Perspectives on Canadian Privacy Protections and Informed Consent

Institute of Medicine Committee on Health Research and the Privacy of Health Information: the HIPAA Privacy Rule

Washington, DC
October 1, 2007

Frank L. Silver, MD, FRCP(C)
Professor of Medicine (Neurology)
University of Toronto
Co-PI, Registry of the Canadian Stroke Network
Privacy Commissioner Launches Probe Into Hospital For Sick Children Medical Info Breach

Wednesday March 7, 2007
CityNews.ca Staff

There can't be anything more sensitive than your health information.

EDITORIAL
Protect health privacy

Mar 12, 2007 04:30 AM

The troubling case of a laptop computer stolen from the Hospital for Sick Children – containing patient information – is a stark reminder of the need for security in an electronic age.

As Ontario’s health-care providers increasingly ir

Sick Kids’ laptop theft angers watchdog

Mar 07, 2007 01:39 PM

CURTIS RUSH
STAFF REPORTER

A laptop computer containing the personal health information of 2,900 patients at the Hospital for Sick Children was stolen in January and the Ontario privacy commissioner plans t

Hospital For Sick Children Ordered To Increase Security Following Theft

Thursday March 8, 2007
CityNews.ca Staff
“According to our new patient protection guidelines, in order to protect your privacy I can’t tell anyone what’s wrong with you … and if they don’t know what’s wrong with you they can’t treat you … so you’re being discharged.”
Outline

• A case study: Registry of the Canadian Stroke Network (RCSN)
• Privacy Legislation in Canada
• Registries and the impact of requiring informed consent
• Some possible solutions
Privacy rules may threaten research

Following PIPEDA has led to biased database for Canadian Stroke Network

BY PIPA WYSCONG

TORONTO - Too many rules governing patient privacy and consent are hindering researchers' ability to collect needed research data.

As a result, this is the conclusion from a group of investigators reporting on the effectiveness of the registry of the Canadian Stroke Network (CSN) at gathering data.

Reporting in the New England Journal of Medicine (NEJM), researchers said the registry ended up with a low participation rate because the requirement by many research ethics boards and government legislation for written informed consent hindered enrollment.

The registry was launched in 2003 and included 30 major stroke treatment centers across the country.

The intent was to collect information on the use INCREASING Page 96

But, Dr. Jack Tu, a senior scientist at ICES, says there are no clear national guidelines for whom and how to use PIPEDA in collecting patient information for research.
Evolution of Privacy Legislation

- Data Protection Act, England, 2000
- Registry of the Canadian Stroke Network funded, 2000
- HIPPA, USA, 2003
- PIPEDA, Canada, January 2004
- PHIPA, Ontario, November 2004
These Privacy Laws have . . .

- Increased focus and awareness of the medical research community on privacy and confidentiality issues
- Many data custodians and IRBs have interpreted the laws very conservatively because of legal concerns and have refused data access and/or required informed consent
The Registry of the Canadian Stroke Network

www.rcsn.org
Registry of the Canadian Stroke Network (RCSN)

- conceived in 2000, at a time of increasing concern about privacy in Canada (PIPEDA Act became effective Jan. 1, 2004)
- 20 of the leading stroke centres in Canada
- funded by the Canadian Stroke Network through a federal program (Networks of Centres of Excellence)
- host institution: Institute for Clinical Evaluative Sciences (ICES) in Toronto
- Data Privacy and Security Committee (chaired by Don Willison)
Purpose of the RCSN

Continuous collection of data on stroke patients across Canada to:

– to facilitate the evaluation and monitoring of stroke care for:
  » hospitals and care providers (CQI)
  » health policy makers

– provide a database for investigator-initiated research projects
Registry of the CSN (RCSN)

Core Database

Entry Criteria:
- ED diagnosis of stroke/TIA
- onset ≤ 2 weeks of hospital visit

Administrative Data
- Physician Services
- Provincial Drug Formularies

Emergency Department Data → Hospital Admission Data → Hospital Discharge Data → Outcomes Data

6 months
Methodology (Phases 1 & 2)

• Each centre had either a full-time or half-time neurological nurse coordinator
• Nurse Coordinators at each centre keep logs of all patients with a diagnosis of stroke or TIA
• Nurses obtain written informed consent from the patient or surrogate
• Data is entered into a laptop computer using custom designed software
• Secure electronic transfer of data to ICES in Toronto, Ontario
• Data analyzed and reported back to centers
• All sites obtained REB approval
Data Security

- Laptop computers double password protected
- Data encrypted using BestCrypt ® software
- Personal patient information stripped before data sent to ICES (encrypted health card number sent separately on encrypted disk)
- Encrypted data uploaded to ICES by direct unpublished telephone line
- Data kept on a secure server without connections to internet or intranet
- ICES has physical security barriers
- Data security and privacy policies
Consent Form

I, ________________________________, have reviewed the material in the patient brochure. I have discussed the above information with the hospital Nurse Coordinator, and I have had the opportunity to ask further questions. I consent to take part in Registry of the Canadian Stroke Network and:

1. allow the researchers access to my current hospitalization records to collect information relevant to my stroke
   Yes ☐ No ☐

2. allow the Nurse Coordinator to contact me or my family 6 months after my stroke occurred
   Yes ☐ No ☐

3. allow the researchers to link my records with the Ministry of Health files to collect information relevant to my stroke
   Yes ☐ No ☐

4. allow the researchers to include my records in analyses performed at ICES for Canadian health care related companies
   Yes ☐ No ☐
Early experience with Registry

• Among those agreeing to participate:

<table>
<thead>
<tr>
<th>Number of Menu Items Excluded</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Frequency (%)</td>
<td>1578 (95)</td>
</tr>
</tbody>
</table>

Don Willison, Chair, RCSN Data Privacy and Security Committee, 2002
Approach Rate / Overall Accrual by Site

Overall Accrual Rate = 39% (Consented Patients)
Phases 1 & 2 of the Registry

• Phase 1 – Jun 2001 - Feb 2002
  – coordinator workshop – strategies to improve consent rate
  – initiated “sampling”
  – removed 30-day follow-up

• Phase 2 – Feb 2002 – Dec 2002

allowed a *Minimal Data Set* collected on all participants to assess generalizability of registry

☐ de-identified

☐ age, sex, LOS, mortality
Impracticability of Informed Consent in the Registry of the Canadian Stroke Network

Jack V. Tu, M.D., Ph.D., Donald J. Willison, Sc.D., Frank L. Silver, M.D., Jiming Fang, Ph.D., Janice A. Richards, R.N., Andreas Laupacis, M.D., and Moira K. Kapral, M.D., for the Investigators in the Registry of the Canadian Stroke Network*

ABSTRACT

BACKGROUND
Government legislators and research ethics boards in some jurisdictions require all patients to give written informed consent before enrollment in clinical registries. However, the effect of such a requirement on the use of clinical registries and the extent to which registry data can be generalized remain uncertain.
## Consent Rates

<table>
<thead>
<tr>
<th>Overall participation rate</th>
<th>Phase 1 (N=4285)</th>
<th>Phase 2 (N=2823)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent obtained from patient</td>
<td>27.9</td>
<td>35.9</td>
</tr>
<tr>
<td>Consent obtained from surrogate</td>
<td>11.4</td>
<td>14.7</td>
</tr>
</tbody>
</table>

## Reasons for Non-participation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Phase 1 (N=4285)</th>
<th>Phase 2 (N=2823)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall nonparticipation rate</td>
<td>60.7</td>
<td>49.4</td>
</tr>
<tr>
<td>Reasons for nonparticipation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient died before could be approached</td>
<td>6.8</td>
<td>4.9</td>
</tr>
<tr>
<td>Patient left hospital before could be approached</td>
<td>19.7</td>
<td>4.9</td>
</tr>
<tr>
<td>Language barrier</td>
<td>1.4</td>
<td>1.9</td>
</tr>
<tr>
<td>Surrogate decision maker unavailable</td>
<td>6.5</td>
<td>5.9</td>
</tr>
<tr>
<td>Other reasons†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than three attempts to contact patient unsuccessful</td>
<td>17.1</td>
<td>20.1</td>
</tr>
<tr>
<td>Patient not admitted</td>
<td>—</td>
<td>4.6</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>—</td>
<td>5.4</td>
</tr>
</tbody>
</table>

Selection bias in enrolled participants

<table>
<thead>
<tr>
<th>In-hospital mortality rates</th>
<th>Participating Patients</th>
<th>Non-participating Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6.90%</td>
<td>21.70%</td>
</tr>
</tbody>
</table>

ODDS RATIO = 3.13
95% CI (2.65-3.70; p<0.001)
<table>
<thead>
<tr>
<th>Variable</th>
<th>Phase 1 Participating</th>
<th>Phase 1 Not Participating</th>
<th>P Value</th>
<th>Phase 2 Participating</th>
<th>Phase 2 Not Participating</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (yr)</td>
<td>69</td>
<td>72</td>
<td>&lt;0.001</td>
<td>72</td>
<td>73</td>
<td>0.09</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>53.3</td>
<td>51.1</td>
<td>0.17</td>
<td>54.7</td>
<td>48.7</td>
<td>0.002</td>
</tr>
<tr>
<td>Alive at discharge (%)</td>
<td>94.3</td>
<td>84.3</td>
<td>&lt;0.001</td>
<td>93.6</td>
<td>84.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Level of consciousness on admission (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alert</td>
<td>78.5</td>
<td>65.7</td>
<td>&lt;0.001</td>
<td>88.1</td>
<td>79.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Confused*</td>
<td>7.7</td>
<td>12.6</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Drowsy</td>
<td>4.3</td>
<td>8.2</td>
<td></td>
<td>9.1</td>
<td>13.0</td>
<td></td>
</tr>
<tr>
<td>Unconscious</td>
<td>9.5</td>
<td>13.5</td>
<td></td>
<td>2.8</td>
<td>7.1</td>
<td></td>
</tr>
<tr>
<td>Race or ethnic group (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>4.0</td>
<td>15.7</td>
<td>&lt;0.001</td>
<td>2.4</td>
<td>8.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>White</td>
<td>91.3</td>
<td>77.3</td>
<td></td>
<td>85.0</td>
<td>63.2</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4.7</td>
<td>7.0</td>
<td></td>
<td>12.6</td>
<td>28.7</td>
<td></td>
</tr>
<tr>
<td>Preferred language (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>59.9</td>
<td>55.9</td>
<td>0.002</td>
<td>75.5</td>
<td>65.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>French</td>
<td>30.3</td>
<td>28.4</td>
<td></td>
<td>14.5</td>
<td>10.1</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>9.8</td>
<td>15.7</td>
<td></td>
<td>6.1</td>
<td>12.1</td>
<td></td>
</tr>
<tr>
<td>Unable to determine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median length of stay (days)</td>
<td>10</td>
<td>3</td>
<td>&lt;0.001</td>
<td>11</td>
<td>9</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* The “confused” subcategory was eliminated in phase 2 of the registry.
Figure 1. Overall Participation Rates during Phases 1 and 2 of the Registry of the Canadian Stroke Network, According to Hospital.

The hospitals (denoted by letter code) are shown along the horizontal axis, sorted by their overall participation rate in phase 2, from the lowest rate (Hospital A) to the highest rate (Hospital T). The participation rate is the percentage of patients who consented to participate relative to the total number of patients who were eligible for the registry (including both those who could and those who could not be approached).
**Table 3.** In-Hospital Mortality Rates among Patients Who Participated and Those Who Did Not Participate during Phase 2 of the Registry Project, According to the Hospitals’ Participation Rank.

<table>
<thead>
<tr>
<th>Hospital and Participation Rank*</th>
<th>Mean Participation Rate</th>
<th>Mortality Rate</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Participating Patients</td>
<td>Nonparticipating Patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P–T (top 5 hospitals)</td>
<td>71.6</td>
<td>7.2</td>
<td>25.1</td>
</tr>
<tr>
<td>K–T (top 10 hospitals)</td>
<td>66.8</td>
<td>8.0</td>
<td>28.6</td>
</tr>
<tr>
<td>A–T (all hospitals)</td>
<td>51.9</td>
<td>6.8</td>
<td>23.4</td>
</tr>
</tbody>
</table>

* The hospitals are denoted by letter codes (which correspond to those shown in Fig. 1). The hospitals were ranked according to their overall rate of patient participation during phase 2 and were grouped into the categories shown.

*Tu et al. NEJM 350:1414-1421, 2004*
The “cost” of obtaining consent

• Median time to enroll patient (arranging interviews, answering stroke related questions and obtaining consent) – 40 minutes
• Median time to abstract minimal dataset – 15 min
• Median time to abstract full clinical dataset – 40 min
• Estimated cost of $500,000 out of a $2,000,000 budget
Conclusions - RCSN Phase 1 & 2

• Obtaining written informed consent led to major selection biases in patients enrolled

• Obtaining informed consent was very costly in terms of both time and human resources

• Although the data was still useful for certain research projects, the full potential of the registry will not be realized

• These results highlight the need for legislation on privacy and policies to permit waivers of informed consent for minimal-risk observational research
View of Editors of NEJM

“Sadly, around the world, data repositories are now at risk of significant bias because concern about privacy has led to the requirement that consent be obtained before an individual person’s data can be included.”

“In our opinion, however, the pendulum has swung too far. Public health is threatened by incomplete data more than individual privacy is threatened by disease registries.”

Drs. Ingelfinger & Drazen, NEJM 350:1452-1453, 2004
Canadian Privacy Acts

PIPEDA, January 2004 (Canada)

Provinces

PHIA, December 1997 (Manitoba)
HIA, April 2001 (Alberta)
PPIA, April 2001 (New Brunswick)
HIPA, December 2003, (Saskatchewan)
PIPA, January 2004 (BC)
PHIPA, November 2004 (Ontario)
Personal Information Protection & Electronic Documents Act - PIPEDA, 2004 (Canada)

*Establishes a right to protection of Personal Information and sets out principles that govern its collection, use and disclosure.*

- Accountability
- Identifying purpose
- Consent
- Limiting collection of data
- Limiting use, disclosure and retention
- Accuracy of data
- Safeguards
- Openness
- Individual access
- Challenging compliance
Personal Health Information Protection Act (PHIPA) November 2004 – Ontario Bill 31

- provincial law governing the collection, use and disclosure of Personal Health Information (PHI) within the health care system
- requires that there be practices, policies and procedures in place to protect the privacy of individuals and to maintain the confidentiality of that information reviewed and approved by the Information and Privacy Commissioner (IPC) of Ontario.
**PHIPA: for research**

- All researchers must create a detailed standard research plan for each project.
- Must obtain informed consent unless a waiver is granted by an IRB
- Waiver may be granted
  - if “impracticable” to obtain consent
  - “Public interest in research outweighs public interest in maintaining privacy”
- $50,000 fine if violated, $250,000 for institution
PHIPA: Responsibilities of PHI Custodians

- Obtain consent except under specific circumstances
- Must take reasonable steps to ensure accuracy of PHI
- Must maintain privacy and security of PHI
- Inform individual immediately if PHI is stolen, lost or accessed by an unauthorized person
- Must have policies and practices in place that comply with PHIPA
PHIPA: ‘Prescribed Person’

- PHIPA allows Prescribed persons (e.g. registry) to collect PHI from custodians without consent (or IRB approval)
- Prescribed registries may use and disclose PHI for the purpose of improving health care
- They may also use and disclose PHI for IRB approved research
- They must make publicly available a description of registries purpose
- Practices and procedures must be approved by Privacy Commissioner
RCSN Phase 3 (July 2003 – present)

• prospective patient ascertainment by sites
• data collected by periodic retrospective chart abstraction without consent
• no follow-up, no commercialization
• health card numbers sent encrypted for linkage studies
  – focus on quality improvement, surveillance
  – research still active (with IRB approval)
RCSN “Prescribed” in PHIPA 2004

• The RCSN is one of only four registries in Ontario which have been granted 'prescription' in the regulations of the Ministry of Health and Long-Term Care under s.39(1)(c )of the Personal Health Information Privacy Act 2004.

• RCSN collects data without consent, “for the purposes of facilitating or improving the provision of stroke care”

• RCSN is the primary means of monitoring and evaluating acute stroke care and outcomes in Ontario
For more information

If you would like to hear more about the Registry project on the Registry, please call the Registry Coordinator at your site.

Name: ________________________________

Phone Number: ________________________

The Canadian Stroke Network has a website where you can find information about the Canadian Stroke Network and you can follow the Registry’s research activities.

Visit the Canadian Stroke Network website at: www.canadianstrokenetwork.ca
Phase 3, Stroke Events (as of September 17, 2007)

Patients Count = 28,834

Last updated September 17, 2007
Data Access

• Data request forms on are available on our web site
• Requests for data for QA are approved weekly
• Requests for Research analyses are reviewed by the RCNS Publication Committee
  – requires a short proposal
• All data requests require PIAs (privacy impact assessment) forms completed
• All data requests reviewed by Sunnybrook Medical Centre IRB
Ontario Stroke Audit

- random sample of all stroke/TIA patients admitted or seen in the EDs of all Ontario’s acute care hospitals
  - first OSA (2002-3) -- 3,388 patients (13%) selected randomly from the DAD and NACRS databases (based on ICD-10 codes)
  - the second OSA (2004-5) -- 4,422 patients (~20%)
- REB approval from all Ontario acute care hospitals
- charts abstracted using RCSN software by trained nurse abstracters
- provides population based data on stroke care in Ontario
Preadmission antithrombotic treatment and stroke severity in patients with atrial fibrillation and acute ischaemic stroke: an observational study


Sex Differences in Stroke Care and Outcomes Results From the Registry of the Canadian Stroke Network

Moira K. Kapral, MD, MSc, FRCP; Jiming Fang, PhD; Michael D. Hill, MD, MSc, FRCP; Frank Silver, MD, FRCP; Janice Richards, RN; Cheryl Jagebin, MD, MSc, FRCP; Angela M. Cheung, MD, PhD, FRCP; for the Investigators of the Registry of the Canadian Stroke Network

Background—Stroke is an important cause of death and disability in women as well as men. However, little is known about sex differences in stroke care and outcomes.

Methods—The Registry of the Canadian Stroke Network (RCSN) captured data on patients with stroke seen at acute care hospitals across Canada. We used data from phase 1 (July 2001 to February 2002) and phase 2 (June to December 2002) of the RCSN to compare stroke presentation, management, and 6-month outcomes in women and men using multivariable regression techniques to adjust for age and other factors.

Results—The study sample included 3323 patients, with 1527 women. Stroke symptoms at presentation were similar in women and men, except that women were more likely to present with headache and were less likely to have brain stem or cerebellar symptoms. There were no sex differences in the use of neuroimaging, thrombolysis, antithrombotic therapy, or consultations. Women were less likely than men to receive care on an acute stroke unit, but this difference was no longer significant after adjustment for age and other factors. Women were more likely than men to be discharged to long-term care and had greater disability at 6 months. Mortality and quality of life at 6 months were similar in women and men.

Conclusions—Among patients participating in the RCSN, there were no major sex differences in stroke presentation or management. Compared with men, women were more often institutionalized and had a slightly worse functional status at 6 months after stroke. (Stroke. 2005;36:809-814.)

Key Words: registries ■ stroke ■ women’s health
Technical Reports

- Registry of the Canadian Stroke Network
  Progress Report 2001–2005
  September 2005

- Registry of the Canadian Stroke Network
  Report on the 2002/03 Ontario Stroke Audit
  June 2006
Thrombolysis Rates by OSS Hospital Type

RCSN Ontario Stroke Audit 2002-3
n = 1580 ischemic stroke patients

- Thrombolysis given if ischemic stroke
- Thrombolysis given if ischemic stroke < 2.5 hrs
tPA Rates by OSS Region

Legend:
- Red: 12.61 to 15.89
- Orange: 10.67 to <12.61
- Yellow: 1.50 to <10.67
- Green: 0.75 to <0.90
- Blue: 0.00 to <0.75

Note: Ontario Provincial total Rate: 3.76%
SPIRIT: Stroke Performance Indicators for Reporting, Improvement & Translation

- Data collected based on *Canadian Stroke Quality of Care Study* and the *Stroke Canada Optimization of Rehabilitation through Evidence* project (SCORE)
- Web-based data entry using TrialStat® application
- Participating sites have real-time access to their data
- Central analysis of data for quality of care evaluation and research
- First project – Ontario Secondary Prevention Clinic Database
Process of Encryption for the Web-based Data System of SPIRIT
Lesson Learned and Recommendations
Medical Research Community Should…

• Educate legislators / privacy officials / IRBs / media / public
  – medical research is not only interventional
  – stress the benefits of observational research and the potential harm of overly strict privacy laws
• Publish effects of privacy laws on IRBs decisions, selection bias and research forgone
• Tighten up existing privacy and security safeguards
• Support harmonization of IRB decisions/multi-centre IRBs
Explore Alternatives to the Traditional Informed Consent Model

- Notification/Opt-out solution
- Separate registry data into identifiable and non-identifiable data – identifiable data encrypted by 1-2 individuals not directly involved in research
- Legalize certain registries (cancer, RCSN, CCN)
- Designate limited number of high-security data institutes (CIHI, ICES, CCO)
Conclusions

• Evolving privacy legislation represents a major challenge to the future of observational research

• We need to strive for a reasonable balance between need for patient privacy and need for observational clinical research.

• Clinical registries collecting de-identified data need to include all patients to avoid bias
  – implies waiver of consent
  – emphasis should be on data security so there is little threat to privacy