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CIHR Pan-Canadian Network for HIV and STBBI Clinical Trials Research

Réseau pancanadien pour des essais cliniques sur le VIH et autres ITSS

Spring meeting notes

April 2026

CIHR Pan-Canadian Network for HIV and STBBI Clinical Trials Research

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info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

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DAY 1

Opening Remarks

Dr. Klein opened the meeting by welcoming all attendees, taking a particular moment for our special guests.

City of Winnipeg is located on Treaty One Territory, the traditional lands of the Anishinaabeg, Ininew, Oji-Cree, Dene, and Dakota, and is the birthplace and heart of the Red River Metis homeland. Recognized pioneer in HIV education for HIV education, Albert McLeod, spoke about the importance of respecting natural systems, deductive reasoning, and honouring the knowledge of the elders. “We survived”.

Klein reflected on the first two years of progress, where the first year was moving from developing structure and procedure, and now we can begin putting projects into action. This action has included:

- Three proactive Network meetings in a year
- Developing an LA-PrEP Working Group
- Fostering the Think Tanks as incubators
- Support regions and build capacity
- Growing community involvement through the CAC and CLT for multi-disciplinary study review and the Community Science Champion Program
- Growing the Indigenous Guidance Circle and building out our IDEA Think Tank for handling other topics of diversity, equity, and inclusion.

Prairies Regional Focus

Presented by: Cara Spence and Souradet Shaw
Spence introduced the full Prairies Regional Team, taking time to introduce Erin Walling as their new Project Manager.

Host Province Highlight

In 202-2024, there’s been a 230% increase in the number of new people diagnosed with HIV. In addition to the issues of rising HIV rates, chlamydia was the most common infection identified through testing in 2025.

Research Priorities

- Absolute top priority: HIV infections
- Co-infections, because HIV does not hang out alone

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- STI prevention and treatment
- Implementation science
- Harm reduction
    - The Saskatchewan harm reduction budget has been cut, and it's a "gaping wound" leading to a high level of deaths due to drug overdoses

SPIKE Objectives

Strengthening Prairies Integrated Knowledge Exchange (SPIKE) is a Prairies-focused initiative meant to address the region's specific issues. Its goals are to:

1. Collect, develop, and share resources and best practices for conducting equitable clinical trials for PWLLE
2. Develop synchronous and asynchronous mentoring platforms to integrate trainees, people with lived and living experiences, researchers, clinicians, and community-based service organizations
3. Develop iKT/KT/KMb experiential learning activities, products, and outcomes from the Prairies region and share throughout the CTN+ network

SPIKE Workplan

- 12 full 1-year immersive training triads across Manitoba, Saskatchewan, and Alberta. The team will develop triads of researchers, trialists, and clinicians to work with community workers
- Engage community members in clinical trials learning
- Increase clinical trial capacity

What Have We Done?

- Hired a regional project manager
- Posted an RN position in Prince Albert for PrEP
- Actively recruiting a coordinator/PDF for the SPIKE Network
- Community engagement activities (establishing connections with pharmacies, prescribers, communities, CBOs, industry)
- Engagement with the Indigenous Guidance Council (IGC)
    - Noreen Reed is a member of the IGC and ensures the regional team's engagement is genuine and serious.
- Curriculum development (SPIKE)

Study CTN 316: The Aspiring Study

Assessing the use of aspirin in reducing the number of HIV target cells in the genital tract of female sex workers in Nairobi, Kenya, to determine if fewer target cells would reduce HIV risk.

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- Study complete, analysis currently underway
- PI: Keith Fowke

Indigenizing Epidemiology: Examining the Impact of Canada's First Indigenous-Led Safer Consumption Site in Winnipeg, Manitoba

Winnipeg is/was the only province without a safe consumption site. There has been pushback due to nimbyism, colonialism, racism, and other complaints. The goal is to document the impact of Manitoba's first safer consumption site on substance use outcomes in Winnipeg's inner-city.

- Did not receive a CIHR grant but received Bridge Funding
- Composed of 15 people with lived/living experience
- PI: Souradet Shaw

Next Steps:

- Develop a master protocol for community partnerships and IGC engagement
- Determine how the CLT and IGC can be more connected and consulted as part of the Prairie Hub
- Connect MB peer support workers with the SK network
- Establish capacity building activities

Regional Outreach

- Academic researchers in each province are:
  Manitoba: 7
  Saskatchewan: 9
  Alberta: 11
- Community researchers: 3
- Which sites are interested in hosting clinical trials?
  Saskatoon, Regina, Prince Albert, Winnipeg, Edmonton, and on-reserve communities
- Folasade is represented on the CLT and provides guidance to the Prairies region
- Noreen provides reciprocal exchange with the IGC

Identified Priorities:

- Expanding and developing HIV prevention strategies, including access to PrEP, with a focus on IVDU *and* women
- Improving the prevention, testing, and treatment of syphilis and other STBBIs
- Enhancing cultural, social, and peer supports
- Improving responsive care and reducing stigma
- Facilitating community engagement, education, and uptake of evidence-based approaches

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What Activities Do You Have Planned for the Next Six Months?

- Establish PrEP studies and trials
- Postdoc application to reduce stigma and enhance trauma- informed and culturally responsive care modules
- Hire a research coordinator in Manitoba for the SPIKE hub
- Hire a postdoc in Manitoba to help with SPIKE applications and mentorship
- SPIKE/IMPACT meeting in Manitoba in April and June to co-develop expectations of community members who want to be involved in clinical trials
- Altogether 4IDEAS (NCCID) is hosting an upcoming CME-accredited training for prescribers on PrEP on April 27th

Major Milestones Achieved/Most Important Updates:

- Submitted several funding applications
- Hired a Project Manager
- Posted for a SPIKE hub coordinator
- Working with inner-city clinics and pharmacies, shelters, and CBOs for capacity building
- Curriculum and event planning
- Phase 2 activities are underway

Community-Based Testing for STBBIs

Presented by: Tracy Taylor (from the National Microbiology Laboratory Branch)

Why Community-Based Testing?

The centralized laboratory model for STBBI diagnostic testing is failing to reach the undiagnosed, with progress to 95-95-95 stalled since 2020. Access to diagnostic testing, and in turn linkage-to-care, remains inequitable due to geographic isolation, stigma, racism, and testing hesitancy.

Community-Based Testing (CBT) is recognized as a powerful public health tool to address persistent gaps in access to diagnostics for underserved populations. Taylor's lab (led by Dr. John Kim) started with the Dry Blood Spot Initiative around 5 years ago, paving the way for community-based testing and community-led initiatives with the collection of dried blood spots, and there are numerous advantages to this system.

Advantages of Dry Blood Spot Testing:

- Does not require a healthcare professional to collect samples
- There are no transportation of dangerous goods requirements for shipping this (a typical

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barrier is getting samples to the lab), meaning that DBS can be put in an envelope and mailed to the provincial lab.
- Labs can do lots of different testing using one dry blood spot or one card with multiple spots on it

Disadvantages of Dry Blood Spot Testing:

- There is still a turnaround time for results
- There is a slight reduction in the sensitivity for testing

Empowering Communities:

The team has developed a training program to bring the collection of dry blood spots to communities. This is something that John Kim's lab has been working on for a number of years now with communities to provide the training that they need to collect those dry blood spots.

There is a push for peer-led collection, and training is provided for the same. There are training modules and a validation of all the collection personnel to ensure that well-collected dried blood spots are submitted to the lab. In the last 5 to 6 years, the lab has engaged with close to 100 communities/sites for dry blood spot training, and over 500 people have received training on dry blood spot testing.

Structural Level Adoption of DBS:

The next step for DBS is to integrate it into the centralized system and have it become part of the processes and case definitions for various STBBIs in all the provinces. They are making that headway right now with the adoption of DBS.

COVID-19 Pandemic – A Catalyst for Change:

The COVID-19 pandemic was a significant catalyst for change for community-based testing. As part of the Northern, Remote, and Isolated (NRI) Initiative, the National Microbiology Lab worked collaboratively with Indigenous leadership, First Nation and Inuit health authorities, organizations, as well as provincial and territorial governments and Indigenous Services Canada to help build capacity to get that diagnostic testing in the community by the community members.

NML provided the laboratory and scientific expertise needed for:

- Clinical validation of assays
- Biosafety and risk assessments
- Training materials and virtual workshops for non-laboratory personnel
- Verification of equipment installation and testing operator training

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- External quality oversight through routine proficiency testing to ensure accurate, reliable diagnostic test results for COVID-19, Influenza, and RSV

CBT Technologies:

Cepheid GeneXpert:

- A device that simplifies and automates a confirmatory PCR-based test using plug-and-play cartridges
- Equivalent sensitivity and specificity to laboratory-based gold standard PCR tests
- Cartridges for a variety of different pathogens
- Tests take 30 to 90 minutes to run, depending on the cartridge type

Current Scope – STBBI Action Plan 2024-2030:

Post-pandemic, Tracy Taylor notes that the NRI Initiative has sun-setted a lot of the activities dedicated to respiratory testing, and is now refocused on STBBIs and the STBBI action plan because it became clear post pandemic that community-based testing was needed to address persistent gaps in access to diagnostics, and the team know they could make meaningful advancements towards priorities and objectives in the action plan, in particular with that second pillar for testing.

Core Pillars of the STBBI Action Plan:

Prevention, Testing, Initiation of Care and Treatment, Ongoing Care and Support, Enabling Environment.

STBBI CBT Toolbox:

The team is now working on their community-based testing toolbox, which includes DBS, rapid antibody screening tests and molecular confirmatory tests (e.g. GeneXpert).

Same-Day Test and Treat:

Focus on same-day testing and treating with non-invasive sample collection through finger-prick → Screening test for antibodies → Followed by a confirmatory test from the same finger stick on the GeneXpert → Confirm in 1.5 hours for HIV and STBBIs → Then report in a way that is cohesive with the standard case definition and reporting in all provinces and territories.

Community-Based Diagnostic Program:

What do we do? We lower barriers to testing!

- Support capacity building for decentralizing CBT
    - We support capacity for building decentralized testing by providing the laboratory and scientific expertise and knowledge sharing, and we do this through a number of

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training materials and workshops
    - Limited supply of equipment to build infrastructure (specifically GeneXpert)
    - Work with all levels of governance to develop processes for CBT
- Quality assurance specific for CBT: Adapting our international program to support domestic, community-based testing for STBBIs
    - Proficiency testing panels
    - Ongoing technical support

Implementation Support:

There are several steps to the implementation process, and they're trying to develop a sustainable way to distribute the equipment. They are working with different groups to support everyone in building capacity in their communities, acquiring the equipment, providing training, and facilitating test operator certification components. They also provide the materials needed to certify test operators and verify the device. Once the community or site has completed the first four steps, they're considered to have achieved functional status and can begin clinical testing. Lastly, they also provide ongoing site support through their quasi-external quality assurance programming.

CBT in Action: Breaking Down Barriers

Working with the Manitoba Harm Reduction Network (MHRN)

- Community-led, peer-led initiative
- MHRN staff from across Manitoba gathered in Winnipeg for a 3-day training workshop in November 2025
- Hands-on training on the complete CBT toolbox: DBS, Rapid Tests, GeneXpert
- Breakout groups to discuss implementation barriers and solutions
- Planning for a community testing event in Swan River, Manitoba, held at the end of March 2026.
    - Massive organizational undertaking that's been spearheaded by passionate community leaders who are dedicated to improving the health and lives of their community members
    - Collaboration between MHRN, community leadership, provincial health officials, doctors, nurses, pharmacists, and other health and social service providers.
    - In-kind contributions for equipment, from Reach Nexus, test cartridges, and technical support from the lab
    - Multi-faceted services (e.g. eye tests and hearing tests) and fun activities (e.g. clothing swaps, manicures and pedicures, haircuts) offered in conjunction with peer-led HCV testing services attracted almost 100 people each day to visits

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CBT Future:

Lowering barriers to testing:

- Technology supports lab-quality results from the community for a range of infectious diseases
- An individual does not have to be a healthcare or laboratory professional to collect these samples and run the tests
- Increases accessibility to testing in a safe, culturally inclusive settings – reduces stigma and testing hesitancy
- Screening and confirmatory testing can be done the same day – improving linkage to treatment and preventative measures

Integration of CBT into centralized diagnostics pathways:

- Acceptance of test results for the positive case definition
- Reporting pathways for results
- Standards for test operators
- External quality assurance

Questions, Answers, and Feedback

Question: We know the machines are expensive, but how much do the cartridges cost?

- **Answer:** The cartridges have different prices. There is a dual cartridge for chlamydia and gonorrhea that's about $30 per test. The hepatitis C cartridge (for finger stick) and the HIV viral load test cartridge are both ~$60. The diagnostic HIV test cartridge (currently not licensed in Canada) is more expensive at about $80.

Question: What is the viral load for HIV in DBTS tests?

- **Answer:** The viral load test is a quantitative plasma-based test, and the finger stick is a qualitative (yes/no) test. For the GeneXpert HIV and HCV tests, it is about 40-50 copies per millilitre. For the dry blood spot test, the viral load is 8,000 for HIV.

Question: How do you integrate DBS testing into the communities and these testing programs?

- **Answer:** The team are trying to integrate the testing program closely into the community. With DBS testing, it has been a very successful initiative because communities can collect the samples themselves and send them to the lab for testing. Peer-led collection has helped reduce the hesitancy with testing. With the next stage, they want to have the expert there in the community so the results can be given out within the hour and with the DBS sample

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sent to the provincial lab, which can be reported to the person's public health record.

Question: Who regulates and controls this test? Is this federally or provincially regulated?

- **Answer:** The test started with Health Canada authorization. There has been a spike in interest in applying this to community-based testing. The HIV one is not being Health Canada-approved yet, so the team has not been working so aggressively on it at the moment. However, they have always come around to working with the province to align with what the province wants. They are working to standardize those requirements, and Taylor would like to eventually see it at the national Level.

Question: The speaker wanted to confirm that Gonorrhea and chlamydia is urine based, and that the GeneXpert provides a cartridge that can test for multiple infections.

- **Answer**: The chlamydia-gonorrhea is a dual test, and the respiratory one is the other multi-test for COVID-19, the flu, and RSV.

Question: Surface antigen, antibodies, and core antibody are all showing promising results for Hep Delta antibody, as seen on a dry blood spot. Is Taylor familiar with that work, and is there some sort of cross-interaction?

- **Answer:** With GeneXpert we have very limited cartridges available. There is a Hep C cartridge that we're using for community testing, and the Hep B one is also showing promise.

Regional Team Breakout Groups

Members of the different regional teams split into groups to discuss regional strategies and priorities.

Setting the Stage for HBV Clinical Trials in Canada

Presented by: Carla Coffin

Background:

Chronic Hepatitis B (HBV) is a major international need. Most people get CHB through birth or small cuts during childhood. Usually asymptomatic-- only 10% of patients know they have CHB, as the only way to be diagnosed is by blood tests. People with HPV have a 25% lifetime risk of dying of liver cirrhosis. There is a wide disparity in vaccine access across Canada

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HBV Management:

- Vaccinating in Adolescence vs Childhood:
  There was an argument that there was waning immunity. However, recent research has found that the Hep B vaccine offers lifelong immunity and booster doses are not needed for most people.
- Antiviral therapy can reduce but does not eliminate the risk of liver disease and liver cancer.
- Simplified HBV management should follow this path:
  Screening → Vaccination → initial management → Treatment → Monitoring

Prepare for HBV Cure: 5x5x5 message

1. Test all adults for Hepatitis B with the triple panel:
   (HBsAg, Anti-HBc total, Anti-HBs)
2. Vaccinate all adults for HBV who are HBV triple panel negative
3. If HBV surface antigen positive - reflex HBV DNA quantitation and Hepatitis Delta antibody (if Delta antibody positive, reflex HDV RNA)
4. Treat all HBV-infected individuals who are HBV DNA-positive
5. Stage liver disease and start surveillance for liver cancer and other forms of liver disease

Recommendations for HVV Surveillance:

Monitoring for HCC is recommended even in patients on antiviral therapy because of the residual risk. Abdominal ultrasound and alpha fetoprotein (AFP) screening every 6 months are strongly recommended in the following patients with chronic infection:

1. All patients with cirrhosis, regardless of age (even those who have lost HBsAg)
2. Men aged 40 years or older
3. Women aged 50 or more
4. Individuals of African (Black) descent aged 30 years or older (due to the risk associated with certain African genotypes of HBV and environmental factors, including exposure to aflatoxin)
5. Family history of first-degree HCC (from age 40 or 10 years before the affected first-degree family member, whichever occurs first)
6. All patients co-infected with HIV (from 40 years of age)
7. All HBV/HDV co-infected individuals (from 40 years of age, or earlier if > F3
8. Risk calculators (i.e., REACH-B, PAGE-B, mPAGE-B) can be useful in supporting clinical practice and identifying patients who may benefit from HCC screening

Progress Towards a Hepatitis B Cure:

Viral elimination in the natural course of infection results from a robust and multi-specific T and B cell response that, however, is dysfunctional in chronically infected patients. Therefore,

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immunomodulatory therapies that strengthen the immune responses are an obvious approach trying to control HBV infection.

Our current treatment method is very good at "trimming the branches" of the infection but does not "remove the roots". Emerging anti-virals promise to change this. Recent findings, among others, drugs that stimulate the innate immune system or overcome CD8+ T cell exhaustion by checkpoint blockade, and transfer of HBV-specific engineered CD8+ T cells emerged as promising approaches. HBV-specific immunity is responsible for viral control, but also for immunopathogenesis. Thus, the development of immunomodulatory therapies is a difficult process on a thin line between viral control and excessive immunopathology. Some promising agents are under investigation.

Immunotherapies are currently being studied. However, to be successful, the patient needs to have an active immune system.

Drug	Mechanism	Development
Selgantolimod® RG7854 Bepivirosen*?	Toll-Like Receptor (TLR) Agonists (Induce Innate Immunity)	Phase 1/ 2 >> ?
NASVAC, GS-4774 HepT cell, VBI-2601, JNJ 64300536, Transgene	Therapeutic Vaccine (n=>20 candidates)	Phase 1 – 2 >>?
PDL-L1	Checkpoint Inhibitors (Restore CD8+ T cells)	Phase 1/2 – ? (unmasked DM)
Other	T cell receptor NOD2/RIG1 agonist	Phase 2 - ? (Inarigavir – Drug induced liver injury, death)

The two studies that have advanced the furthest are:

A. Bupiravision by GSK, which is an ASO that has been shown, compared to placebo, to have about a 9-10% greater chance of surface antigen loss or a functional cure. The Phase III studies will be read out in April, and it's showing a higher percentage, but the rest of the data is under embargo.

B. AusperBio is developing a treatment in China. They found that because of the chemistry of the ASO, their drug has a greater clinical benefit with higher chances of a functional cure being developed in their Phase II studies.

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Keep an eye on the Hep B Foundation Drug Watch page to keep up to date with drugs coming out.

HBV Cure Clinical Trials: Practical Tips

What can we do to organize ourselves in preparation for these clinical trials?

- Flexible hours for younger participants, full-time workers with 9-5 schedules.
- Not everyone with HBV gets started on anti-virals, but that is generally a requirement to be eligible for clinical trials. However, these are not universally covered by insurance, so this poses a financial barrier.
- Pre-screening database or registry. (For example: Track their markers, genotypes, ethnicity/background, etc. We do not want to continue misrepresenting Black/African genotypes.)

Clinical data can help you predict disease progression in patients. However, access to qHBsAg testing in Canada varies across different provinces:

- BC: Available at St. Paul's Hospital in Vancouver.
- Alberta: Available through clinical specialists through provincial laboratories.
- Quebec: Available at CHUM in Montreal.
- New Brunswick: Can send their samples to Quebec.
- Ontario: Only available routinely to specialists at the Toronto Liver Clinic; one-day turnaround.
- Budget considerations are more significant for less sparsely populated provinces and territories.

Is early treatment a catalyst for drug development? Because their T cells are more effective.

Questions, Answers, and Feedback:

Question: What does it really mean to work with someone who only speaks a language like Tagalog to get involved in a clinical trial with full informed consent?

- **Answer:** It is not easy. It requires long-term engagement and relationship building. Remember, however, patients can be and often are highly educated despite the difference in language, and can do the research themselves, so respect their ability to understand.

Question: When we're trying to think about future trials, how can the CTN+ help in terms of either identifying sites or developing a group that thinks about where these should be set, or should it get rolled into CanHepB?

- **Answer:** Absolutely, if we want to move forward and be ready for either what's coming or develop our own. CanHepB established all the data sharing agreements a decade ago, so we

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www.ctnplus.ca
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can house the data from multiple sites across the country without having to reinvent the wheel.

Question: Have you been thinking about cohort design and re-think design?

- **Answer:** Coffin was not a clinical trialist, so when it comes really deep into clinical trial design, she felt she was out of her depth, but broadly speaking, she agreed with the question asker.

Question: The speaker's colleague at UNSW Sydney just published a diagnostic accuracy study using the GeneXpert for HBV DNA, finger-stick point-of-care testing. Could you please share your thoughts on the value of novel diagnostics in the HPV space and how such a test could kind of fit and enhance existing initiatives?

- **Answer:** Coffin full thinks it's needed. There is one novel rapid diagnostic test that's been approved by the FDA, but not yet by Health Canada. Like, there is one that's…CTN Meeting - Delta B&C: approved, FDA approved, but not Health Canada approved, the rapid diagnostics that could be helpful. Since 40-60% of HBV cases are undiagnosed, more point-of-care testing or initiatives such as Liver Health Days, spot testing could catch Hep C, Hep B, and HIV all in one place. Alternatively, people could get kits themselves to do the testing. Point-of-care testing was involved with Action Hepatitis Canada, meaning we have platforms such as GeneXpert, and it would be interesting to see the opportunities to leverage that infrastructure for HBV DNA of care testing as we have new evidence coming in.

Think Tank Presentations of Concepts for Flagship Studies

Members from three of the existing Think Tanks gave presentations on flagship study concepts.

Prevention & Testing Think Tank: Implementing a minimal monitoring strategy for HIV Pre-exposure Prophylaxis (PrEP) amongst gay, bisexual, and other men who have sex with men (GBM) and Transgender women (TGW)

Presented by: Mark Hull

Study Overview:

Rates of HIV diagnoses continue to increase in GBM. We've had PrEP available for over 10 years, but uptake remains limited. Some of the barriers to uptake include growing bottlenecks and capacity issues in larger PrEP centres in urban areas. In smaller centres, people have limited access

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to clinicians because they are overwhelmed by the complexity of PrEP monitoring, or they cannot access laboratory services.

But at a larger scale, the PrEP landscape is shifting:

- The advent of long-acting modalities and the need to adapt clinical visits/monitoring strategies
- Changing risks of bacterial STIs with the proven concomitant use of doxycycline PEP
- Changing views regarding the appropriate frequency of STI testing
    - Guideline recommendations for Q3 monthly testing based on the US PrEP Demonstration Project data showing increased rates in STI if testing is delayed
    - This was pre-DoxyPEP
    - Data from places in Europe suggests that many STIs, like gonorrhea, may be transient, and we're just picking up completely asymptomatic and perhaps clinically meaningless cases.

Intervention:

- Evaluation of a minimal monitoring strategy for HIV PrEP and STI testing amongst stable GBM PrEP users
- Randomized to continued standard of care, Q3 monthly laboratory-based HIV, STI-testing and associated clinical visits for PrEP renewal
- Or an alternate monitoring schedule: Q6 monthly laboratory HIV/STI and PrEP visits, with home-based HIV and optional STI self-testing at the other Q3-month time points

Study Design:

Study type: Randomized trial

Multicentre: 6 PrEP clinics in Vancouver/Toronto.

Population: GBM/TGW stable on PrEP > 12 months, stable renal function

Sample size: A sample size of 440 individuals to see 10% difference between arms in treatment satisfaction

Randomization: 1:1 randomization

Blinding: Open-label

Comparator: Standard of care.

Study Intervention:

Component 1: Study questionnaires at baseline, week 24 and week 48. Evaluation of demographics, sexual behaviours, substance use, and use of Doxy PEP.

Main questionnaires:

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- Simplified Medication Adherence Questionnaire for PrEP
- Doxycycline Adherence Questionnaire (based on DISCO trial)
- Modified HIV Treatment Satisfaction Questionnaire (adapted for PrEP)
- PrEP Difficulty Scale
- Direct questions regarding preferences for monitoring strategy and self-reported clinical visits

Component 2: Longitudinal qualitative interviews

- Matched between both arms
- Conducted over 3 time points by community-based Peer interviewers supported by Community Based Research Centre (CBRC)
- Evaluating participant preferences (and changes over time) for PrEP monitoring, PrEP modalities, STI Testing, and home-based HIV testing

Objectives and Endpoints:

Primary Objectives:

- To determine the acceptability of a reduced monitoring schedule compared to standard of care monitoring in stable GBM/TGW PrEP users, as determined by measures of participant satisfaction (client-level outcomes)
- Evaluation of rates of actual clinical service utilization (planned and unplanned clinical appointments for PrEP/STI services)

Implementation outcomes: Acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration, sustainability

Service outcomes: Efficiency, safety, effectiveness, equity, patient-centeredness

Client outcomes: Satisfaction, function, symptomatology

Primary Endpoints for Satisfaction:

- Weeks 24 and 48 outcomes of the 10-point HIV Treatment Satisfaction Scale evaluating domains of control, convenience, flexibility, lifestyle fit and willingness to continue with the regimen
    - Allows comparison of current monitoring to experiences with prior approaches, which will be completed by those in the Min-Mon arm
- The validated PrEP Difficulties Scale includes domains focused on PrEP logistics (getting transport for lab appointments, returning for PrEP appointments, and getting refills), and these will be compared between arms
- As the final aspect of evaluating outcomes, we can ask some of these direct participant satisfaction questions based on standard clinical trial PRO-based questionnaires.

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- Clinical utilization endpoint: mean/median rates of clinical visits for PrEP or STI-related management between arms

Secondary Endpoints:

- Frequency of STI testing and outcomes over the study period to determine the proportion of individuals experiencing an STI, and incident rates (per 100 PY) of chlamydia, gonorrhea, and syphilis between arms

Exploratory outcomes: Qualitative thematic analysis of participant experiences

Methodology:

Anticipate 36 months to recruit sample size. All participants will be followed for 12 months.

Outcomes and Impact:

Main outcomes addressed:

- Can stable oral PrEP users undergo reduced monitoring intervals for HIV?
- Are home testing kits for HIV acceptable for PrEP users as a means of monitoring HIV?
- What is the current preferred testing frequency for STIs in PrEP users? The study will provide data regarding STI rates if Q6 monthly testing is undertaken, particularly for doxyPEP users, and in communities where doxyPEP use is prevalent.

Impact: Reduced service burden for collaborating clinics, increased PrEP services, and lead to trials of reduced monitoring in other populations.

Knowledge Translation: Publications and conferences, work with community partners (CBRC/HIM) to guide community webinars, social media, small groups and other discussions

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Questions, Answers, and Feedback:

Question: Health Canada has approved point-of-care testing for HIV, hepatitis C, and syphilis. What about chlamydia and gonorrhea, and how does that impact the tests you will use in this study??

- **Answer:** The research team will only be using HIV tests; people will not be getting syphilis tests at that point. Instead, they will administer one every 6 months. The rationale for that comes from the fact that point-of-care syphilis tests are harder to interpret in people who have had it before. Also, the data available from DISCO and the local syphilis rates show that the incidence rates are no longer high in GBM populations.

Question: Will you be building into the protocol self-testing for anyone who has symptoms of acute seroconversion? And will you have those folks break protocol and go for standard testing or supply additional self-test kits?

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- **Answer:** What the team has built in is that if people mess up their self-test kits, they have to go into the lab. The reason they did not stick to 6-month testing is that there's a lot of clinical nervousness around going more than 3 months without testing. [Mark name] think by selecting a group that has been adherent for a year, they should not anticipate seeing any HIV seroconversion; they can also build in an extra caution step, saying if you have symptoms suggesting seroconversion, the protocol can allow tests as well.

Question: Relevant to Quebec, pharmacists can now prescribe PrEP, which is great news for accessibility, but it seems likely that there will again be zero women getting prescribed PrEP. Are there plans to repeat this study for women?

- **Answer:** Moving our focus across urban and rural centres really opens up the demographic because, as we shift towards rural areas, we also start seeing more diverse audiences (outside of GBM). [Mark Name] does think there's a potential to incorporate women or even run a women-specific replicate study.

Cure & Immunotherapies Think Tank:
Patient perspectives on a Hep B Cure to inform future flagship clinical study

Presented by: Kritika Iyer

Introduction:

This study targets chronic hepatitis B virus infection. It uses a cross-sectional, questionnaire-based survey to understand how people living with HBV feel about a future cure and what treatments they would accept. The target population is adult patients with chronic Hepatitis B currently on effective antiviral therapy.

This study will provide patient-centred evidence about how people with HBC value a cure and what trade-offs they're willing to accept. It will also help set the foundation for and inform future clinical trials and flagship clinical trials.

HBV Globally and In Canada:

Over 200 million people are living with chronic HBV globally, with a mortality rate of 1.1 million people annually.

In Canada, the rates for HIV are slightly higher in males compared to females, and it is similar for HBV. A significant number of people who are infected are coming from China, Vietnam or the Philippines (which is reflective of the global burden data).

Study Overview:

The current standard of HBV care includes nucleoside analogs (NUCs) and Interferons (IFNs). However, these treatments have their limitations. They do not eradicate HBV and have to

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www.ctnplus.ca
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be taken lifelong. They can also impose financial, psychosocial and adherence burdens, while not fully eliminating the long-term risks of liver disease.

Recent advances have accelerated the development of novel therapeutic strategies for a functional cure. Examples include Bepirovision (from GSK), which is currently undergoing Phase 3 trials and announced a 9-10% functional cure rate in previous trials. Oscar Bio's AHB137, an antisense oligonuconucleotide has shown even higher rates of functional cure in their trials in China and is about to start Phase 2 trials in the rest of the world.

It is essential to understand the perspectives of patients for a cure and how to incorporate patient preferences early in therapeutic development.

Gap in the HBV Field of Research:

There is a gap in the HBV field of research when it comes to surveying patient perspectives on a cure. The presenter highlighted two studies: "The CanCURE Survey: Gender—Based Differences in HIV Cure Research Priorities" and "Willingness to participate and take risks in HIV cure research: Survey results from 400 people living with HIV in the US." This study aims to bridge the gap.

Objectives and Endpoints:

The primary objective would be to understand the perceived importance of discovering an HBV cure and participants' willingness to accept these cure therapies under different probabilities of success and routes of administration over a period of six months. Then they intend to describe these preferences across participant demographics and clinical characteristics.

The secondary objective of the study is to determine whether:

1. Adding potential benefits like reduced risk of liver cancer and liver failure increases participants' willingness to accept therapy
2. Are participants willing to accept certain side-effects or increased side-effects if the cure efficacy is high
3. Do participants identify other perceived benefits (e.g., reduction in social stigma) to the cure beyond the end of treatment
4. Participant demographics have a correlation to perceived importance of care and willingness to accept treatment.

Study Design Feasibility:

The Think Tank is proposing that this study be a multicentre one with the University of Calgary and the University of Ottawa participating. CanHepB Network will facilitate the survey distribution and physician participation.

Surveys by CanHepB:

CanHepB Network has conducted surveys similar to this one before:

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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1. **'Participant-reported outcomes and quality of life measures after Hep B Surface Antigen loss'**: They sought to understand patients' quality of life before and after surface antigen loss and found that the quality-of-life increases.
2. **'Impact of financial barriers and patient willingness to accept Antiviral therapy for chronic Hep B'**: They surveyed patients and physicians, with the former feeling that side effects were the important barrier, not cost and vice versa for physicians.

Study Design:

The study has a pretty broad inclusion criterion with a sample size of 100:

- Includes: Adults (18 and older) with a chronic HBV diagnosis who are currently on effective antiviral treatment and able to understand and complete the questionnaire.
- Excludes: Individuals under the age of 18 who are not on effective antivirals and are unable to complete the survey due to language barriers.

Methodology:

Intervention will be a cross-sectional questionnaire using Likert-scale items and scenario-based preference questions. Convenient sampling will be conducted, and patients will be asked to fill out the survey during routine clinic visits. The survey will take about 20 mins to complete, and recruitment will continue until the sample size is reached.

Expected Outcomes and Impact:

Outcomes:

- The team expects to generate patient-centred data on the acceptability of potential chronic HBV cure strategies.

Impact:

- Patient-centred insights that guide the development and design of future HBV cure strategies and clinical trials
- Ensure emerging therapies are aligned with patient preferences
- Improve trial feasibility, participant recruitment, adherence and successful translation of novel therapies and successful translation of novel therapies into clinical practice

Knowledge Mobilization:

- Disseminate results through publications, conference presentations, and partner with communities and individuals with lived experience to co-develop, interpret and share the findings in meaningful, accessible ways.
- They also intend to facilitate community-facing activities like workshops, webinars and forums.

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www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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Questions, Answers, and Feedback

Question: Have you considered a discrete choice experiment design, which can specifically help quantify trade-offs between different things like willingness to pay, willingness to accept different degrees of an outcome (like rates of side-effects or success)?

- **Answer:** I understand that there will be pros and cons with this approach, but yes, this is something that's worth considering.

Question: There is a wealth of literature on HIV cure and psychosocial issues, and we've learned there are dynamics beyond personal effects, different strategies or concerns– more altruistic things. Have those been included?

- **Answer:** Iyer was unsure if their study answers that question, but it's something they would definitely consider and look into.

Question: While going through considerable effort to reach out to people for survey responses, have you considered also tapping into the same people for clinical trial preparation by adding a pre-consent section to the survey?

- **Answer:** The team will discuss with their colleagues and decide how to proceed.

Treatment & Management Think Tank:
Supporting Health Aging in Older Adults Living with HIV in Canada: Multicentre adaptive platform trial for geriatric syndromes

Presented by: Alice Zhabokritsky

Introduction:

Study Overview:

- Background: The HIV Population is aging, and the majority of older adults with HIV experience geriatric syndromes like polypharmacy, falls, frailty, depression, and cognitive impairment, among others. These comorbidities also tend to occur earlier and more intensely (when compared to people not living with HIV), leading to loss of independence, lower quality of life and premature functional decline. The current HIV care models prioritize virologic suppression and management of individual comorbidities, but geriatric syndromes remain under-recognized and under-treated.
- Geriatric syndromes among CHANGE HIV participants at cohort entry (65+) have over 550 people recruited across Canada, and when they were assessed for geriatric syndromes, the

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

findings showed that only 15% had none, but a majority experienced one or more at the same time.

Proposed intervention and strategy:

- A national multicentre, pragmatic adaptive platform trial to evaluate targeted interventions for geriatric syndromes. It will comprise a flexible, efficient and patient-centred framework for studying multiple comorbidities, with an emphasis on embedding community prioritization, codesigned interventions, and centralized delivery to ensure relevance, scalability and equity. It will also be well-suited to HIV and aging, where individuals often experience multiple co-existing syndromes.
- The target population is older adults living with HIV across Canada, 50 and older

Objectives and Endpoints:

- **Primary objective:** To determine whether a geriatric syndrome-guided package of interventions can help improve the quality of life among older adults living with HIV.
- **Primary endpoint:** A change in medical outcomes study-HIV Health Survey (MOS-HIV 35-item scale) scores
- **Secondary objective:** To reduce the prevalence and severity of targeted geriatric syndromes, improve healthy aging, and evaluate the impact of interventions on inflammation and immune activation, as well as evaluate safety, feasibility, acceptability, and equity of implementation across diverse Canadian HIV care settings.
- **Secondary endpoints:** Measuring for changes in syndrome-specific outcomes (fall incidence, frailty scores), Healthy Aging Scores, biomarkers (e.g., CD4:CD8 ratio, CRP), safety measures, feasibility and acceptability of interventions, and the uptake of interventions across clinical sites (urban vs rural).

Study Design:

Design: Multicentre, pragmatic, adaptive platform trial

Multicentre: About 10 clinical sites across Canada to achieve representation across academic, community-based, urban, rural and remote settings

Population: Older adults living with HIV (50 and older) with one or more geriatric syndromes

Comparator: Older adults living with HIV with no geriatric syndromes

Sample size: 70 participants per intervention group and 70 per control group

Blinding: Open-label

Methodology:

Interventions: Each geriatric syndrome will be addressed through a predefined, evidence-informed intervention package, co-developed with community members and clinicians.

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www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

- Participants with multiple syndromes may receive multiple interventions, reflecting real-world multimorbidity.
- Each participant will be followed for 1 year
- Anticipated enrollment would be for 5 years.

Expected Outcomes and Impact:

Outcomes:

- Improve the healthy aging trajectory for older adults living with HIV, including health-related quality of life
- Reduced burden and impact of key geriatric syndromes
- Evidence to support scalable, integrated models of HIV and aging care

Impact:

- This study has the potential to transform HIV care for older adults by shifting from siloed disease-oriented management to an integrated, person-centred healthy aging approach
- Findings will inform clinical practice, service delivery, and policy, while establishing Canada as a leader in adaptive, community-engaged HIV and aging research

Knowledge mobilization:

- Partner with the community and individuals with lived experiences to prioritize syndromes and co-develop interventions, and to interpret and share findings in meaningful and accessible ways.

Questions, Answers, and Feedback:

Question: With the idea of a 5-year enrollment period, what is the expected engagement period or follow-up period for each person? Do you anticipate that a certain number of patients will be needed to be recruited per site in order to participate in the study?

- **Answer:** The five years are to recruit everyone in the study, with a year of follow-up for each patient, starting with baseline assessment, intervention, and one or two assessments at the 6 and 12-month period. The team do not intend to burden specific sites, so once they've done the baseline assessment physically, the intervention and follow-ups can be done virtually.

Question: We do not have a lot of evidence-based mental health services and providers in Ontario. How will medications be provided for that, and who will administer them?

- **Answer:** For mental health therapy-related interventions, Zhabokritsky can think of things like online Cognitive Behavioural Therapy groups offered through the clinical trial and social interventions for depression and loneliness. For medication, we can think about how to

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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package that intervention, for instance, a recommendation that goes to the primary care provider to look at the evaluation and say they might be a candidate for treatment.

Feedback: The speaker would strongly recommend including a randomization of allocating intervention as part of this study; the intervention groups here are the sicker patient and we compare them to the healthier people who will be doing better. They would also recommend putting in a biobank component to be able to identify subpopulations that have biomedical pathways that are targetable, that lead to specific geriatric syndromes, the frequency of which will be defined by this work, so we can do a precise sample size calculation.

Question: Have you considered the gender aspect?

- **Answer:** Absolutely, we struggled during the CHANGE HIV Study to recruit women. It's largely due to the shifting dynamics of the epidemic (it affected men first, and women later), so we're hoping to capture sufficient numbers to look at those differences.

Question: The speaker is concerned that this study is set to look at way too many interventions from a trial perspective. Why not consider focusing on just one or two and then building on them?

- **Answer:** Zhabokritsky agree that the team will have to limit it to a certain number of relevant, pressing concerns.

Question: What are you offering the individuals who come to participate in the survey?

- **Answer:** We're recruiting 70 individuals per intervention, and we'll be offering an honorarium in addition to the potential benefits of participating in the study.

Question: Looking at the secondary endpoint (biomarkers), the speaker is wondering what the baseline characteristic is for participants. Are you planning to recruit only participants who have a specific threshold or viral load?

- **Answer:** Zhabokritsky had not given it much thought yet, but it is something we would be measuring and accounting for.

Question: The study is focusing on geriatric syndromes and age thresholds, but is a 55-year-old who's had HIV for 5 years the same as a 55-year-old who has had HIV for 30 years? The speaker wonders whether the duration of the infection, rather than just their age, could be a consideration.

- **Answer:** The question about how we include folks who have been living and aging with HIV for a long time comes up every single time I give a talk, and I love it, so thank you. Perhaps we can include an arm of folks who are young and have had HIV for X number of years. In our CHANGE HIV Cohort, we didn't see a high difference in comorbidities based on duration of HIV, leading us to think that age and lifestyle factors play a huge role. So that will be one of the variables we assess for as we work through the trial.

Question: How can we best connect with the IGC?

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www.ctnplus.ca
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- **Answer:** Renee Masching answered that the best way is through Jaydee Cossar, who can make sure you have conversations with the IGC as a collective.

Flagship Feedback Sessions

After hearing all three presentations, the attendees broke out into different breakout rooms to discuss and provide feedback.

Open Networking

Jon Ehrich closed Day One of the CTN+ Winter Meeting 2026.

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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DAY 2

Opening Remarks

Dr. Marina Klein welcomed everyone and thanked them for their continued participation.

External Advisory Committee Report

Presented by: Tripp Gulick

Introduction:

Gulick introduced himself and Judy Auberbach as two of the in-person external advisory board members here for the conference. They congratulated the CTN+ on entering its second year, firming operations and establishing new committees to take on the many challenges in clinical research.

Gulick's team is excited to see community involvement earlier on in the research process, and the encouragement for them to bring their own ideas into clinical research. One of the themes heard loud and clear is prevention must be our top priority – they cannot and will not wait to be involved

Challenges

- In the United States, young people wanting to enter the infectious disease research field are being blocked by curbed government funding. Thankfully, this is not an issue in Canada.
- However, Canada does have issues surrounding leadership and succession roles. Some of the younger/earlier career researchers should be asking themselves questions like "Am I the one?" and "Should I take on this role?" and "Do I have what it takes to lead a network like this?" The answer is a resounding yes.
- There's also some tension between a central approach (taking Canada as a whole country) versus the separate regions. Some of the regions have been in the game for a long time, and some are newer, so it's great to see that you're going back to the regions and asking them what's important to them, what their community thinks, what issues they are facing and how they can be studied better.

Collaborations:

The CTN+ has been involved in a number of collaborations over the years. It was great to see your involvement with US projects while they were funded and the contributions you made to them. It's also nice to see your involvement with ANRS through the IPERGE study. Overall, the CTN+ is doing a great job bringing the entire country together.

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info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

LoS and Grants Update

Presented by: Marina Klein

The CTN+ has changed the way we approach providing support for studies or trials that will be CTN+ trials. To that end, we are trying to move things upstream to request Letters of Support (LoS) at the time of the initial grant submission, but when those letters of support come in early there's also an opportunity to request for feedback from the Methods Think Tank, and data, regulatory, knowledge mobilization consults to help improve the grants as they come in versus after they've been funded.

Klein offered congratulations to everyone who submitted in this very competitive funding environment! This is largely in part due to funding reductions in the south, which in turn is driving the increase in grant applications to CIHR.

This was the first iteration of the new processes, review structures, and reviews also changed. We now have an interdisciplinary review process that brings together community, methods and science, so we're no longer doing these in isolation.

In 2025, we submitted 35 letters of support, mostly for CIHR Project Grants and Team Grants.

Team Grants:

- CTN+ researchers are involved in 13 of the 19
- All 4 proposals supported by CTN+ were funded (HIV and STBBI CBR).
- CAHR/CIHR event showcasing CBR teams on April 23rd

Project Grants:

- 16 LoS submitted and 4 were successful + 1 bridge
- 25% success rate, 2x the CIHR rate

Coming to the CTN+ early can help enhance your chances of getting funded. It is also a good justification for us to stick with this new model going forward.

HIV/STBBI CBR Team Grants	Primary Investigators	Pool	CTN+ Connection
Surviving and Thriving into the Future and on Our Own Terms: Developing a Two-Spirit	K McCrady; D Peltier; C Davey; T	Distinctions-Based Indigenous Pool	Prevention and Testing Think Tank

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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Framework for Indigenous Sexual Health, Sovereignty, and Futurity	Hart, R Jackson, H Pruden		
Empowering Voices, Building Solutions: Addressing Intersectional Stigma in Community-Driven HIV/STBBI Prevention with Northern and Indigenous Youth in the Northwest Territories, Canada	C Logie, C Lys, R Monchalin	Indigenous	REDI Think Tank, Atlantic Region (Masching)
Equity-Focused Expansion of Trauma-Informed HIV Prevention and Treatment for Women in Ontario via Non-Specialist Providers: Co-Design and Hybrid Type 2 Pilot Cluster RCTs	M Biondi, M Bannerman, K Campbell, C Chiutsi, G Fontaine	Young Women	Methods Think Tank
Advanced HIV, STBBI Health Equity through Substance Use Health: A Pan-Canadian Research, Knowledge Translation and Capacity Building Network	C Strike, C Johnson, R Penn, A Guta	People who use drugs	Org-wide collaboration

Project Grants	Primary Investigators	Competition	Focus	Regions	Think Tanks
Hormones and Markers of Aging in Women	M Murray	Spring 2025	Women, HIV	BC-Yukon	Treatment and Management Think Tank
Consolidating Evidence for the Implementation of Decentralized PoC Testing for STBBIs	G Fontaine, J Grebely, M Klein	Spring 2025	STBBI, Implementation Science	Quebec	Methods Think Tank
Scaling the Syphilis PoC Test and Treat Outreach Model of Care	S Saeed, M Carter, M Klein	Spring 2025	Syphilis	Ontario	Prevention and Testing Think Tank

info@ctnplus.ca
www.ctnplus.ca
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Preparing for the use of long-acting antiretrovirals in HIV post-exposure prophylaxis	D Tan, D Grace, P O'Byrne, P Woodward	Fall 2025	HIV	Ontario	Prevention and Testing Think Tank
Long-Term Follow-Up Study of NOVA-HIV: Nonavalent HPV Vaccination in Women Living with HIV	E McClymont, D Money (J Brophy)	Fall 2025 Bridge	Women & HIV	BC & Yukon	Treatment and Management Think Tank
Predictors for Early Characterization and Identification of Sequelae in Newborns with CMV	F Kakkar (J Brophy)	Spring 2025	Neonates & CMV	Quebec	Treatment and Management Think Tank

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Project Grants:
Hormones and Markers of Ageing in Women

Presented by: Melanie Murray

Background:

Compared to men with HIV and women without HIV, women living with HIV experience lifespans 5 to 10 years shorter than women with HIV and 7 years less than men with HIV. This is caused in part due to shorter 'health spans', with earlier and higher burden of comorbidities (e.g., liver, kidney, metabolic, and neurocognitive disease), and higher systemic inflammation.

Sex hormones are largely anti-inflammatory and protective of comorbidities and cellular damage. Compared to controls, women living with HIV have:

- Higher incidence of low hormone states, like prolonged amenorrhea and early menopause
- Lower free estradiol (E2), bioavailable E2, and progesterone (P4) than their peers without HIV despite similar sociodemographic factors

Hypothesis: Women living with HIV experiencing disparities in life and health span may be driven by hormonal dysregulation.

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www.ctnplus.ca
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Recruitment Goals:
Leveraging the BCC3 cohort:

- Visit 1 (launched 2020, 94% complete) – 350 women living with HIV and 350 women not living with HIV
- Visit 2 (launched 2026) – 150 women living with HIV and 150 women not living with HIV

At both visits, we will measure:

- Hormone cell receptor expression to see hormone levels
- How cells are responding and what the important hormone receptors are doing, as well as some measurements of lifetime estradiol exposure.
- Aging markers (e.g. phenotypical age, mitochondrial dysfunction, plasma markers of inflammation, and immune cell senescence and exhaustion)

They are also examining associations between hormone and aging markers within a single time point and longitudinally between the two time points (around 4-6 years for most women).

Team:
Multidisciplinary expertise from clinicians, researchers across clinical, basic, social science, and community research, community members and trainees. Community involvement includes women living with HIV trained as Community Research Associates (CRAs), the Community Advisory Board includes over 100 members representing the diverse HIV/STBBI community, CRAs and community partners involved in guiding research questions, survey development, administering surveys, and co-presenting findings.

Impact:
Our project could inform:

- Mechanistic studies examining sex hormones' role in healthy ageing
- Clinical trials of hormone therapy for women with prolonged amenorrhea or early menopause, particularly for those living with HIV
- Screening, counselling, and support of hormonal imbalance, particularly for midlife women entering the menopause transition
- Ultimately, our project may identify hormone dysregulation as an additional hallmark of ageing for all women

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

CIHR Pan-Canadian Network for HIV and STBBI Clinical Trials Research

Consolidating Evidence on the Implementation of Decentralized Point-of-Care Testing for STBBI Testing: A Knowledge Synthesis and Framework Development Study

Presented by: Guillaume Fontaine

Background:

Consolidated 2022-30 WHO GHSS strategies on HIV, viral hepatitis and STI discuss the need to:

- Foster learning across the disease areas
- Leverage innovations and new knowledge

The strategies recommend shared and disease-specific country actions for the next 8 years:

- “Implementation science should guide the scaling-up programs of STIs, including decentralized services.”
- “Implementation research that will be required for countries to optimally tailor service delivery models to meet their needs”

Funded Grant:

A three-and-a-half-year grant (2025-29), we got just over $600,000 with co-PI Marina Klein, Jason Grebley, and a range of different investigators, primarily in Australia.

Study Objectives:

The study will investigate:

- Clinical effectiveness of point-of-care testing in enhancing testing, linkage to care, and treatment initiation for HIV, viral hepatitis and sexually transmitted infections (STIs; syphilis, chlamydia, gonorrhea, trichomoniasis and HPV infection).
- Cost-effectiveness of point-of-care testing for HIV, viral hepatitis and STIs
- Barriers and facilitators to the implementation of point-of-care testing for HIV, viral hepatitis, and STIs
- Effectiveness of implementation strategies in enhancing implementation outcomes of point-of-care testing for HIV, viral hepatitis, and STIs.
- To create an implementation framework tailored to the Canadian context for point-of-care testing of HIV, viral hepatitis and STI testing

Methodology:

Overall design:

Multi-stage knowledge synthesis and framework development approach guided by implementation science frameworks

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Four systematic reviews in one project – Effectiveness systematic reviews (x2), mixed-methods systematic review, cost-effectiveness systematic review:

- JBI methodology
- Cochrane methodology
- PRISMA guidelines

Comprehensive search strategy for all 4 reviews:

- On May 12, 2023 (update in 2026)
- Databases: EMBASE, PubMed, and Web of Science
- No language or publication date restrictions

Progress:
455 studies across all 4 reviews.

Timeline:
Started a few years ago with seed funding, but now into increased data analysis; all of those are hoped to be completed before the end of 2027.

Community Involvement:

- A Canadian implementation framework with evidence for point-of-care STBBI testing/treatment, key implementation and contextual factors, and implementation strategies mapped to barriers/facilitators
- A suite of practical implementation tools for point-of-care STBBI (e.g., readiness assessments, quality assurance frameworks, and community engagement toolkits)
- A report co-designed with our KUs (PHAC, AHC, CanHepC, CTN+, CATIE, INHSU)

Impact:

- Development of an evidence-based framework that will support Canadian healthcare in the context of point-of-care testing.
- Creation of practical implementation tools to support point-of-care testing
- Integration into national and global evidence-based policy recommendations in collaboration with knowledge users from PHAC and CATIE
- Help achieve increased testing and treatment to address key targets outlined in the Government of Canada's 2024-30 STBBI Action Plan

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Leveraging Momentum: Scaling the Syphilis Point-of-Care Testing and Treat Outreach Models of Care

Presented by: Sahar Saeed

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Background:

Syphilis has reemerged as a global public health threat. In 2023, there were more than 12,000 cases reported in Canada. This is actually a 16% decline since the peak in 2022. However, this represents a 77% increase since 2018. There are significant geographical disparities across Canada, and over the last 5 years, there's been a significant demographic shift. One population that has come out as an emerging population are people who are street-involved, so this includes people who are using drugs, survival sex workers, individuals who face homelessness or are unstably housed.

We know that this population encounters unique social and healthcare challenges that increase both the vulnerability to infection and also hinder access to timely diagnosis and treatment. To combat this, we collaborated with 8 public health units across Ontario and 86 community-based organizations, and implemented the SPRITE Study.

SPRITE study is a decentralized model of care that leverages the approval of the INSTI dual syphilis HIV point-of-care test. What we're doing is rapidly testing and treating the street-involved population.

Implementation is Facilitated By:

- Establishment of medical directive: Public health nurses could provide immediate treatment for syphilis with Penicillin G Benzathine-Long Acting (Bicillin L-A)
- Capacity was built across public health units through a community of practice (monthly meetings with implementors) and more broadly with a community advisory group
- Flexibility in research design: Each PHU tailors the implementation strategies of this model of care to its local capacity and context.

Our Impact to Date (September 2023 to December 2025):

Almost 2000 tests, 683 outreach events, 93 individuals tested were true positives, 46 individuals were likely new/reinfections requiring treatment, 39 individuals were treated immediately.

CIHR 5-year Project Grant: Study overview:

Generate policy-relevant evidence to assess how this model can continue to be scaled, adapted and sustained, while determining long-term cost effectiveness.

Research Objectives:

- Identify the structural and contextual factors that influence both the horizontal and vertical scalability of this public health-led intervention to meet the needs of street-involved populations
- Evaluate the cost-effectiveness of implementation strategies compared to the standard of care, incorporating healthcare costs and local transmission dynamics.

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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Knowledge Mobilization:

On top of papers and events, team members regularly meet with decision-makers, have given multiple presentations at the provincial and federal level, have shared resources across the country and have a public-facing website.

Impact:

- This research will provide decision-makers with the evidence needed to inform POCT reimbursement
- Inform who, when and how to scale-up/down the model of care, while also yielding transferable lessons on equity, sustainability, and organizational preparedness relevant to other STBBIs and emerging point-of-care technologies.

Saeed would like to thank our principal knowledge users and the great team at the Southeast Public Health Unit and the many, many people who help make all of this research possible.

Preparing for the Use of Long-Acting Antiretroviral in HIV Post-Exposure Prophylaxis (Plan PEP)

Presented by: Darryl Tan

Background:

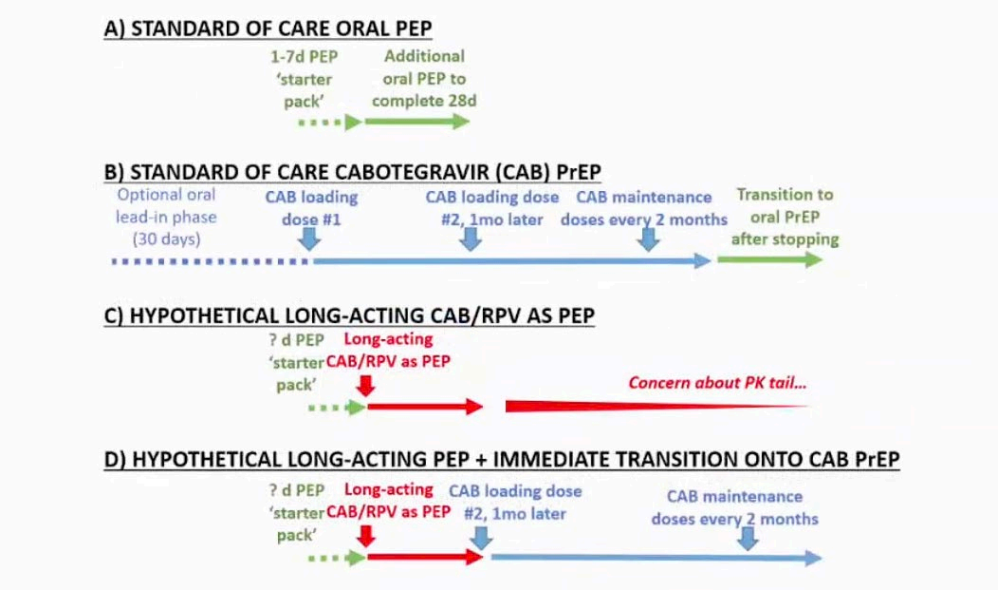
Post-exposure prophylaxis classically involves 28 days of pills but comes with some challenges, including the fact that a lot of people aren't able to follow through with taking 28 days of pills. There's a lot of stigma and self-stigma associated with taking the pill. Some of the regimens have tolerability issues, but there are also access problems. And a big question that we had is whether the advent of long-acting antiretroviral drugs could help address some of these challenges.

Community Interest in Simpler PEP Regimens:

There are recent interesting research findings where people were asked about their interest in a single-dose PrEP regimen/PEP regimen, which found that single-dose PEP is more popular than PrEP.

A potential care pathway that could be an elegant solution:

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There's already some data that shows that this combination of care works.

Objectives:

- Assess acceptability, preferences, and opinions related to long-acting PEP in Ontario.
    - Estimate the proportion of oral PEP users who would accept long-acting formulations of PEP
    - Estimate the proportion of oral PEP users who would directly transition onto any form of PrEP
    - Characterize community opinions on the potential impact of LA-PEP on PEP access and uptake
    - Characterize clinical stakeholder opinions on risks, benefits and logical feasibility of LA-PEP
- Quantify the clinical outcomes associated with standard-of-care oral PEP.
    - Proportion with public and/or private drug coverage
    - Nature, severity and frequency of PEP-related adverse events
    - Proportion completing the full 28-day PEP regimen on time
    - Proportion of PEP users undergoing follow-up HIV testing at 4-6 weeks, 12 weeks and within 2 years.
    - Proportion who transition onto PrEP during the 12-week PEP follow-up period
    - Proportion who test HIV positive, a) within 12 weeks and b) within 2 years of exposure

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Prospective Cohort:
100 people enrolled at three sites, in Ontario, Toronto and Ottawa. In-depth interviews were conducted with 60 different community members and 35 providers

The Team:
We have a wonderful team that represents different clinical, academic, and community representatives.

Timeline:
2025 Q2 – 2026 Q1: Finalized study document, trained study coordinator, hired a postdoc fellow, recruited CAB.

2026 Q2: Convene CAB, REB Submission and approval, study launch.

2026 Q3 – 2027 Q2: Data collection, OHTN final reporting March 2027

2027 Q3-Q4: Data analysis

2028 Q1: Reporting

Impact:
- Short term: Raise awareness about long-term anti-retroviral
- Medium term: Establish a protocol for a clinical trial of long-acting ARVs as PEP informed by community and clinical input
- Long-term: Expand the HIV care toolbox and help reduce HIV incidences

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Questions, Answers, and Feedback:

Question: If the Merck long-acting pill gets approved on your timeline, would that be something that could be integrated into a study?

- **Answer:** Yes, absolutely. If there are enough partners and we'd need a full regimen, but I think it would be attractive to a lot of people.

Long-Term Follow-Up Study of NOVA HIV: Nonavalent HPV Vaccination in Women Living with HIV

Presented by: Jason Brophy

Background:

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www.ctnplus.ca
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- Women with HIV are disproportionately affected by cervical cancer, which can be prevented by HPV vaccination
- There is limited data on the 9vHPV vaccine in women with HIV, and no data on the long-term immunogenicity and efficacy
- We are currently conducting a multi-center randomized trial of the 9vHPV vaccine in women with HIV (NOVA-HIV Trial) to:
    - Investigate the immunogenicity, safety, and efficacy of the vaccine
    - Evaluate a 2 versus 3-dose HPV vaccine schedule (with both groups receiving 3 doses by month 12)
- This study will extend the follow-up of the ongoing NOVA-HIV Trial to evaluate the immune durability and efficacy of the 9vHPV vaccine in women with HIV

Study Overview:
The study team includes HIV and infectious disease care providers, laboratory experts, and patient partners. They received Priority Announcement funding in the Fall 2025 Project Grant Competition and re-applied for funding in the Spring 2026 Project Grant Competition.

Impact:

- Data from the ongoing NOVA-HIV Trial may support the implementation of reduced-dose schedules in women with HIV
    - This would make HPV vaccination more feasible and accessible, contributing to cervical cancer prevention in women with HIV
- Given that immune protection from vaccination can decline more quickly in people living with HIV, the Long-Term Follow-Up study will generate long-term immune decay and efficacy data specific to women with HIV
    - This will support equitable, evidence-based HPV vaccine programs for women with HIV, who are at increased risk for developing cervical cancer
    - Findings will inform HPV vaccine policy globally and advance progress towards cervical cancer elimination

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Precise CMV Cohort Study – Predictors of Early Characterization and Identification of Sequelae in Newborns with Congenital CMV Infection

Presented by: Jason Brophy

Background:
Cytomegalovirus (CMV) is the most common infection passed from mother to baby during pregnancy and is the leading cause of non-genetic sensorineural hearing loss and the 2nd leading cause of developmental delays in children.

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www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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10-15% of infants with congenital CMV are born symptomatic, and 30-50% of these will go on to have long-term disabilities. Treatment with valganciclovir for 6 months for symptomatic infants has been shown to reduce the risk of sequelae.

For the 85-90% who are asymptomatic, there is still a 10-15% chance of sequelae. Treatment of these children has not been studied yet.

Currently, we have difficulty predicting which babies will develop severe sequelae (especially among those asymptomatic at birth).

PRECISE will aim to elucidate predictors for sequelae in newborns with CMV infection (symptomatic and asymptomatic).

Study Overview:

- The PRECISE study team includes pediatric ID clinicians at 7 sites (Montreal, Ottawa, Toronto, Winnipeg, Saskatoon, Calgary, Vancouver), including the 3 provinces with the cCMV dried blood spot screening programs, which will ensure enrollment of asymptomatic infants
- The team includes a strong community partnership with CMV Canada, a community-based organization started by and for families of children born with cCMV (Rob Tetrault-Winnipeg), which will support study set-up, recruitment and KTE
  - 1ST project of the recently created Canadian cCMV Research Consortium
- Observational study cohort – will recruit 300 infants for bio-sample collection at diagnosis, 2, 4, 6 months, as well as neurodevelopmental assessment at 24 months. A variety of biology assays will be performed (VL, cytokines, inner ear proteins, neuronal injury markers) to correlate with risk of outcomes (hearing loss, neurodevelopmental delays)
- Aim for 100 infants/year x 3 years; enrollment can be expanded to additional sites if recruitment is slow
- Ontario was the first place in the world to start testing babies for CMV through DBS testing. Strong community partnership with CMV Canada.
- An observational cohort study will recruit 300 children, 2/3 symptomatic and 1/3 asymptomatic, utilizing a variety of biological assays
- Aim is 100 infants/year [x3 years]

Impact:

PRECISE-CMV will generate the largest, most comprehensive Canadian dataset linking viral dynamics, host immune responses, and end-organ biomarkers to long-term outcomes in cCMV. The results are expected to inform clinical guidelines, refine follow-up strategies, and support evidence-based decisions regarding antiviral therapy, particularly for infants with mild and asymptomatic infection. The results from this study could lead to future intervention studies of targeted anti-inflammatory agents if specific inflammatory pathways are identified as hypothesized.

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www.ctnplus.ca
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Seed Funding Projects Update

Presented by: Mariana Klein

These regional grants are intended to foster young researchers to support research in regions and perhaps target underserved groups.

Atlantic – Funding 1 study for $50,000 (1 concept submitted)

Establishing dried blood spot testing for STBBI surveillance in the Atlantic

- Principal Investigator: John Law

Ontario – Funding 3 studies for $20,000 (6 concepts submitted)

Co-designing a Deprescribing Program to Manage Polypharmacy and Potentially Inappropriate Medications in Older Adults Living with HIV

- Principal Investigator: Alice Zhabokritsky

Towards an equity-centred doxy-PEP intervention: A qualitative exploration with immigrants of colour who are sexual minority men and care providers in the Peel Region

- Principal Investigator: Tin Vo

WISE-PREP: A Women-Informed Support Tool Using Evidence-Based Provider Education on PrEP

- Principal Investigator: Sheliza Halani
- Supervisors: Mona Loutfy and Darrell Tan supervisors

Prairies – Funding 1 study for $50,000 (2 concepts submitted)

The 5 P's of HIV Prevention: PrEP, People, Providers, Peers, Policy

- Principal Investigator: Cara Spence

BC/Yukon – Funding 1 study for $50,000 (4 concepts submitted)

Evaluation of a Hospital-Initiated Hepatitis C Treatment Quality Improvement Initiative for Patients with Untreated Infection

- Principal Investigator: Kate Salter

Regional Team Breakout Reports

BC & Yukon Region

Presented by: Naveed Janjua

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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What Have They Done?

The team has hired the BC & Yukon Research Coordinator: Farnaz Azarmju (start date on April 27).

Projects in progress include:

- Cataloging BC & Yukon Community groups/clinics
- Developing researcher resources – research and funding
- Developing a one-page fact sheet (CTN+ / BC & Yukon Region) for recruiting new regional team members
- Planning for a meeting in Prince George

The team were awarded the following grants:

Planning and Dissemination Grant

- Northern Networks: Building Collaborative Capacity for HIV and STBBI Research - A Planning Grant to Engage Communities, Clinicians and Researchers *(Murray, Melanie)*

Catalyst Grant

- How Sociostructural Factors Shape the Comorbidity Gap for Women with HIV *(King, Elizabeth)*

Project Grants

- Long-Term Follow-Up Study of NOVA-HIV: Nonvalent HPV Vaccination in Women Living with HIV *(McClymont, Elisabeth K; Money, Deborah M)*
- Identifying service pathways to reduce overdose risk among youth: a multi-method, population-based, and co-design study *(Palis, Heather; Barbic, Skye P; Janjua, Naveed Z; Marchand, Kirsten I; Mathias, Steve M)*
- Addressing HIV and STBBI among Two-Spirit, Gay, Bisexual, Trans, and Queer Men in Canada Through Community-Led Research and Capacity-Building: Centring the Needs of Indigenous People, Black People, and People Living with HIV *(Community-Based Research Centre, Burke, Orville; Durrant, Garfield S; Kwag, Michael; Dame, Jessy M; Klassen, Benjamin J; Lachowsky, Nathan J; McCready, Lance T; Sinno, Jad; Skakoon-Sparling, Shayna P)*
- Equity in Implementation of Anal Cancer Screening (EQUIPS) *(Burchell, Ann N; de Pokomandy, Alexandra; Fahim, Christine; Grennan, Jonathan (Troy); Ibanez-Carrasco, Francisco; Leung, Shuk On A*

What Research is Being Conducted/Planned Outside of Larger Urban Centres?

- BCC3 Study
    - The team will be going to Prince George in May for a week-long recruitment drive and knowledge translation event
- The TIE Study

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- Digital Determinant of Health Study
- ASTERR study
- Access feasibility to expand studies to other parts of the province (e.g. HepC and PrEP)

How Can the Regional Team/CTN+ Support Early Career Researchers?

- Access to methodologists, statistics
- ECR/PDF/new community members networking event during CTN+
- CT+ ECR award
- CTN+ hosted event-- panel discussion on career pathways
- Have ECR landing page on CTN+ for info on what can be provided

CLT and IGC Engagement:

The BC & Yukon Regional Team have Darren Lauscher and Claudette Cardinal to assist as representatives from the CLT and IGN, respectively.

Regional Priorities:

- **Prevention and New Interventions**: DoxyPEP, DoxyPrEP, long- acting injectables, real-world intervention trials, gender-specific and inclusive approaches to prevention
- **Access and Equity in Rural, Remote, and Underserved Regions:** Improve equitable access to HIV/STBBI services and research across BC & Yukon
- **Living Well with HIV and STBBIs:** Advance research on comorbidities, holistic health, and well-being for people living with HIV and STBBIs
- **Aging and the Lifespan of Care:** Examine how needs and experiences evolve across generations and stages of life
- **Community Capacity, Training, and Knowledge Exchange:** Strengthen community and researcher capacity to engage in collaborative, community-driven research

Prevention and New Interventions

- **LA-PrEP Flagship study development** - Mark Hull, Ben Klassen, Chris Fraser
- **CTN+ Studies**
- **CTN 339 study** (enrolling; PI: Deborah Money): The Nova-HIV Study – A study of reduced dosing of the Nonavalent HPV Vaccine in Women Living with HIV
- **CTN 329 study** (enrolling; PIs: Troy Grennan, Darrell Tan, Mark Hull): Doxycycline Intervention for bacterial STI ChemoprOphylaxis (DISCO)
- **CTN 324 study** (enrolling; PIs: Irving Salit, Troy Grennan): Assessing the efficacy of an HPV vaccine in preventing anal pre-cancers in men living with HIV

Access and Equity in Rural, Remote, and Underserved Regions

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- Regional Team Meeting in Prince George: Northern Networks: Building Collaborative Capacity for HIV and STBBI Research - A Planning Grant to Engage Communities, Clinicians and Researchers

Living Well with HIV and STBBIs

- **CTN 333 study** (enrolling; PI Kathleen Deering): Sexual Health and HIV/AIDS; Longitudinal Women's Needs Assessment (SHAWNA)
- **CTN 330 study** (enrolling; PI: Troy Grennan): Predicting and evaluating anal cancer in HIV with novel biomarkers (The Peach study)
- **CTN 222 study** (enrolling; PI: Marina Klein; **BC Site Investigators**: Katherine Plewes, Brian Conway, Mark Hull): Canadian co-infection cohort – A prospective clinical cohort of HIV and hepatitis C virus co-infected patients

Aging and the Lifespan of Care

- **CTN 335 study** (enrolling; PIs: Melanie Murray, Hélène Côté, Angela Kaida, Elizabeth King): The BC CARMA-CHIWOS Collaboration (BCC3) - The role of female sex hormones and chronic/latent co-infections on cellular aging and comorbidities in women living with HIV
- **CTNPT 050 (e**nrolling; PIs: Elizabeth King, Melanie Murray): Perception of menopausal hormone therapy among women living with HIV
- **CTNPT 046 study** (enrolling; PI: Melanie Murray): The FIND+ Study (assessing fertility in youth living with HIV since childhood)

Community Capacity, Training, and Knowledge Exchange

- **Phase 2: STRIVE-STBBI –** Developing community training curriculum
- **BC & Yukon Regional Team Meeting in Prince George:** Northern Networks: Building Collaborative Capacity for HIV and STBBI Research - A Planning Grant to Engage Communities, Clinicians and Researchers

Major Milestones:

Organizational structure is now in place with the terms of reference finalized for all committees, members recruited and meetings scheduled for the year.

- 5 Committees: Executive Committee, Steering Committee, Training Curriculum Committee, Recruitment and Selection Committee and Community Capacity Building Committee

Activities Currently Underway:

- Curriculum development: Review of comparable programs (academic and community training), planning for curriculum consultation, and developing learning outcomes for all training components

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- Recruitment: Integration of EDI considerations into the recruitment and selection process, developing promotional and application materials
- Evaluation: Development of program evaluation framework (in collaboration with CTN+ and other phase 2 programs)

Next Steps:

- Finalize curriculum for academic training and community training streams
- June 2026: Launch call for academic trainee applications
- Oct 2026: Launch call for community trainee applications
- Oct 2026: Launch monthly webinar series

Prairies Regional Team

Presented by: Erin Walling and Cara Spence

- The region's #1 priority is HIV prevention.
- There is a need for a full inventory of current research, research interests, and community-based organizations
- There is significant work underway in diagnosing, treating, and managing Hep B:
    - Research collaboration underway between the University of Calgary and the University of Saskatchewan
    - Winnipeg has specialized Hep B testing, suggesting hosting a health liver day to reduce the stigma of testing
    - Suggestion to host a Liver Health Day to reduce the stigma surrounding testing
- Coordinate community engagement and messaging so we are not over-extending our community partnerships- leveraging existing infrastructure and relationship building from national microbiology lab testing, NEIHR, etc., to expand testing, treatment, and prevention
- A focus on opening up PrEP access to everyone who wants it. The largest take-up has been seen among women.
- Ongoing write-up of newly captured syphilis data.
- Spence successfully received funding from a PMTCT program to support research both for low-resourced environments, which will go towards a postdoc based out of Rwanda, as well as Saskatchewan-based research.
- Working in Edmonton with women not born in Canada regarding testing and screening

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Ontario Region

Presented by: Jason Brophy and Lawrence Mbuagbaw

info@ctnplus.ca
www.ctnplus.ca
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Regional Priorities:

- Focus on African, Black and Caribbean communities for diagnosis and treatment
- Improving uptake of preventative interventions (HIV & STBBIs), especially among youth/young adults
- Improving health among people with HIV – healthy aging, reproductive & mental health, well-being/QoL
- Advancing implementation science research
- Developing strengths in administrative database health research
- Advancing inclusivity and diversity in both people and research methodologies, and embedding equity, diversity, inclusion, accessibility, justice, and Indigenous reconciliation across the design, conduct and interpretation of clinical trials.

What Have We Done So Far? (From Winter Meetings to Now):

- Ongoing inventory of partners and stakeholders, and ongoing trials with over 50% response rate to the STBBIs Research Inventory, where one question asked for possible new contacts
- Finalized committee membership
- Approved Terms of Reference
- Begun committee work for Phase 2 (ON-TRACK) – ON-TRACK website is in development

Phase 2:

What key Phase 2 activities are currently underway?

- Finalized committee
- Developing the ON-TRACK website
- Developing curriculum
- What should we look forward to in the next 6 months?

Start committee work (curriculum, recruitment, networking, and executive committee)

- Recruit mentors
- Put out a call for candidates
- Launch the program

Priorities:

Plans for the next 6 months to further these activities:

- Inventory of current and past work (ongoing)
- Reach out to Indigenous partners about relationship-building
- Moving ahead with Phase 2 activities (ON-TRACK)
- Working with the CTN+ central team to send out the new researcher application and site feasibility questionnaire

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www.ctnplus.ca
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- Working with other regional teams to support the roll-out of the new flagship studies
- We'll be prioritizing reaching out to both the CLT and the IGC to set up a meeting before December 2026

Plans for the next 6 months and beyond to further these activities (from the breakout discussion):

- Update the wording on all the team's outward-facing documents to reflect our approach to inclusivity
- Seek out guest lectures for ON-TRACK
- Share the program outline with the ON regional team
- Create a list of Ontario data sources with a brief description of the content
- Take advantage of the newsletter to share updates, disseminate information and shine a spotlight on new researchers and their work
- Explore the relationship between CTN+ with PHO, ICES and OCS/OHTN to generate more complete burden data for all STBBIs (similar to existing work on syphilis, mpox and HIV); make this available to CTN+ researchers for future work by leveraging existing resources

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Quebec Region

Presented by: Serge Vicente

L'EQUIPE:

- Awarded 5 mini-pilot awards of 10k each in the fall of 2025
- Seed-funding 2026 and 2027 (4x $25k) – Call for Concept Forms – 9 Concept forms received so far
- In the last year, the team organized a symposium on improving access to PrEP in Montreal:
    - Presented a poster at the CBRC summit in November
    - Preparing manuscript for submission, highlighting the discussion
- Jaime Rencontre de la Recherche Communautaire – June 2025, Montréal
- Journée québécoise du VIH, Montréal – March 2026
    - Presentation by the fall mini-pilot award winners
    - Phase 2 launch – Trainee applications
- Newsletter – December and April (planning for 4x/year)

Priorities:

- Strengthening the research continuum across community-based, clinical and basic research, with meaningful engagement of people with lived experiences
- Sustaining and enriching our network, promoting cross-disciplinary collaborations and enhancing coverage of regional, gender and ethnocultural diversity

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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- Develop adaptive platform trials to test innovative interventions in the fields of prevention, cure, healthy aging and implementation science, co-designed with people with lived experience
- Evaluating and co-designing community-based prevention, linkage to care and treatment strategies across diverse populations and settings.
- Recruiting, training and mentoring the next generation of diverse actors in the fight against HIV and STBBIs, promoting and supporting Science in French.

Phase 2:

Major milestones:

- Completed training mapping for research axes
- Launched the first award competition at Colloque de la Journée Québécoise in March 2026
- The application webpage is live and accepting submissions

Phase 2 activities underway:

- Finalized training mapping
- Promoting the award competition to potential applicants
- Collecting applications via the CTN+ Quebec webpage

Looking forward in the next few months:

- Application deadline: May 24, 2026
- Applicant decisions expected by fall
- Continued development and updates on the training platform

Priorities in terms of activities to come:

- Seed Funding
- Mini-pilots (in the fall)
- CAHR 2027 – in Montreal
- Site feasibility and engagement of clinics

Discussions:

The previous day's discussion focused on the necessity of adequate representation of researchers featured on the team. The majority of the Quebec Regional Team's researchers are based out of Montreal, but they hope to diversity that by holding events in Quebec City. They would also like to include representation from beyond only medical doctors, to also include healthcare practitioners from other fields and community members.

They also re-evaluated how membership status is assigned at CTN+, since researchers typically have to be associated with a site that can hold CIHR funding and that could be acting as a barrier to inclusion of talent. The suggestion is to implement different categories of membership: trainee,

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www.ctnplus.ca
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mentor, administration of funding, associate member, etc. These roles could be defined in a way that is coherent with administrative and ethical considerations.

Community Leadership Team and Indigenous Guidance Council Engagement:

- A meeting will be planned with CLT and IGC to discuss how collaboration and mutual engagement can be achieved to meet respective priorities
- The team will consider the possibility of including Indigenous researchers, as well as researchers from key communities and regions
- Develop culturally-sensitive approaches to increase accessibility and manage barriers

Common evaluation framework for Phase 2:

- Assessment of whether and when we complete each step
- Number of application types (students, people with lived experiences, etc.) and mentors
- Assessment of diversity in terms of applicant types, fields, research teams, and regions represented in applications.
- Number of publications, knowledge dissemination, and mobilization activities
- Diversity of training attended and cross-fertilization between domains and disciplines

Process of Decision-Making and Leadership in Quebec:

Preference for an agile decision-making and management process.

- No need for constant consultations among all researchers
- Researchers could be informed of decisions made by the executive community
- Leads and project managers are responsible for accounting for how decisions were made, and how leaders consider that they fulfill regional priorities
- Researchers are welcome to poke and ask questions to better understand the decisions made and provide feedback

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Atlantic Region

Presented by: Peter Daley

The Atlantic Regional Team is coming together in six locations to represent four provinces. Most of our sites are hospitals, not clinical units, which poses its own challenges and force the team to build from very little. The team has solidified the membership and held the first steering committee meeting. Coming from four separate provinces, they're now attempting a successful network. Peter also introduced the new project manager, Jerome Siromani.

What They Have Done So Far:

1. Regional STBBI database for cascades of care

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www.ctnplus.ca
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2. Dried blood spot for basic science and diagnosis ($50k seed)
3. Xpert HCV RNA in corrections and harm reduction
4. PO for syphilis meta-analysis and future trial

- Grants and Contracts
- Steering Committee

Regional Outreach:

- Outreach
    - AIDS committee newsletter
    - Atlantic Interdisciplinary Research Network
    - Memories University Indigenous VP
    - Wabanaki-Labrador Indigenous Health Research Network
    - Harm Reduction/RECAP Clinic
    - Public Health database between provinces
- 6 trials to become trial-ready
- Community Leadership Team and Indigenous Guidance Council Engagement: Need to make connections

Priorities:

- Clinical and basic science research
- 6-site trial participation support
- HCV/HBV elimination
- STBBI Community-Based Testing
- Regional Epidemiology
- ACHIVE meeting in September in Fredericton
- 2 Postdoc Fellows

Phase 2:

- Phase 2 project manager to be hired – Applicant with MSc Clinical Epidemiology
- CANTRAIN has been a useful springboard for training and a mentorship program. However, the future of CANTRAIN is uncertain, so it's unclear if they will be able to continue using it long-term.
- Plan to train one team member per site

Feedback:

Comment by Dr. Cara Spence: Dr. Beverly Modell (Infectious Diseases Specialist) is moving from the Prairies region to the Atlantic region. She would appreciate being involved in this work. Spence also mentions the CIHR Project with the Women Not Born in Canada (the STI project) with three sites in

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www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Edmonton, Saskatoon and St. John's (Newfoundland), which could be an opportunity for the Prairies and Atlantic Teams to collaborate.

LA PrEP Update

Presented by: Darrell Tan, Zoe Moodie, and Guillaume Fontaine

The epidemiology of new HIV diagnoses in Canada as of 2024 is shifting a little:

- About 1/5th of new infections are occurring in Indigenous people.
- Women are the largest group, rather than men who have sex with men.
- Transgender and non-binary identities are erased in the mainstream data.

Additionally, we are now squarely in the period of PrEP choice, with options of daily and on-demand tablets, as well as emerging long-action options that include vaginal ring, injectable, implants, and antibodies. Having a choice is associated with higher population-level uptake. Across many areas of medicine, it has been well established that having choice with different options is associated with uptake, so we should be looking to scale up.

All of this sets the stage for the **PrEP Cascade**. If PrEP is to be effectively used to prevent HIV transmission, it requires the following conditions to be met among the population:

Eligibilityà Awareness à Willingness à Access à Uptake à Adherence

All of this then needs to be underpinned by persistence for control to continue over the long-term.

PIPC Study Background:

Goal: Provide informed choice and adherence support for oral PrEP or CAB-LA to the priority population in Canada through an implementation study.

Previously referred to as "LA-PrEP", the PIPC study will help provide scalable models for the impact of increasing PrEP uptake nationwide.

Impact:

- Provide evidence on PrEP uptake, initiation, and persistence across key underserved populations
- Identify barriers/enablers and optimal delivery modes

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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- High potential to reduce HIV infections

The team wants this to be a model for optimal delivery that can be used as a template for other regions across Canada.

Study Development:

- Investigator site applications reviewed in early Jan 2026
- Identified sites to participate in Stage 1 (prep work for Stage 2) and in Stage 2 (PIPC study)
- Gilead funding awarded for Stage 1 work
- Awaiting funding approval from Viiv
- Site readiness assessment tool provided to investigators in April 2026
- Protocol development to begin in March 2026

PrEP options offered through PiPC:

- Daily oral Prep
- On-demand oral PrEP (for MSM and trans women)
- CAB-LA
- Lenacapavir (hoping to be able to include this)

After PrEP counselling, participants are able to choose their preferred PrEP option. Participants are allowed to change to a different option throughout the study, and this adherence will also be tracked.

Priority Populations:

Interactions between all of the following: Women, Indigenous Peoples, People who use Drugs, and men who have sex with men.

Stage 1 Work:

- Identify staffing and other site needs to successfully conduct Stage 2 study (e.g. study nurse, counsellor, private screening area, research coordinator)
- Developed tailored PrEP choice counselling material for the site's specific priority population(s)
- Identify PrEP adherence support tailored to the site's priority population(s)

Resources for PrEP choice counselling material development:

- https://www.catie.ca/prep
- PrEP Decision Support Tool — St. Michael's Hospital / Unity Health Toronto

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

- https://mypreptool.org/en/
- https://whai.ca/wp-content/uploads/HIV-Prevention-Medications_PrEP-PEP-PIP_English_AODA.pdf

These existing tools are valuable, but need adaptation for the modern clinical trial setting. This includes using positive, encouraging, sex-positive language. Nothing too dry or clinical, so that people understand it, and want to engage and be involved in the research.

Adjunctive Interventions = PrEP Adherence Support

- Wrap-around support, including STI care, family planning, opioid replacement, shelter/housing support, and social services
- Digital support (daily or weekly text message/calls)
- Group support (in-person or virtual group meetings)
- Individual support (extra counselling sessions or peer buddies)
- Extended clinic hours

Study Design: Hybrid Type 2 Clinical Implementation Study

- Will assess initiation and persistence among participants who self-select to use injectable or oral PrEP over an 18-month period
- Evaluate potential implementation strategies that could be used to support PrEP adoption, initiation, and persistence
- Modelled after PrEP are adoption, initiation, and persistence
- Modelled after the 'PrEPared to Choose' study underway in South Africa
- Study will be conducted across stage 2-ready sites in Canada's

Duration: 18 months
Clinical visits will be timed according to product refills (oral PrEP) or administration (CAB-LA). Missed visits will be monitored, encouraged to return at any time. Product switching will be allowed throughout the study

Secondary Objective 1: Describe the long-term persistence (over 18 months) overall and across PrEP modalities.

Secondary Endpoint 1: Persistence is defined as sustained, continuous use of the selected PrEP product as intended, with a 7-day gap in daily dosing (for oral prep) or subsequent injection for CAB LA.

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Primary Objective 2: Evaluate PrEP initiation following PrEP choice counselling overall and by PrEP modality.

Primary Endpoint 2: PrEP initiation overall and by PrEP modality following PrEP choice counselling among enrolled participants.

Objective 4: Reach

- Time to recruit the target sample (n=300)
- Representation across priority populations and settings
- Characteristics of initiators, persistent users, and non-persistent users

Objective 5: Participant-level effectiveness/experience

- Social harms, including stigma and intimate partner violence
- Shared decision-making experience (CollaboRATE)
- Satisfaction with the PrEP delivery model and follow-up experience

Objective 6: Adoption

- Frequency, timing, and nature of **product switching**
- Frequency and reasons for **PrEP discontinuation**
- Qualitative reasons for non-persistence and switching

Objective 7: Implementation / Acceptability / Feasibility / Appropriateness

- Fidelity to **PrEP choice counselling**
- Fidelity to **CAB-LA initiation and follow-up workflow**
- Type, timing, and rationale for **adaptations**
- Exposure to site-level supports/tools
- Participant and provider ratings using AIM / IAM / FIM
- Brief qualitative feedback at selected sites

Objective 8: Maintenance

- Sustainability of PrEP choice delivery at sites
- Site leadership assessment
- Continuation intent at final planned visit

Objective 9: Determinants

- Barriers and enablers using the determinant framework

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

- Explanation of variation across sites and populations

Objective 10: Economic evaluation

- Is the model acceptable and feasible now, and can sites sustain it over time?

Overall, PIPC will generate evidence on:

- Which delivery components are needed for different populations and settings?
- Where oral PrEP, CAB-LA and other modalities (e.g., LEN) fit best within a **choice-based** model
- What levels of staffing, workflow redesign, and support are required?
- Which barriers are most modifiable through implementation strategies?
- Which costs may be worth subsidizing to improve equitable access?

Questions, Answers, and Feedback:

Question: When looking at interventions from an Indigenous perspective, adherence and persistence of PrEP need to be considered within that cultural context. The community is going to support that adherence, not just text message reminders. An example from Cree culture might be the ceremony sweats. How can we capture those to show that parallel works with adherence in Indigenous communities?

- **Answer:** From Darrel Tan's perspective, these are definitely part of the PrEP adherence supports, or the adjunctive interventions, which can be socio-structural in nature. They are looking at many different interventions that can work within specific cultures and communities, and they very much would appreciate suggestions and feedback on that front.

Question: There is a risk that with so many objectives and outcomes, there is the potential to overcomplicate something we want to be simplifying. How is the team going to prevent that?

- **Answer:** Many of these study-process measures are actually quite light-touch. The team are looking at an in-depth analysis on a small/manageable database. Additionally, while we all agree that PrEP needs to be simplified, the multiple new modalities mean we are now in a position where it can become complicated again. That's why PrEP choice counselling is being built into the intervention.

Question: Can we do the initial follow-up virtually, or will it be purely in-person? Because it can be difficult for remote recruitment otherwise.

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5252 boulevard de Maisonneuve Ouest, 3rd floor
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- **Answer:** Some of the appointments will need to be in person (e.g. HIV testing), but if it's possible for remote visits, the team would be open to that. The team will need to consider how this can be built into Stage 2.

Question: Is the medication being provided free of charge?

- **Answer:** No. Insurance will need to be navigated.

Question: What is study and what is clinical practice? How are you going to collect the data that's a clinical endpoint or a clinical data set that's separate from a study questionnaire or something similar? What is the burden going to be on the clinics?

- **Answer:** Being a Stage 2 site means being able to enroll patients to whatever number they have signed up for, collect data according to a pre-decided schedule, and upload that data centrally to RedCap. There should not be significant implementation work placed on the clinics. A second wave of sites might be selected that need additional support in being able to do this level of work.

Question: Will there be funding for coordinators to support that administrative burden?

- Answer: The funding budget for that is currently being built.

Question: How would the ongoing study contribute to the Gilead study in the prairies?

- **Answer:** This is separate from the PIPC study, though they might inform one another.

Question: You're providing housing support but not housing proper, and so it would be advisable to measure participants' housing at each visit, especially for hard-to-reach populations.

- **Answer:** This was simplified. Instead, we're working through a Shelter; they're the ones helping with housing.

Question: Why have the Francophone and black communities in Ontario not been centred?

- **Answer:** There has been no group excluded; it's rather the inclusion criteria of anyone who can benefit from PrEP, of which many people from the African, Black, and Caribbean populations would. However, we hear that we did not speak to the black population first and foremost. But we hear you for both Francophones and also those who speak neither French nor English. This is a platform, not a panacea, and after the launch, we would like people to come forward and give pitches for incorporating and engaging other community groups.

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Rethinking Engagement in HIV and STBBI Research

Presented by: Muluba Habanyama

Why expanding our circle of community voices is the next chapter of our mission.

Since 1993, CAC has been founded (formal, structured input from the community), creating a legacy worth acknowledging.

The unique history of HIV advocacy made space for community engagement, but it hasn't been the case for other STBBIs. Are we only building engagement where there has already been pressure, advocacy?

The epidemiological landscape has shifted. For example, syphilis rates are the highest they've been in decades, Hep C disproportionately affects indigenous communities, Gonorrhoea and chlamydia rates continue to rise among youth and young adults, and there are significant overlaps between HIV and STBBIs.

In this context, we need to ask the following questions:

- When we say community, who specifically are we picturing and who aren't we?
- What drives community engagement in different STBBI contexts?
- How can we ensure that community engagement is not just courtesy, but impactful?

If people most affected by Hepatitis B, C and other STBBIs, what would they make different about our engagement framework? New Conversations are needed. We must expand who we listen to, create conditions, don't wait, adapt, replicate and name the responsibility.

Help us help you help us! The communities we serve can help design better research. But only if we build the structures that make that possible.

- Expand community advisory scope to include STBBI affected pops
- Codesign engagement pathways, with community, not for community.
- Committing to rescoring these structures.
- Don't rely on the community to recruit the community

IDEA Think Tank Discussion: Advancing Inclusion, Diversity and Accessibility in CTN+: Championing Equitable HIV/STBBI Clinical Trials

Presented by: Carmen Logie

Overview:

Purpose: The IDEA Think Tank advances integration of inclusion, diversity, equity and accessibility

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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principles across CTN+ activities and clinical trials. This also means simultaneously challenging stigma, discrimination, social exclusion, and different forms of intersecting oppression.
Focus:

- Embed IDEA across the research lifestyle
- Promote equitable participation in clinical trials
- Address systematic barriers affecting marginalized communities
- Support accessible and inclusive knowledge mobilization

The IDEA Think Tank should not be an add-on, but instead function like the Methods Think Tank; it will be integrated in all other think tanks and regions, with the potential for a postdoc working across all groups, including engagement with the IGC.

Strategic Focus Areas:

The IDEA Think Tank advances its mission through three key areas:

1. Integration of IDEA principles

The Think Tank will promote IDEA integration across all stages of research, including:

- Research training and education
- Study design and methodology
- Participant recruitment strategies
- Data analysis and interpretation
- Knowledge mobilization and dissemination

2. Innovation in inclusive research practices

Tools and strategies to reduce bias and amplify diverse voices. For example:

- Bias-reduction frameworks
- Inclusive research tools
- Strategies to address systemic barriers
- Methods to amplify diverse voices in research

3. Capacity building:

The Think Tank should strengthen CTN+ capacity through training, education, and consultation across the network. For example:

- Education and training initiatives
- Workshops and consultations
- Collaboration with regional teams
- Engagement with the Indigenous Guidance Circle

Structure:

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Think Tank Composition:

- Core Team Structure: 2 co-leads, 1 early career researcher, 1 community member, 1 administrative support staff
- Optional expansion: Committee or Community of Practice

Reporting and Governance:

The IDEA Think Tank reports through: CTN+ Executive Committee – CTN+ Steering Committee

Key responsibilities:

- Provide progress reports
- Contribute to the CTN+ strategy
- Support accountability to CIHR

Reports submitted:

- Quarterly progress reports
- Annual CIHR reporting

Measuring Impact:

The accountability framework evaluates:

Research outputs and impacts:

- Number of members incorporating IDEA strategies
- Annual workshops with measured learning outcomes

Knowledge integration:

- Influence on CTN+ processes
- Integration into evaluation and reporting
- Research output and impact, knowledge integration: influence CTN+ processes, integrate IDEA into eval and reporting

Collaboration and Engagement:

The Think Tank fosters:

- Dialogue with CTN+ members
- Awareness of IDEA principles
- Addressing racism and discrimination in clinical trials

Activities include:

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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- Community engagement initiatives
- Anti-racism education
- Collaboration with the CTN+ KM Hub

Knowledge Translation:

- Key dissemination will be through presentations, webinars, and workshops
- Success will be measured through the adoption of Think Tank recommendations in study protocols, research processes, Network guidelines, and knowledge mobilization activities

Capacity Building and Sustainability:

Training and mentorship:

- Mentoring trainees and early career researchers
- All Network members will be invited to participate in training programs.

Sustainability:

- Securing grant funding
- Expanding the Think Tank network
- Long-term integration of IDEA practices into the broader CTN+ network

Co-Lead Appointment:

Candidates can demonstrate expertise across many different fields, including HIV and STBBIs, LGBTQ+ issues, sex and gender, anti-racism, stigma around people who use drugs, and more. The team is hoping to develop a panel that captures the many aspects of stigma and discrimination.

Candidates must demonstrate:

- Expertise in IDEA principles
- Lived experience or professional engagement in equity work
- Capacity to lead collaborative research initiatives

Appointment:

- The National Director may be selected and approved by the Executive Committee, but the process has yet to be confirmed.

Requirement:

- The Think Tank will require representation from both the community and early-career researchers.

Co-Lead Responsibilities:

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Co-leads are responsible for:

- Coordinating Think Tank activities
- Embedding IDEA principles across CTN+ research
- Supporting inclusive study design
- Engaging researchers and network members
- Representing the Think Tank in CTN+ governance
- Review study submissions
- Support knowledge mobilization activities
- Maintain a Network of Expertise

Governance and Operations:

Operational considerations include:

Meetings:

- Monthly virtual meetings, in addition to virtual spring and fall virtual meetings, and a spring in-person meeting.

Confidentiality:

- All documents will be treated as confidential
- Bound by a CTN+ confidentiality agreement

Conflict of Interest:

- All members must recuse themselves when conflicts of interest arise

Administrative support:

- Provided by CTN+ National Centre

Budget and Resources:

The IDEA Think Tank has discretion to allocate its resources to support:

- IDEA initiatives
- Research support activities
- Training and workshops
- Network engagement

All expenditures must follow the tri-Agency financial administration policies.

Closing:

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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The IDEA Think Tank aims to drive inclusive, equitable, accessible research across the CTN+ and ensure that all the trials supported by the network reflect and serve diverse communities.

Open Mic

The floor was opened to anyone who had discussion points they wanted to raise regarding the following discussion points:

- Focus: the need for real-time data to inform research.
- How to capitalize on existing projects and databases
- How could the CTN+ accelerate this?

Comments included:

- Every time we have a clinical trial, we should take a time to ask: 'Is there a way to add a different component or accelerate outcomes?' e.g. an add-on to a trial for data linkages.
- We need to create a cross-country inventory of the top viruses we are interested in, outcomes, etc.
- We should implement a common standard across the country for data collection.
- We should be leveraging administrative databases.
- We need to make AI automatically part of the conversation. Every sector in health across Canada is behind on guidelines. It pertains to any information in the Cloud or on a computer. We need to not demonize it, but also address the many logistical and ethical concerns.
- Many black individuals/communities are very wary of having their data kept within medical systems, and we need to be aware of those concerns and how we handle them. H
    - How can we make healthcare data be two way? Is there a way people who agree to share their healthcare data learn all the ways it's used? That way, people still have control, ownership, and agency.
    - Ontario-bass concern regarding mpox data and the challenges inherent in gathering this data. How are we to balance the inherent bias caused by full, informed consent?
    - Good people to contact for expertise on this topic include: Kim McGrail and Simon Fraser University, the CTN+'s Kathleen Inglis, and Pratel Patel at the BC Centre for Excellence.
    - Mariana Klein commented that this might require the creation of a working group to discuss the topic.
- How can we begin to integrate data across provinces? For example, some provinces don't give full specificity in data codes (such as the Ontario government's codes not making a

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
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distinction between children living with HIV versus those exposed to HIV)
- Are there ways to continue tracking children as they move into adulthood, instead of having them age out of the system?
- How can we work together to resolve these outcomes to improve data integrity?

Knowledge Mobilization Hub Updates

Presented by: Michaela Davies and Enrico Mandarino

Progress So Far:

- Continued support for the regional newsletter
- Continued support for the PrEP guidelines learning activity and knowledge mobilization (KM)
- Hub eval framework finalized
- Working with IGC to support engagement with existing and proposed CTN+ studies
- Planning additional KM capacity strengthening opportunities and launching the community capacity strengthening series
- With the approval of CTN+'s new studies, KM support will start
- New: Video explainers/social content

Hub Support for CTN+:

- Consultation and guidance on KM planning
- Bilingual plain language study listing
- CTN+ website support and resource hosting
- Website content development, as appropriate
- Basic recruitment, comms material and strategy review
- Online presence for study
- Events/webinars
- Facilitate connection to community/knowledge users for co-design and outputs, through CLT and the community

Community Science Champion Program:

Built by community, for community.

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

This is a self-paced online course intended to help community members learn how clinical research works. Fully online and free, it will allow learners to meet with renowned investigators, build resources with peers, and access new opportunities

Course Structure

- Introductory and intermediate learning through the first six units (A-F):
    - Unit A: Introduction to Clinical Research
    - Unit B: Research Ethics and Why It Matters
    - Unit C: Good Clinical Practice and the Canadian Regulatory Context
    - Unit D: The Benefits of Community Involvement
    - Unit E: How to Engage Community in Research
    - Unit F: Study Review 101
- The course features a case study on Vancouver's community response to the mpox pandemic. Members from the local Vancouver gay, bisexual, and men who have sex with men (MSM) community played a big part in making sure the public health response to mpox was so effective. The section is based on interviews with Dylan Wall, a Health Promoter at Health Initiative for Men (HiM), and Mark Gilbert, a public health physician at the BC Centre for Disease Control.
- Some phase 2 projects will offer further, more specific learning opportunities for the community (STRIVE BC, ONTRACK).
- Pipeline to Community Advisory Committee (CAC) and Community Leadership Team (CLT)

The course features a case study on Vancouver's community response to the mpox pandemic. Members from the local Vancouver gay, bisexual, and men who have sex with men (MSM) community played a big part in making sure the public health response to mpox was so effective. The section is based on interviews with Dylan Wall, a Health Promoter at Health Initiative for Men (HiM), and Mark Gilbert, a public health physician at the BC Centre for Disease Control.

What's Next?

- The second course will take 9- 12 months to develop.
- Focus on training for researchers to work with the community, and will be a rethink of our former "Community Engagement Guidelines booklet" (working with ONTRACK to make a complementary course, instead of duplicate courses)
- Expanding the new Community Partnerships Category
- Recruiting a community fellow
- Further expanding CAC with recruitment

info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5

Closing Remarks

Presented by: Marina Klein

Klein gave thanks to participants and the team that gets it done, as well as supporters and collaborators, including CanHepC, CanCURE, and FEAST. It's an inspiring time for CTN+. In particular, she expressed gratitude to the CIHR and CANFAR for renewing next year's postdocs. CanHepC and FEAST. Accelerating Clinical Trials Initiatives has opened up apps to other networks in Canada, meaning that the CT+ will be at the table.

It was announced that Sharon Walmsley will be retiring as National Co-director. She was thanked for all her decades of hard work and contributions to science.

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info@ctnplus.ca
www.ctnplus.ca
5252 boulevard de Maisonneuve Ouest, 3rd floor
Montréal, QC H4A 3S5