CTN+ Atlantic Update

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Peter Daley MD MSc FRCPC DTM+H

NL Health Services/ Memorial University

Background

- Regional research network does not exist
- No active CTN+ studies
- Annual ACHIVE meeting stopped during COVID, 2025
  - Industry funded
- No dedicated research time or resources
- STBBI epidemiology unclear

NLHS Trials Unit

- Health Sciences Center in St. John’s
- Health region priority (single health region)
- PhD director, PhD manager, dedicated HREB team
- Infectious Diseases research staff
  - 1 FTE RN, 4 FTE RA
- 10 ongoing trials, 1-2 consents/week
- Startup team (contracts, accounts) 90 days
- Can’t receive CIHR funds directly
- EPIC CTMS April
- MSc/PhD Epidemiology students
- CANTRAIN national training

Current ID Trials NLHS

Academic

- SNAP
- BALANCE+
- REMAP-CAP
- ATTACC
- PETERPEN
- PREPARED (observational)

Industry

- VEDANTA VE303 FMT
- ATEA BEM/RZR

Recruitment Challenges

- NLHS receiving positive lab results
- Some patients are unaware of the result
  - No primary care provider to inform or refer
- First call for notification is research

Phone Survey of Investigators

- 5 MD, 3 PhD, 1 community (St. John, Halifax, Moncton, Fredericton, St. John's)
- Minimal previous CTN involvement
- Interest in CTN+ site development, most have done trials but not currently, clinicians
- Lack of site research staff
- Control/access more than exploration (cascade of care)
- Vulnerable populations some involvement
- Good basic scientist interest
- Hospital research systems not university research systems

Collaborators

- Atlantic Interdisciplinary Research Network on Social and Behavioural Issues in HCV/HIV
- REMAP clinics
- Action Hepatitis Canada
- MUN basic scientists Grant, Russell, Lok
- Pharmacy testing and treatment

STBBI Control Research Questions

	Canada Epi	Atlantic Epi	Prevention	Testing	Treatment
HIV	Incidence 6.1/100,000	Incidence 2.4/100,000	PrEP	Point of care	Long acting ART
HCV	RNA positive: 37% PWID 5% incarcerated 3.3% First Nations	Increasing?	Vaccine	Point of care, corrections	Too expensive
HBV	4.2% among immigrants	Increasing?	Screening at immigration	qSAg	Cure
Syphilis		Increasing?	Vaccine	Point of care	
CT/GC		Unknown	Vaccine		

CTN+ Atlantic Budget

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Research Personnel	223,369.00	223,369.00	223,369.00	223,369.00	223,369.00	1,116,845.00
Project Management	102,629.00	102,629.00	102,629.00	102,629.00	102,629.00	513,145.00
Clinical Coordinator	84,518.00	84,518.00	84,518.00	84,518.00	84,518.00	422,590.00
Community Coordinator	36,222.00	36,222.00	36,222.00	36,222.00	36,222.00	181,110.00
Study-Related Support and Community Program Funding	50,000.00	50,000.00	50,000.00	50,000.00	50,000.00	250,000.00
Seed Funding		50,000.00	50,000.00	50,000.00	50,000.00	200,000.00
Total	273,369.00	323,369.00	323,369.00	323,369.00	323,369.00	1,566,845.00

Doing ID Research as an ID Clinician

- Set up the hospital research site
  - Space
  - Staff
  - HREB
  - Contracts
  - Shipping
- Don’t write a grant
- Recycle project funds
- Work with industry
- Try to achieve sustainability
- Don’t be narrow
- Define your clinic population for eligibility estimation

Can we put patients into trials now?

	St. John's Daley	Halifax Barrett	Moncton Smyth	Fredericton Chase/Rosa	St. John Webster
HIV	Y	Y	Y	Y	Y
HBV	Y	Y	Y	?	Y
HCV	Y	Y	Y	?	Y
Syphilis	?	?	?	?	?

Available Industry Trials

- HCV ATEA Bemnifosbuvir/Ruzasvir vs SOF/VEL
  - BEM NS5B more potent than SOF
  - RUZ NS5A
  - SVR12=98% in phase 2
  - 11 visits, $18k/patient
  - Requires 6 months of RNA positive
- HBV GSK Daplusiran/Tomligisiran then Bepirovirsen for functional cure
  - Need qHBSAg, HDVAb, FibroSure/FibroTest/FibroScan
  - Patients on therapy with suppression

Enrolling CTN+ Trials Prevention and Testing

- HPV
  - Mapping Opportunities for HPV Vaccination and Screening Engagement and Uptake in Trans Men and Gender Non-Binary Individuals Assigned Female at Birth
  - A multicenter, randomized controlled trial of the efficacy, safety and immunogenicity of the 9-valent human papillomavirus (HPV) vaccination in preventing recurrence of high-grade anal dysplasia in HIV-positive men who have sex with men (MSM)
- HIV
  - Long acting PrEP national trial under development
  - Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance u0026 Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario
  - A Study of Reduced Dosing of the Nonavalent HPV Vaccine in Women Living with HIV
- CT/GC
  - A randomized trial of doxycycline chemoprophylaxis for the prevention of sexually transmitted infections in gay, bisexual and other men who have sex with men (gbMSM)
- Syphilis
  - Using a novel assay to detect syphilis infection early in asymptomatic men who have sex with men (MSM) undergoing STI screening

Enrolling CTN+ Trials Treatment

- HIV
  - Aging, hormonal therapy, fertility, cannabinoids, violence/stigma, fatty liver, DDI, anal cancer biomarkers, cascade of care, impact of COVID, adherence, vitamin D deficiency, cognition, osteoporosis, brain health, inflammatory markers, Valacyclovir, micronutrients, cohort, neuropathy, heart disease prevention, cognitive development
- HCV
  - Nurse lead treatment, vaccine (terminated)
- Mpox
- Syphilis
  - Penicillin therapeutic drug levels
- HIV+HCV
  - Kaletra/Celsentri, access to food, Raltegravir switch, cohort
- HBV: none

Enrolling CTN+ Trials Cure and Immunotherapy

- HIV
  - Fecal transplant, letermovir
  - Completed: response to COVID vaccine, mucosal CD4 cells, cohort of slow progressors, valproic acid, vaccine, chloroquine, treatment interruption, probiotics, Camu Camu, treatment combinations, immune modulation, metformin
- Others: none

Atlantic CTN+ Research Priorities

- Atlantic STBBI Epidemiology
- Access to testing
- Cascade of care
- Defining a regional STBBI cohort
- HBV cure
- HCV human challenge
- PO syphilis treatment

Proposed CTN+ Atlantic Structure

- Modeled after AMMI CRN
  - Pitch new studies for feedback and update previous studies
  - Plan grant submissions
  - One virtual (ACHIVE), one in person annually
  - St. John’s lead site, run by project manager

Funding Flow

- CIHR
- McGill
- Memorial University
- NL Health Services
- Provincial health services NB, NS, PEI

Phase 2 Training and Mentorship

- Not funded yet

Next Steps

- ACHIVE Sept 20/21 Moncton
  - Develop ACHIVE format
- Hire project manager
- Get funds for staffing to sites
- Get researchers approved by CTN+
- Decide which national trials to join
- Eventually write a regional proposal
- Seed application by January?