9% Goal
  - 5% Remainder

**9,090 people** living with HIV in Canada remain undiagnosed.<sup>1</sup>



# Context / Access Really Matters – and Personal Choice

# 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





# POC and Self-Testing - We have the evidence we can act on:

#### Ease of use of HIV Self-Tests





## Widespread support for POC / HIV Self-Testing





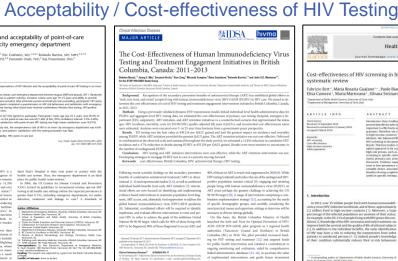


## Promoting testing interventions: Reviews













St. Michael's

## We have the knowledge; We have the tools – We know:

- POC testing and self-testing / home testing can dramatically increase rates of HIV testing and significantly reduce # of those undiagnosed
- PrEP and PEP can dramatically reduce chance of HIV infection for those at high risk, or for those who have had high-risk exposure to HIV
- Treatment as Prevention (TasP) works
- U=U; Those living with HIV who are on ART for at least 6 months and who have undetectable levels of virus in their blood cannot transmit HIV
- Efforts to help people living with HIV to have access to ARVs, be linked and retained in care work and are essential for optimal health and wellbeing
- <u>From work outside Canada</u>: Most G7 countries have dramatically scaled up testing, prevention, and access to and support for treatment – with very progressive results



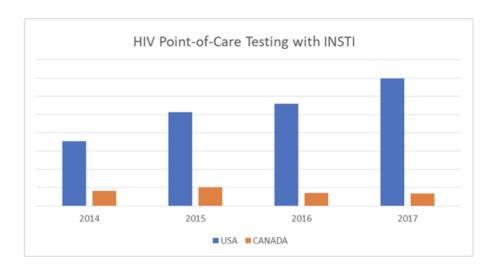
# Canada has been losing ground with POC testing



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



# HIV Self-Testing – The Pragmatics



Dr. John Kim - National HIV/AIDS Labs, NML

\*\* and OBSTACLES 05 – Leadership, Partnerships and Action





## **HIV/AIDS**



Number of countries adopting HIV selftesting policies rises sharply 25 July 2017 | Geneva 48 40 16 2017 2017 2016 Dr. John Kim - National HIV/AIDS Labs, NML



### I. Bringing New HIV and STBBI tests to Market in Canada

## Build private-public partnerships with:

(a) bioLytical Laboratories and OraSure to support the applications for investigational testing authorization (ITA) to Health Canada for medical device approval to get HIV self-tests to marketplace in Canada. Data is needed from 1,000 participants on accuracy, usability and acceptance of HIV self-tests. INSTI Self-Test study launched Aug 22<sup>nd</sup>, 2019 (Rourke Lead).

Discussions underway with OraSure to bring both HIV and HCV selftest to Canadian market.

(a) BC Centre for Disease Control to enable and support industry to conduct assay development and validation of STBBI tests (to start - bioLytical will be working with BC-CDC on HCV and syphilis POC tests).

Additional partnerships with industry partners are in development / beingexplored.





# II. HIV SELF-TESTING IMPLEMENTATION AND LINKAGE TO CARE

Major aim is to evaluate the impact of an HIV self-testing strategy on access, detection of new HIV infections, and linkages to counselling and care (using innovative App technology) in 3,000 people who are at-risk and those undiagnosed presenting to test for HIV in community and outreach clinics, spread across 5-6 provinces.

There will be two different supervised HIV self-testing strategies (service delivery models) evaluated and the preferences for oral vs blood-based self-tests.

Studies will be led by Dr. Pant Pai and her team at McGill University





# Our 1<sup>st</sup> Self-Test Study – Launched Aug, 22, 2019

# Study to Evaluate the Accuracy, Usability and Readability of the INSTI HIV Self Test Performed by Observed Intended Users in Canada

- To evaluate the device performance i.e. sensitivity, specificity, positive and negative percent agreement, compared to laboratory reference testing (N= 1,000).
- 2. To document if intended users (non-professional and inexperienced in HIV self-testing), can successfully perform the steps to use the INSTI Self-Test device, without product familiarization.
- To document if intended users (non-professional and inexperienced in HIV self-testing) can successfully interpret contrived strong positive, weak positive, negative and a range of invalid results (n=400).





# Our 1<sup>st</sup> Self-Test Study – Launched Aug, 22, 2019

# **Device Accuracy:**

- Compare the results of observed INSTI ST obtained and interpreted by intended users (N= 1,000) in simulated intended use settings to results of licensed laboratory-based Comparator Methods (CM) i.e. HIV Ag/Ab combo test and confirmatory tests for positive confirmation performed by laboratory professionals.
- A minimum of 3 geographically distinct Canadian sites: Study has started in Ontario, and Quebec, Manitoba, Saskatchewan, British Columbia will come on-line in September / October.
- The self test portion of the study includes recruitment of subjects who
  have consented to be tested for HIV per the study site's standard of
  care procedures (POC sites).





# HIV Testing and Diagnosis in Canada



Canadian Population: 37 million

**2016 Incidence:** 6.0 per 100,000 people (range 3.3-8.7/100,000)

Government of Canada 2030 Goal: 0.6 per 100,000 people

**Number of Tests:** Annual HIV diagnostic tests in Canada = 1.5-1.7 million\* \*includes 59,000 INSTI POC tests in 2018 (our only POCT approved in Canada)

To end the HIV Epidemic in Canada – How many HIV tests are required to reach those who need them??



# Reaching the Undiagnosed with HIV – 10,000 People

# **IMPLEMENTATION / EXECUTION** (Baseline 1.5 million)

Type of Testing	<u>2020</u>	<u>2021</u>	<u>2022</u>
Venous Blood Draw	1.5M	1.5M	1.5M
Dried Blood Spots	5K	5K	5K
POC (2-3 tests)	125K	750K	1.5M
Self-Testing (2 tests)	125K	750K	1.5M
Multiplex	?	?	?
TOTAL	1.755M	3.05M	4.55M

K=1,000; M=Million





## Testing / Reaching the Undiagnosed - Website/Portal & Mobile App

## Website Functionality:

- Houses all information about campaign with the who, what, when, where and how answered effectively
- Site will have all HIV testing info and tailored where appropriate for priority populations – with links to trained peer navigators (with secure linkages and modes for communication)

## APP Functionality: Android / IOS

- Links clients to HIV testing locations / resources and trained peer navigators
- Order HIV self-test kits on-line (have subsidized programs)
- Provides immediate access to all Q&A associated with HIV testing
- Ability to link clients (securely and confidentially) to care services / counselors
- Access to peer navigators to provide knowledge and support for access to test and linkages
- Track testing patterns for epi surveillance and access/responsiveness







# **Execution** – Once Approved in early 2020

- 1. Procurement / Bulk buying
- 2. Cost Building private-public partnerships for testing AND linkages to care (with access to PrEP and ARVs)
- Distribution (a) Community-based AIDS service organizations – peer workers; (b) Community health centres; (c) Website / online; (d) Pharmacies
- 4. Education and awareness campaigns needed
- 5. Surveillance + connections with labs
- 6. Monitoring and evaluation



