

**The Ontario HIV Treatment Network**  
Promoting excellence and innovation  
in HIV research and care


**Epidemiology of Vulnerable Populations:  
The Ontario HIV/AIDS Experience**

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## Overview: Provincial (Ontario) and International Initiatives

- The OHTN Cohort Study
- Positive Spaces, Healthy Places
- The NA-ACCORD (North American AIDS Cohort Collaboration on Research on Design)




## HIV and AIDS in Ontario

- At the end of 2005, 26,461 people were ever diagnosed with HIV in Ontario. Roughly 25% are women
- It is estimated that 27% of people in Canada with HIV are unaware of their infection, increasing the previous number to 33,605.
- 57% of HIV infections in 2005 attributed to MSM, 11% to IDU, 7% endemic country, 22% heterosexual sex, and 3% to other exposures.



## The OHTN Cohort Study


- Third generation / revitalization of HOOD
- Longitudinal retrospective cohort study of approximately 4,000 people infected with HIV in Ontario
- Informed consent provided to study
- Largest HIV cohort in Canada



## OHTN Cohort Timeline

<b>1985</b> 7,803 HIV 275 AIDS 113 deaths	<b>1990</b> 13,124 HIV 2,805 AIDS 1,528 deaths	<b>1992</b> December: James Thatcher, in his capacity as CEO, demands better drug access and announces funding to develop an observational study of HIV in Ontario.	<b>1994</b> HIV Ontario Observational Database (HOOD) study funding conversion. Dr. James Thatcher agrees to lead the project.	<b>1995</b> 20,284 HIV 6,472 AIDS 3,060 deaths
<b>1996</b> Ethics approval received. HOOD recruitment begins.	<b>1999</b> HOOD merges with OHTN. The HIV Information Infrastructure Project (HIIP) Advisory Committee now governs HIIP and HOOD and maintains a 50% majority.	<b>2000</b> 26,029 HIV 7,942 AIDS 6,523 deaths	<b>2005</b> OHTN Board of Directors approves OHTN Cohort Study development in its new Strategic Plan. Cohort Study Governance Committee replaces HIIP Advisory Committee, retaining control over the Cohort Study and the protection and use of data.	

Members of the board consist of: Charles Reynolds & Associates



## The Thatcher REPORT

Winter 2006

All you need to know about the OHTN Cohort Study

**James Thatcher**  
*A man with a mission*



James Thatcher was raised in Bermuda by Canadian parents. After moving back to Canada, he received his BA and MBA from the University of Western Ontario. He was diagnosed with HIV in the late 1980s.

An activist by nature, James joined AIDS Action Now! (AAN) in 1988 and became co-chair (with Darlen Taylor) in 1991. He loved politics, was well connected and had an inside track on who could do what. James was instrumental in developing protest strategies to challenge the government on its poor record on drug distribution, HIV research and standards of care. He even handcuffed himself to the Health Minister's door, demanding a meeting. James was also a co-founder of HALCO, the HIV/AIDS Legal Clinic of Ontario. In spite of failing health, he would host HALCO meetings in his apartment while hooked up to an IV drip for the CMV that was causing him to go blind.

Sunnybrook Hospital in Toronto, had just received a grant to begin the database research that would become HOOD (the HIV Ontario Observational Database—now the OHTN Cohort Study). The video will soon be viewable online at the OHTN website. James lived in Toronto at the time of his death in 1993 at the age of 36.

The OHTN Cohort Study is a community-governed research project that represents the realization of James' challenge to us all: See "A Living Legacy." The OHTN exCHANGE Autumn 2005. The Cohort Study grew out of the successes of HOOD and HIIP (the HIV Information Infrastructure Project). To date, more than 4,000 HIV positive participants have volunteered to have their anonymized health data compiled for HIV research.

*"From an early age, James was a born leader: independent, confident and a strategic thinker—characteristics that bore him well following his devastating HIV diagnosis."* — Jack Thatcher, mother of James

## The OHTN Cohort Study

- ✓ The OHTN Cohort Study (OCS) collects health related data from people living with HIV/AIDS throughout the province of Ontario. OCS data are used by researchers and health care providers to improve:
  - ✓ Our understanding of HIV/AIDS
  - ✓ Optimal HIV/AIDS treatment strategies
  - ✓ Access to care and treatment for people living with HIV/AIDS

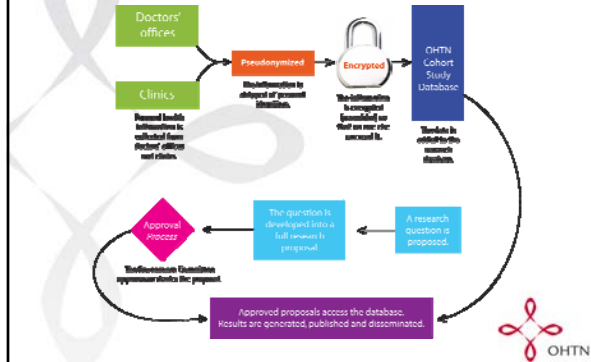


## What Data is Available?

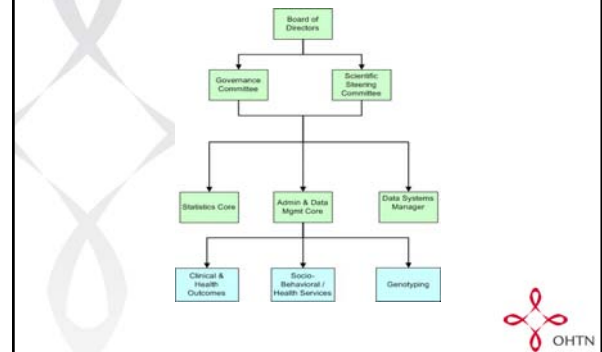
- Clinical data are collected (extracted) from patients' medical records (by hand or by CMS) dating to their first HIV positive test result.
- Data updated at least every 6 months
- Yearly interviewer administered questionnaires / survey which includes detailed socio-demographics and social determinants of health information.
- Linkages to administrative databases (such as OHIP, Public Health Laboratories, etc.) to further expand the OCS dataset.



## Schematic of OCS: Data Access



## OCS Governance Structure



## OCS Governance Committee

- Governs use of and access to OCS data
- Membership: Composed of 50% + 1 persons living with HIV with researchers and health policy lawyer
- Committee reviews research protocols
- Recommends research policies to OHTN Board of Directors
- Reviews research output for consistency with OHTN values & principles



## OCS Scientific Steering Committee

- Develops research agenda and principal aims and objectives with input from the community
- Oversees all research projects using OCS data
- Composed of representatives from all OCS sites, Chair of Governance Committee and 2 community representatives
- Each SSC member sits on 1 of 3 OCS working groups



## OCS Working Groups

### • Sociobehavioural and Health Services Working Group

#### Principal Aims:

- Examine the social context of HIV/AIDS in Ontario
- Examine issues related to health services use among people living with HIV in Ontario
- Examine issues related to mental health and addictions among people with HIV in Ontario



## OCS Working Groups

### • Genotyping Working Group

#### Principal Aims:

- Examine the factors involved in the evolution of HIV drug resistance
- Examine the clinical impact of drug resistance
- Determine optimal management and care strategies in the face of drug resistant HIV



## OCS Working Groups

### • Clinical Working Group

#### Principal Aims:

- Examine HIV infection and its complications
- Examine HIV treatment and its complications
- Examine chronic diseases and conditions associated with HIV infection (e.g., cardiovascular and co-infection complications, cancer, neurocognitive impairments)



## Vulnerable Populations

The OHTN Cohort Study (OCS) can be used to monitor and address issues among vulnerable populations infected with HIV

- Injection drug users (8.3%)
- Aboriginal Peoples (3.6%)
- Women (10.8%)
- People from endemic countries (6.0%)
- Youth



## Examples of Research on Vulnerable Populations Using the OCS

- Analyses of quality of care, comparing persons from vulnerable populations to the rest of the cohort.
- Analyses of access to treatment (e.g., anti-retroviral treatment, treatment for hepatitis C co-infection, etc.) among vulnerable subpopulations such as injection drug users, and their relative risks for morbidity and mortality



## Examples of Research on Vulnerable Populations Using the OCS

- Expansion of data collection on the social determinants of health: enable examination of quality of life as an outcome of treatment, as well as the relationship between a range of social determinants of health (such as housing, employment, social support, income) and adherence to treatment, as well as both clinical and quality of life outcomes
- These results can also be compared across different vulnerable populations



Ontario HIV Treatment Network

Home Funding Programs Research Conference Cohort Study CBR Knowledge

### OCS Protocol Submissions

**ABOUT SUBMISSIONS**  
All investigations using OHTN Cohort Study (OCS) data require the approval of the OCS Scientific Steering Committee (SSC) and the OCS Governance Committee. This approval process is in place in order to ensure that:

1. the proposed research is consistent with the established scientific Principal Aims of the OCS
2. the proposed research is scientifically practical, necessary and sound
3. the proposed use of data is consistent with OCS Research Policies

**PROTOCOL SUBMISSIONS FOR RESEARCHERS**  
The protocol submission process for researchers is detailed in Overview of the OHTN Cohort Study Approval Process and Investigation Approach and all required forms are available in the resources section. Any questions or concerns can be directed to the OCS Manager.

**PROTOCOL SUBMISSIONS FOR STUDENTS**  
The protocol submission process for students is detailed in Overview of the OHTN Cohort Study Approval Process and Investigation Approach and all required forms are available in the resources section. Any questions or concerns can be directed to the OCS Manager.


**RESEARCH POLICIES**  
OCS Research Policies

**TRAINING OPPORTUNITIES**  
Nothing available at this time.

**FOR MORE INFORMATION**  
Cohort Study  
+1 647 642-6486 x213


**RESOURCES**  
Overview of OCS Approval Process for Researchers  
OCS Concept Sheet for Researchers  
Overview of OCS Approval Process for Students  
OCS Student Concept Sheet for Students  
OCS Protocol Checklist  
Data Solicit Request Form  
OCS Publication Policy  
Confidentiality Agreement  
Committee Site

Search




Positive spaces  
Healthy places

Community-based research exploring  
HIV, housing & health




## Investigator Group

**Principal Investigators**  
Ruthann Tucker, Executive Director, Fife House  
Dr. Saara Greene, York University, School of Social Work  
Dr. Dale Guenter, McMaster University, CLEAR Unit


**Co-Investigators**  
Michael Sobota, Executive Director, AIDS Thunder Bay  
Jay Koornstra, Executive Director, Bruce House  
Steve Byers, Executive Director, AIDS Niagara  
Lea Narciso (On Leave), Ontario AIDS Network  
LaVerne Monette, Executive Director, Ontario Aboriginal AIDS Strategy  
Dr. Steven Hwang, Centre for Research on Inner City Health (CRICH), Univ of Toronto  
Dr. James Dunn, CRICH, Univ of Toronto  
Dr. Sean B. Rourke, OHTN, Univ of Toronto, CRICH


**Project Coordinator**  
Dr. Amrita Ahluwalia


**Peer Research Assistants**  
D. Hintzen, James Watson, Jim Truax, Michael Hamilton, Pius J. White, Marie Kayitesi





## Funders

 Canadian Institutes of Health Research (CIHR) - \$300,000


 Ontario HIV Treatment Network (OHTN) - \$170,000 + in-kind (office space, teleconference calls etc)

 Ontario Ministry of Health and Long-term Care, AIDS Bureau - \$35,000

 Wellesley Institute - \$18,750

 Ontario AIDS Network (OAN) - \$6,600

**Total = \$530,350 over 3 years**



## Partners

**Community-Based AIDS Service Organizations**

AIDS Niagara  
AIDS Thunder Bay  
Bruce House  
Fife House  
Ontario AIDS Network  
Ontario Aboriginal HIV/AIDS Strategy


**Universities Hospitals & Research Centres**

Clear Unit  
McMaster University  
School of Social Work, York University  
University of Toronto



## PSHP Study Objectives

- Establish a baseline of the housing status of PHAs in Ontario.
- Identify the range of housing and supportive housing options currently available to PHAs in Ontario, including those provided by ASOs, community-based health and social service organizations and other housing and/or homelessness agencies.
- Identify the characteristics of appropriate housing and supportive environments for PHAs applicable at various stages of the disease course.



## PSHP Study Objectives (2)

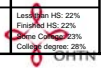
- Determine the kind of housing options desired or required by PHAs that will ensure access to health care, treatment and social services.
- Identify the factors that affect the housing status and stability of PHAs; and to understand how such factors may impact the physical and mental health of PHAs and their access and utilization of health care, treatment and social services.
- Determine possible variations in the housing and/or homelessness experiences of PHAs from specific communities: aboriginal communities, ethnocultural communities, women, families, sexual identities, youth and ex-prisoners.



## Demographics

	Ontario Sites				Total (N=605)
	Greater Toronto (n=377)	Eastern Ontario (n=94)	Central & Southwest (n=94)	Northern Ontario (n=40)	
Age (in yrs)	43 (8) (range 21-70)	43 (8) (range 25-65)	45 (8) (range 26-70)	46 (8) (range 20-55)	43 (8) (range 20-70)
Gender Male / Female / Transgender	289 / 83 / 5	70 / 23 / 1	70 / 23 / 1	27 / 13 / 0	456 / 142 / 7
Sexual Orientation	62% Gay 08% Bisexual 29% Heterosex	36% Gay** 10% Bisexual 53% Heterosex	51% Gay 09% Bisexual 36% Heterosex	23% Gay** 08% Bisexual 68% Heterosex	54% Gay 08% Bisexual 36% Heterosex
*Member of Aboriginal Grp	11% (28 / 10 / 0)	21% (10 / 7 / 3)	7% (2 / 4 / 0)	31%*** (10 / 2 / 0)	13% (N=80)
Speak English at Home	92%	92%	96%	98%	93%
Education	Less than HS: 18% Finished HS: 21% Some College: 22% College degree: 32%	Less than HS: 30% Finished HS: 19% Some College: 21% College degree: 21%	Less than HS: 20% Finished HS: 25% Some College: 25% College degree: 29%	Less than HS: 45%** Finished HS: 23% Some College: 18% College degree: 12%	Less than HS: 22% Finished HS: 22% Some College: 23% College degree: 29%

\* First Nations / Métis / Inuit; \*\*\* p < 0.001



## Income, Expenses and Housing Risk

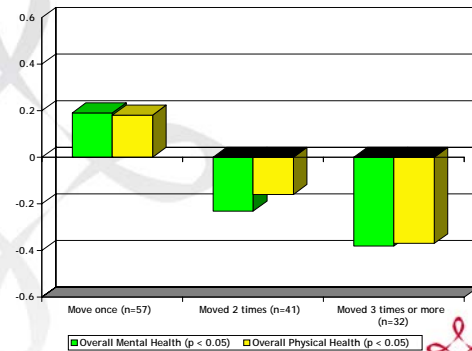
	Ontario Sites				Total (N=605)
	Greater Toronto (n=377)	Eastern Ontario (n=94)	Central & Southwest (n=94)	Northern Ontario (n=40)	
Gross monthly income (median)	\$ 1,559 (0 - 17,500)*	\$ 1,300 (300 - 4,000)	\$ 1,535 (100 - 9,000)	\$ 1,202 (350 - 3,800)	\$ 1,489 (0 - 17,500)**
Monthly amount for rent / mortgage	\$ 462	\$ 483	\$ 503	\$ 479	\$ 473
Live in RGI Unit	48%	43%	39%	11%***	43%
Currently working for pay	21%	15%	23%	15%	20%
Face difficulty buying food	56%	65%	55%	55%	57%
Face difficulty buying clothes	51%	57%	55%	65%	54%
Housing at risk <sup>^</sup> (mo. rent/income)	29%	40%	33%	23%	31%

\*\*72% had income < \$ 1,500/month; 90% had income < \$ 2,500/month; income > \$ 5,000/month (n=10); \*\*75% had income < \$ 1,500/month

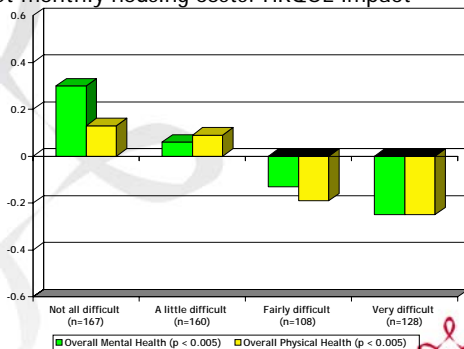
\*\*\* p < 0.01; ^ excluding those with RGI unit



## No. of times moved in past year: Impact on HRQOL



## Considering your income, how difficult is it to meet monthly housing costs: HRQOL Impact



## Key Findings and Main Messages

- 75% of sample report income less than \$ 1,500 per month
- 1 out of 3 people living with HIV are at risk for losing their housing
- Number of times moved in the past year, as well as uncertainty about ability to meet monthly housing costs, has significant and negative effects on both physical and mental HRQOL
  - 42% of sample have significant difficulty meeting monthly housing-related costs and these individuals have lower health related quality of life relative to those who can make ends meet
  - Moving **more than once** in past year has a significant effect on both mental and physical health-related quality of life



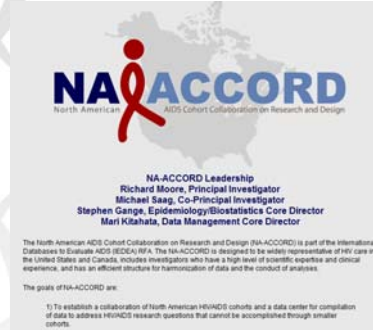
## Key Findings and Main Messages

- Housing with support services has quality of life benefit
- Feeling of "belonging in one's neighbourhood" and that "one's home provides a good location of where to live" are significantly and positively related to virtually all health-related quality of life dimensions.
- 1 out of 4 people living with HIV do not feel that they belong in their neighbourhood
- 1 out of 3 people living with HIV often worry about being forced out of their homes and these individuals have lower health-related quality of life
- 1 out of 5 people living with HIV do not feel that their home provides a good place for them to live
- People living in unstable housing situations are younger and have more substance-related issues and higher rates of being in jail



## Website:

<http://statepiaps.jhsph.edu/naaccord>



## NA-ACCORD Goals

- Establish a collaboration of NA HIV cohorts to address research questions that cannot be accomplished through smaller cohorts.
- Develop and apply novel statistical and epidemiological methodology to these scientific research initiatives.
- Establish a mechanism to identify, prioritize and efficiently address new scientific issues that arise.
- Collaborate with other regional cohorts in IEDEA to compare results, and address questions of inter-regional importance.



## The OCS and the NA-ACCORD

- The OCS is also part of a larger NIH-funded collaboration of multiple clinical databases from across North America: the NA-ACCORD
- With more than 95,000 patients enrolled, the NA-ACCORD will have the power to address clinical questions for vulnerable sub-populations (e.g., women, injection drug users, racial minorities)

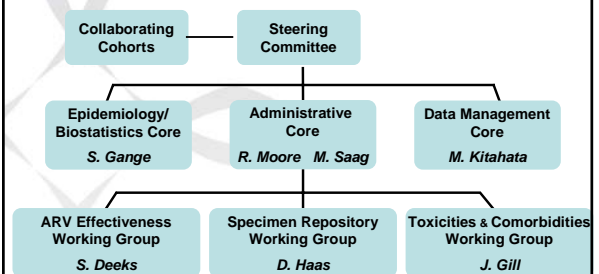


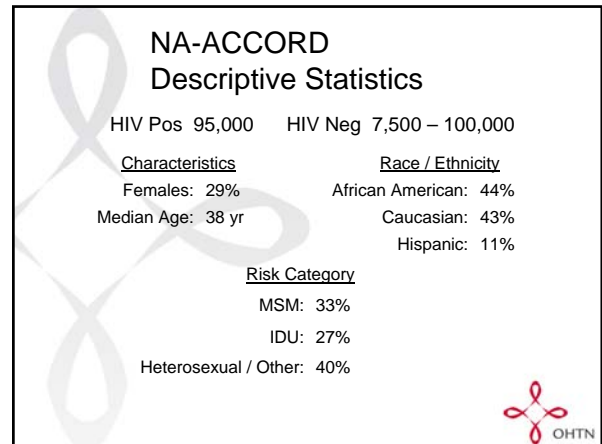
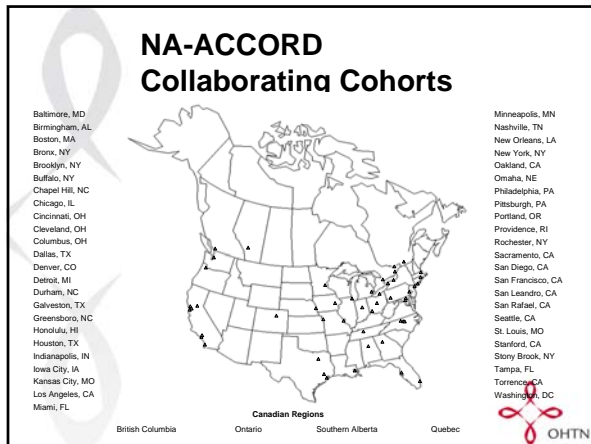
## NA-ACCORD Collaboration

- Single-site, multi-site and networked cohorts.
- Spans academic medical centers and community-based facilities that deliver HIV primary and specialty care.
- Combination of classical ("interval") epidemiologic cohorts and clinical HIV cohorts with both HIV-seropositive and seronegative persons.
- Access to unique specimen repositories for conducting translational and pathogenesis research.
- Represent over 50 sites with greater than 95,000 patients from the United States and Canada who collectively have produced over 1,500 HIV/AIDS publications over 20 years. However, for the most part, these NA cohorts have not collaborated to date.



## Administrative Structure





- ## Specific Aims (1)
- For patients who are highly antiretroviral (ARV)-experienced and have multi-drug resistant (MDR) HIV, we will determine the optimal management strategies to slow disease progression.
  - Determine factors associated with disease progression in patients who are highly ARV-experienced and have incomplete viral suppression, and to characterize the risk of clinical deterioration based on these factors over time.
  - Determine (and monitor) the prevalence of MDR virus and identify factors associated with increased risk of disease progression in MDR patients who have incomplete HIV viral suppression.
  - Determine guidelines for using combination ARV therapy in patients with incomplete viral suppression.
- OHTN

- ## Specific Aims (2)
- Determine the optimal initial treatment strategies with contemporary HAART regimens.
  - Determine the risk of disease progression (ADI and survival) and treatment-related co-morbid events (dyslipidemia, diabetes mellitus, hypertension, cardiovascular disease) among patients who initiate HAART at higher CD4+ cell counts as compared with patients who delay ARV treatment.
  - Determine whether the benefits and risks of early vs. late ARV initiation are consistent across sub-populations of patients.
  - Determine the most potent regimen(s) for ARV-naïve patients that result in the greatest proportion of individuals with suppressed HIV RNA within six months from initiation, and to determine differences among sub-populations.
- OHTN