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 Darien 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.

> **"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."** — Joan Thatcher, mother of James

From his living room at home in late 1992, James summoned his friends to record his dying words on videotape—challenging the government, researchers and the HIV community to work together to improve life for people with HIV/AIDS (PHAs). He specifically demanded better care and treatment and access to drugs. In this same video he announced that Dr. Anita Rachlis, of 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, and more than 60 studies have been carried out using this data (see "Improving Care & Policy," page 6).

We dedicate this newsletter to the memory of James Thatcher, who continually challenges us to meet and exceed his expectations. For updates on the Cohort Study, look for *The Thatcher Report* in future issues of the *The OHTN exCHANGE*.

The Evolution of the OCS

Consolidating the early years, building on our strengths

In 1996, HOOD began collecting anonymized medical data from people with HIV/AIDS (PHAs) in Ontario. In the late '90s, HIIP began providing clinics with computerized tools for data collection and patient care.

The OHTN Cohort Study (OCS) is a new and improved approach to gathering richer and better data for HIV research. Building on the successes of HOOD and HIIP, the OCS gives participating clinics more flexibility. If an existing HOOD clinic does not choose to move to electronic data extraction methods, information can still be gathered from its patients. This ensures that all current HOOD and HIIP participants can continue to contribute valuable information.

The OCS will provide an extremely broad range of data on HIV treatment and health outcomes, helping to make Ontario a world leader in HIV research. More importantly, it will produce tangible outcomes that we hope make a positive difference to the lives of PHAs in Ontario.

New participants will be able to enroll in the OCS through participating clinics at any time. All participants who originally consented to the HOOD study will be asked for re-consent to the OCS before any of their data is transferred.

The Re-Consent Process

All HOOD participants will be invited to re-consent to the OCS. They will have three options to choose from:

1. Join the OCS and have their HOOD data transferred into the OCS database.
2. Agree to have their existing HOOD data transferred into the OCS database, but decline further participation in the OCS.
3. Decline participation in the OCS and have their HOOD data permanently deleted.

Data deletion—a change in procedure

Previously, HOOD participants could choose to have their existing data deleted if they withdrew from the study. People who choose not to re-consent to the OCS may still have their records deleted. If participants consent to enter the OCS, they may still leave the study at any time but will no longer be able to request the deletion of data that has already been collected. (This "retroactive deletion" option was seldom used in HOOD and is not offered in other studies of this nature.)

Re-consent will occur wherever a participant originally consented for HOOD. If you have changed doctors since first enrolling, we may not know where to approach you for this consent process.

To discuss your consent options, contact the physician who originally enrolled you in HOOD or call the Ontario AIDS Network at 1.800.839.0369. Your confidentiality is assured.

1985
7,863 HIV
275 AIDS
113 deaths

1990
13,424 HIV
2,905 AIDS
1,929 deaths

Numbers refer to total cases in Ontario by end of given year.

1992
December: James Thatcher, in his legendary video, demands better drug access and announces funding to develop an observational study of PHAs

1994
HIV Ontario Observational Database (HOOD) study funding committed;
Dr. Anita Rachlis agrees to lead the project

1995
20,254 HIV
6,479 AIDS
5,060 deaths

Protecting Your Privacy

The OHTN has gone to great lengths to guarantee the safety and security of personal medical information. Here are some of the ways we make sure to protect OHTN Cohort Study participants' anonymity and confidentiality:

Consent

No information is ever collected without voluntary, informed consent. Participants are free to withdraw from the study at any time.

Anonymity

When a patient consents to participate in the OCS, data from his/her electronic health record is stripped of all personally identifying information (such as name and address) before it is transferred to the database. A computer then uses a mathematical formula to turn the person's health number into a unique, unbreakable code. This unique ID results in anonymized information which allows each person's information to be accurately tracked, while keeping his/her identity completely confidential.

Transport Security

All data sent to the OCS database is encrypted (scrambled) during transmission. Some participating sites use a computer-based system—the Clinical Management System (CMS)—for keeping medical records. These sites communicate with the OHTN over a secure communications network that uses the same state-of-the-art transmission security as financial institutions. Data is sent to the research database over this secure connection. Other sites keep paper charts, which are transferred to computer for entry in the OCS. Data sent to the research database from these sites is transferred to the OHTN via an encrypted data storage device.

Who Uses the Data?

The OCS Governance Committee is made up of people living with HIV/AIDS and other stakeholders in the Ontario HIV community. This committee determines who can access specific datasets and for what purpose. Each request is assessed regarding the soundness and ethics of the data's intended use.

Other Privacy Protection

All OHTN staff, consultants and service providers must sign **confidentiality agreements**. Health care providers are guided by their professional codes of conduct.

All OHTN Cohort Study staff receive comprehensive technical and **privacy awareness training**.

The OHTN's **privacy policy** meets health care industry standards and includes specific policies on the scope of data collected, the purposes of data collection, limits on disclosure, accountability and openness.

An official **Complaints and Dispute Resolution** process is available for participants who feel that their confidentiality may have been compromised.

1996
Ethics approval received, HOOD recruitment begins

1999
HOOD merges with OHTN. The HIV Information Infrastructure Project (HIIP) Advisory Committee now governs HIIP and HOOD and maintains a PHA majority

2000
26,659 HIV
7,845 AIDS
6,553 deaths

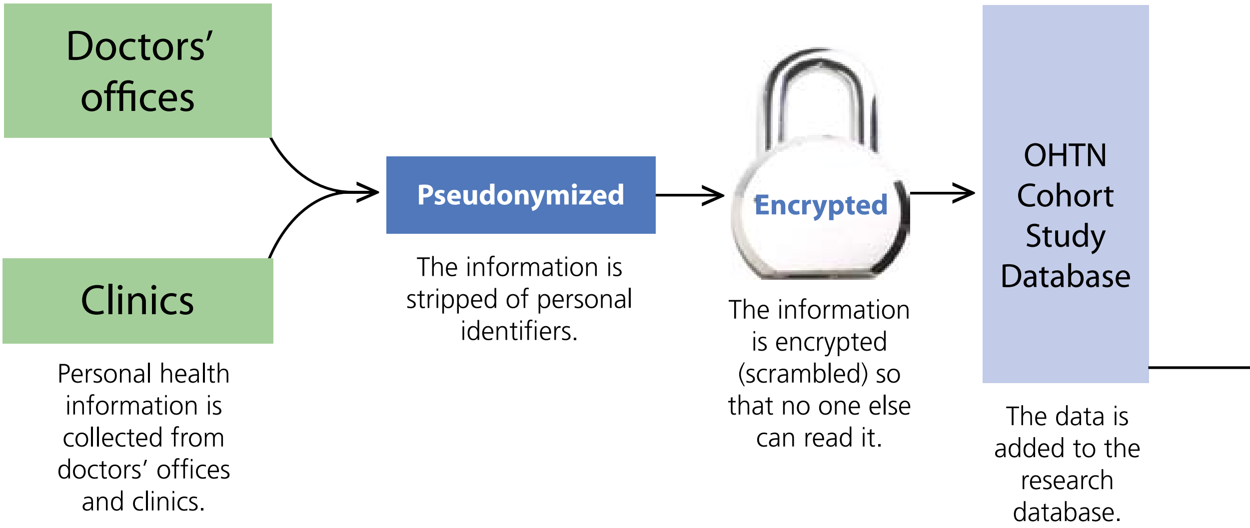
2005
OHTN Board of Directors approves OHTN Cohort Study development in its new Strategic Plan. Cohort Study Governance Committee replaces HIIP Advisory Committee, retaining control over the Cohort Study and the protection and use of data.

OCS Inform

The OCS Govern

The Governance Committee is responsible for overseeing the OHTN Cohort Study, specifically:

- the policies relating to the security and confidentiality of data collected, transferred and stored in the OCS database, and
- approving the research to be carried out using the OCS data.



Doctors' offices

Clinics

Personal health information is collected from doctors' offices and clinics.

Pseudonymized

The information is stripped of personal identifiers.

Encrypted

The information is encrypted (scrambled) so that no one else can read it.

OHTN Cohort Study Database

The data is added to the research database.

What is the OHTN Cohort Study?

The OHTN Cohort Study (OCS) is a research project that studies people living with HIV/AIDS (PHAs) across Ontario to help improve their care, treatment and support.

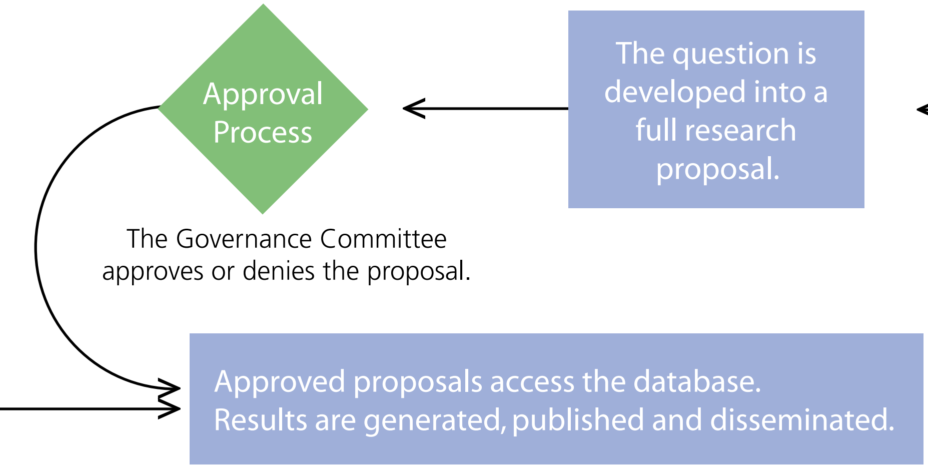
The OCS collects comprehensive—and completely anonymous—health data from the medical records of volunteer participants.

Until now, the OCS has collected mostly medical data. In the near future, the OCS will be collecting more social and behavioural information so that research can investigate how these factors affect health and quality of life.

nation Flow

ance Committee

Committee members have expertise in ethics, HIV research, legal and other areas. There is 50%-plus-one PHA representation on the OCS Governance Committee, giving the PHA community final control over all decisions.



A research question is proposed.

The question is developed into a full research proposal.

Approval Process

The Governance Committee approves or denies the proposal.

Approved proposals access the database.
Results are generated, published and disseminated.

Why participate in the Cohort Study?

HIV is a complex disease and our understanding of it is constantly evolving. HIV care and treatment changes frequently as we learn more about the disease, and researchers need faster access to more comprehensive health data. The OCS collects "real-time" data on a large number of patients, creating unprecedented research opportunities to:

- improve our understanding of HIV disease
- identify better treatments
- help PHAs get better access to care

More than 4,000 individuals have already volunteered to participate in HOOD—providing information that will be rolled into the OCS. Additional participants will make the research results more relevant and reflective of the entire PHA community. Every single study participant makes a valuable contribution.

Improving Care & Policy

Key findings from the OCS benefit people with HIV

More than 60 OCS/HOOD/HIIP studies have been presented at conferences since 1994, with nine publications in scientific journals. Here is just a sample:

Health Services Research

Viral load testing: In 2005, Janet Raboud and team ("et al.") found that in Ontario fewer viral load tests were accessed by: injection drug users, Toronto residents, younger PHAs, those with less than high school education, and those with lower viral loads. Also, fewer tests were done in more recent calendar years. These factors should be addressed to ensure optimal use of viral load testing.

TB testing: In 1999, Peggy Millson et al. found that only 54% of HOOD participants had a recorded TB test at the time of enrollment. This encouraged many clinics to consider more standardized care guidelines for TB skin testing and other public health issues.

Patient Care

Lipid-lowering drugs: In 2002, Elizabeth Phillips et al. found that more people on protease-inhibitor-based regimens used lipid-lowering drugs. Use of PI-sparing combinations may: avoid elevated lipid levels, decrease overall pill burden, prevent potential drug interactions, and cost less.

Starting HAART: In 1999, Ahmed Bayoumi et al. found that gender and injection drug use did not affect the likelihood of accessing HAART. The strongest predictors of starting HAART were medical factors, such as low CD4 count.

Gender Analyses

In 2002/2003, Tonya Forte et al. found that men's and women's overall success rates on HAART were similar. However, while men's viral loads stayed undetectable longer, women had better CD4 responses. More male than female PI-users experienced a rise in cholesterol levels.

Complementary and Alternative Medicine (CAM)

CAM use: In 2003, Shelly Furler et al. showed that 77% of PHAs interviewed used CAM (89% when vitamin and mineral use was included). CAM costs ranged from $0 to $250 a month. Only 38% of physicians were aware of the entirety of their patients' CAM use: Doctors and patients should routinely discuss CAM use to reduce the potential for drug interactions.

Marijuana use: In 2004, Furler et al. found that 43% of PHA participants reported marijuana use; 29% described their use as medicinal. The most commonly reported reason was appetite stimulation and/or weight gain. Many more women than men reported using marijuana for pain management.

Economic Analysis

The cost of HIV: In 1999, Dale McMurchy et al. used HOOD to determine the cost of HIV in the province of Ontario. Direct medical costs for HIV in 1997 were estimated at $147 million, or $18,140 per patient per year, with a high proportion of medication costs borne privately.

The NA-ACCORD: *OCS Goes International*

The North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) is a collaboration of 15 HIV cohorts, or study groups, from across the continent. This collaboration makes it possible to study more than 50,000 participating PHAs (and 7,500 HIV negative controls) as though they were a single group. Such enormous numbers of participants make it possible to conduct research into the best possible treatment strategies. In fact, the NA-ACCORD is poised to become part of an even larger global research group in the future.

The NA-ACCORD, led by Dr. Richard Moore of Johns Hopkins University, was formed in response to a call from the U.S. National Institutes of Health (NIH). In August 2005, the OCS Governance Committee and the OHTN Board of Directors approved collaboration with the NA-ACCORD, and funding from the NIH was announced in February 2006.

Participation in the NA-ACCORD gives Ontario researchers access to a wealth of information to answer questions that cannot be answered by smaller cohorts. Any research question that proposes to use Ontario data within the context of the NA-ACCORD will be reviewed by an ethics board and the OCS Governance Committee. Data will only be released in accordance with the OHTN's own research policies.

The OCS Research Agenda

The OHTN is developing a revitalized research agenda for the OCS. The new agenda will ensure that Ontario researchers have the time, resources and knowledge to investigate important topics in the following areas:

- **Clinical issues:** HIV-related cancers, drug resistance, salvage therapies, adverse events and metabolic problems, including lipodystrophy and cardiovascular abnormalities.
- **Social and behavioural issues:** the effects of poverty, housing, mental health and employment on PHA health outcomes and quality of life.
- **Health services:** issues of access to care, and the costs and cost-effectiveness of medical care.

Message from Darien Taylor

Chair, OCS Governance Committee

Since the 1980s, when HIV first shook our confidence in the ability of medicine and research to safeguard our health, our knowledge of this virus has grown. Yet many questions still remain to be answered. The complexity of HIV continues to challenge researchers, health care providers, people who work in AIDS service organizations and people living with this disease. For these reasons, the OHTN Cohort Study (OCS), which includes participants across the spectrum of HIV disease, is a critical tool to help researchers find answers. Collecting important social and behavioural data will further strengthen this study's ability to respond to evolving questions related to HIV in the years to come.

Taking the OCS international, through our link with the NA-ACCORD, improves Ontario's access to research information about HIV care and treatment. It also provides a unique opportunity to link to research teams across North America that are developing and answering questions similar to ours. The data we contribute to this "cohort of cohorts" will help answer questions of international significance and, in turn, we at the OHTN will benefit from the power of additional data to answer our own.

Rest assured that the confidentiality of the data provided by PHAs in Ontario is a top priority for the OCS Governance Committee. We are also committed to ensuring that the OHTN contributes to high-quality research that will lead to improvements in HIV care, support and treatment in Ontario and beyond.

The future directions for the OCS are very exciting. Dr. Sean B. Rourke, the Principal Investigator of the OCS, has developed an ambitious research agenda with contributions from a wide variety of stakeholders. The work that lies ahead will be demanding, but we are convinced that the outcomes—improvements in the lives of people living with HIV—will be well worth it.

D. Taylor

For additional information on the
OHTN Cohort Study, please see:
www.ohtn.on.ca/OHTNCohort.htm

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