# The Registry of Canadian Stroke Network : An Evolving Methodology

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**Abstract-**

Stroke registries can provide information on evidence-based practices and interventions, which are critical for us to understand how stroke care is delivered and how outcomes are achieved. The Registry of Canadian Stroke Network (RCSN) was initiated in 2001 and has evolved over the past decade. In the first two years, we found it extremely difficult to obtain informed consent from the patient or surrogate which led to selection biases in the registry. Subsequently (2003 onwards), under the new health privacy legislation in Ontario, Canada, the RCSN was granted special status as a "prescribed registry" which allowed us to collect data on all consecutive patients at the regional stroke centres without consent. The stroke data was encrypted and all personal contact information had been removed, therefore we could no longer conduct follow-up interviews. To obtain patient outcomes after discharge, we linked the non-consent-based registry database to population-based administrative databases to obtain information on patient mortality, readmissions, socioeconomic status, medication use and other clinical information of interest. In addition, the registry methodology was modified to include a periodic population-based audit on a sample of all stroke patients from over 150 acute hospitals across the province, in addition to continuous data collection at the 12 registry hospitals in the province. The changes in the data collection methodology developed by the RCSN can be applied to other provinces and countries.

**Key Words:** stroke, registry, informed consent, administrative database linkage, audit

## INTRODUCTION

The Registry of Canadian Stroke Network (RCSN, www.rcsn.org) was established in 2001 to allow for the measurement and monitoring of stroke care delivery and outcomes in Canadian patients, and also to serve as a rich clinical database for investigator-initiated research projects[1,2]. In this article, we review the lessons that we

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have learned over the past 10 years. In particular, we aim to assess the impact of linking a clinical database to administrative databases on stroke research, and to address the advantages of population-based clinical audit over a hospital-based registry.

**Consent issue during early phases**

The RCSN has had three phases, each with distinct methodology (Table 1). In the first two phases, we previously required informed patient or surrogate consent for full data collection. Consenting patients participated in a six-month follow-up telephone interview to determine their survival, functional status and quality of life. It was estimated that the nurses spent one third of their time obtaining patient consent, and about half a million Canadian dollars was spent on consent-related activities during these two phases[3]. However, despite nurse training and an intensive effort to obtain informed consent for participation, only 39% of eligible patients in Phase-1

and 51% in Phase-2 provided consent for their inclusion in the registry[3]. Patients who were enrolled in the registry were different from those who did not. Patients with mild stroke were more likely to be enrolled than those with severe stroke. Patients with either fatal strokes (died in the Emergency Department) or very mild strokes (sent home from the Emergency Department) were not consented. The in-hospital mortality rate was much lower among the consented patients (7%) than among non-consented patients (22%). Obtaining informed consent from stroke patients or their surrogates proved to be impracticable, costly, and led to great patient selection biases[3].

Recognizing that in order for the registry to be most effective, it must gather information from all eligible patients, or from a non-biased sample of these patients[4]. With this lesson learned from the early phases of the RCSN, the ethics review boards in the participating hospitals approved data collection without patient consent.

**Table 1.** Summary of methodology of the RCSN

| | Phase-1 Registry | Phase-2 Registry | Phase-3 | | |
| --- | --- | --- | --- | --- | --- |
| | | | Registry | Ontario Audit (2002/03) | Ontario Audit (2004/05) |
| Study period | Jun 2001 – Feb 2002 | Jun 2002 – Dec 2002 | Jul 2003 – Mar 2009 | Apr 2002 – Mar 2003 | Apr 2004 – Mar 2005 |
| Patient selection | Hospital-based | Hospital-based | Hospital-based | Population-based | Population-based |
| Provinces – n | 8 | 8 | 2 | 1 (Ontario) | 1 (Ontario) |
| Acute care hospitals – n | 21 | 25 | 12 in Ontario, 1 in Nova Scotia | 153 | 154 |
| Hospital level in Ontario | RSC | RSC | RSC, some of DSC | RSC, DSC and NDH | RSC, DSC and NDH |
| Informed consent | Yes | Yes | No | No | No |
| Random sampling | No | No | No | Yes | Yes |
| Stroke events – n | 4,612 | 3,291 | 42,170 | 3,388[a] | 4,913[b] |
| Patients – n | 4,483 | 3,047 | 39,905 | 3,388[a] | 4,913[b] |
| 6-month follow-up interviews | Yes | Yes | Not available | Not available | Not available |
| Linkage to administrative databases | Not available | Not available | Yes | Yes | Yes |

Note: Some patients may have had more than one stroke event.

RSC: Regional stroke centre, DSC: District stroke centre, NDH: Non-designated hospital

[a] Random sample of all 25,905 stroke/ transient ischemic attack patients in fiscal year 2002/03

[b] Random sample of all 23,800 stroke/ transient ischemic attack patients in fiscal year 2004/05

Data cited from the RCSN Progress Report 2001-2005[2], and Reports on the 2003/03 and 2004/5 Ontario Stroke Audit[6,7]

At this time, the RCSN was designated as a prescribed registry under the new health privacy legislation in Ontario, the *Personal Health and Information Protection Act* (www.ipc.on.ca), which permitted the RCSN to compile or maintain a registry for purposes of facilitating or improving the provision of health care without consent to prescribed persons. Accordingly, we also had to stop conducting follow-up interviews with the patients[1,2,5]. The data collection was now limited to 12 stroke centres in Ontario and one in Nova Scotia.

### Linking the clinical registry database to administrative databases

Compared to Phase-1 and 2, the most significant change to the data collection in Phase-3 was that the patients could no longer be contacted for the follow-up interviews after discharge. Phase-3 only collects data from the hospital chart. However, at the Institute for Clinical Evaluative Sciences (www.ices.on.ca) where the RCSN database is managed, we had the ability to link the registry patients to population-based administrative databases to trace their outcomes after discharge under the provincial health law. Linkages are done using unique encrypted identifiers that ensure privacy and confidentiality of data and are used to conduct the linkage across databases.

The linkage enables us to obtain a more comprehensive view of specific health care issues, such as patient socioeconomic status, stroke readmission, in-hospital treatment, and out-of-hospital mortality. The important administrative databases at ICES are the Registered Persons Database (RPDB), the Discharge Abstract Database (DAD), the Ontario Drug Benefit Database (ODB), and Canadian Census Database.

The RPDB maintained by the Ontario Ministry of Health and Long-Term Care provides basic demographic information about all residents who has ever received an Ontario health card number, including their gender, birth date and all-cause death date. Linking to the RPDB allow us to trace the out-of-hospital death within a certain time period, e.g., 30-day or 1-year.

The DAD is maintained by the Canadian Institute for Health Information (www.cihi.ca), and contains patient-level information on all hospital admissions across Canada. The information includes patient demographics, admission diagnoses, comorbidity, in-hospital procedures, in-hospital complications, length of stay, in-hospital mortality and discharge destination. Through linkages, we can capture readmissions due to stroke or other diseases based on ICD-10 diagnosis codes, and treatments/procedures that patients receive based on ICD-10 Canadian Classification of Interventions (CCI) codes, for example, carotid endarterectomy and angioplasty.

The ODB database contains claims for prescription drugs for all Ontario residents aged over 65 years. The ODB database contains drug identification numbers, quantity dispensed, dispensing date, as well as the number of days supplied from each prescription. Using unique patient identifiers, we can link the stroke patients in the registry to the ODB to obtain medication use (e.g., use of antihypertensive and antithrombotic drug usage prior to stroke onset and after discharge).

The RCSN database does not contain individual-level measures of socioeconomic status. Therefore, we use the Canadian Census Database to impute the patient's socioeconomic status (e.g., median neighborhood income and income quintiles) and sociodemographic factors (occupation, and education). The dissemination area is the smallest geographical unit used for reporting census data. Each patient from the RCSN is linked to the dissemination area of his or her principal residence using his or her postal code.

### Impact of consent and database linkage on publication

There were only 11 papers published via the consent data collected during Phase-1 and 2 (Table 2), including one paper in *New England Journal of Medicine,* which indicated the impracticability of informed consent in the RCSN. One common limitation of these publications was that the registry patients were not representative of the typical patients with stroke, which limited the generalizability of the results of analyses of patient characteristics and outcomes. However, through the non-consent registry data in Phase-3, the RCSN team now has 27 papers published in the journals like *Stroke, Lancet*

**Table 2.** Publication of the RCSN (as of October, 2010)

| | RCSN | | |
|---|---|---|---|
| | Phase-1, 2 | Phase-3 | Phase-3 |
| Publication Status | Published | Published or in press | In process |
| Number of papers | 11 | 27 | 17 |
| Linked to Administrative database – n (%) | 0 (0%) | 17 (63%) | 13 ( 76%) |
|     Death from the RPDB – n (%) | – | 13 (76%) | 13 (100%) |
|     Readmission/Treatment from the DAD – n (%) | – | 4 (24%) | 2 ( 15%) |
|     Socioeconomic status from Canadian Census – n (%) | – | 1 ( 6%) | 4 ( 31%) |
|     Medication from the ODB – n (%) | – | 1 ( 6%) | 1 ( 8%) |
| Journal Names | | | |
| High impact journals in stroke study field | | | |
|     *New England Journal of Medicine* – n (%) | 1 ( 9%) | 0 ( 0%) | – |
|     *Lancet Neurology* – n (%) | 0 ( 0%) | 1 ( 4%) | – |
|     *Neurology* – n (%) | 2 (18%) | 5 (19%) | – |
|     *Stroke* – n (%) | 2 (18%) | 9 (33%) | – |
| Other journals – n (%) | 6 (55%) | 12 (44%) | – |

*Neurology, Neurology,* as well as 17 manuscripts submitted or in process as of October 2010 (Table 2).

Among the published papers in Phase-3, 17 (63%) used administrative databases to determine the mortality after discharge (n = 13, 76%), readmission/treatment (n = 4, 24%), socioeconomic status (n = 1, 6%) and drug usage (n = 1, 6%). In addition, the recent 17 manuscripts used more of the additional information from the administrative databases (76% vs. 63%), compared to the published papers in Phase-3 (Table 2).

**Population-based clinical audit**

As part of the implementation of a province-wide coordinated stroke strategy now known as the Ontario Stroke System, the Ontario Ministry of Health and Long-Term Care designated all acute care hospitals as one of the three groups, nine Regional Stroke Centre (RSC), 17 District Stroke Centre (DSC), and 128 Non-Designated Hospitals (NDH). DSC is a hospital that has facilities with written stroke protocol for emergency services, emergency department and acute care including transport and triage protocols, ability to offer thrombolytic therapy, and timely computed tomography scanning. RSC is a hospital with all requirements of a DSC plus neurosurgical facility and interventional radiology. NDH is an acute care hospital that does not fit the definition of DSC or RSC.

Table 3 shows the characteristics betweens RSCs, DSCs and NDHs. Compared to NDHs, RSCs and DSCs were larger stroke volume hospitals in the urban area, most of them had stroke unit on site. All nine RSC hospitals and three DSC hospitals participated Phase-3 registry (Table 1). These RCSN hospitals each see 500 to 1000 stroke cases annually (approximately 20% of all stroke/transient ischemic attack cases in the province)[6,7]. The core RCSN collects data on all consecutive patients seen at 12 Ontario stroke centres (9 regional sites plus 3 enhanced district stroke centres). This database is useful for many types of study but for some types of research, data from a more representative sample of hospitals is needed.

To obtain population-based stroke data, a supplemental data collection, the Ontario Stroke Audit (OSA), was undertaken starting fiscal year 2002/03. The province-wide audit collected data on a random sample of all stroke and transient ischemic attack patients which were seen at all acute care hospitals in Ontario (Tables 1 and 3).

**Table 3.** Characteristics of acute cure hospitals by Ontario Stroke System designation in fiscal year 2004/05

|  | Ontario | Non-Designated Hospitals | District Stroke Centres | Regional Stroke Centres |
|---|---|---|---|---|
| Number of hospitals – n | 154 | 128 | 17 | 9 |
| Annual stroke patient volume – n |  |  |  |  |
|    Low (< 33) | 34 | 34 | 0 | 0 |
|    Medium (33-99) | 49 | 48 | 1 | 0 |
|    High (100+) | 71 | 46 | 16 | 9 |
| Hospital location – n |  |  |  |  |
|    Urban | 90 | 64 | 17 | 9 |
|    Rural | 64 | 64 | 0 | 0 |
| Stroke unit on site – n | 31 | 10 | 12 | 9 |

Table modified from 2004/5 Ontario Stroke Audit Report[7]

The OSA has been performed three times, in fiscal years 2002/03, 2004/05 and 2008/09 (Table 1). As expected, the OSA Reports indicated that stroke patients seen at the registry hospitals were significant different in baseline characteristics than those seen at non-designated hospitals, except gender (Table 4)[6,7]. Compared to patients seen at non-designated hospitals, those seen at registry hospitals were younger (2002/03: 72 years vs. 76 years, $p < 0.01$; 2004/05: 73 years vs. 76 years, $p < 0.01$), and less likely from rural areas (2002/03: 10% vs. 21%, $p < 0.01$; 2004/05: 7% vs. 21%, $p < 0.01$). Hemorrhagic patients were more commonly seen at registry hospitals than at non-designated hospitals (2002/03:

24% vs. 10%, $p < 0.01$; 2004/05: 22% vs. 7%, $p < 0.01$). In contrast, both transient ischemic attack patients and stroke-type-undetermined patients more likely presented at non-designated hospitals than at registry hospitals (Table 4).

**Strengths and limitations between healthcare databases**

Healthcare data may be derived from either administrative or clinical sources; the latter including both retrospective and prospective chart abstraction. Administrative databases are originally designed for claims submission and benefits coordination, but not for

**Table 4.** Patient demographics by Registry hospitals and non-designated hospitals

|  | 2002/03 OSA | | 2004/05 OSA | |
|---|---|---|---|---|
|  | Non-designated hospital | Registry hospital | Non-designated hospital | Registry hospital |
| Female sex – % | 51% | 52% | 52% | 49% |
| Median age – years** | 76 | 72 | 76 | 73 |
| Rural residence – %** | 21% | 10% | 21% | 7% |
| Stroke type** |  |  |  |  |
|    Intracerebral hemorrhage – % | 7% | 14% | 5% | 12% |
|    Ischemic stroke – % | 47% | 47% | 44% | 50% |
|    Subarachnoid hemorrhage – % | 3% | 10% | 2% | 10% |
|    Transient ischemic attack – % | 35% | 28% | 37% | 25% |
| Undetermined stroke type – % | 8% | 1% | 12% | 3% |

**: $p < 0.01$

Data cited from the RCSN Reports on the 2002/03 and 2004/5 Ontario Stroke Audit[6,7]

clinical research[8,9]. They have the obvious advantages of being easily available at low cost and population-based (Table 5). They provide a valuable source of information to answer predefined clinical question, for example, incidence and prevalence from the DAD and all-cause death from the RPDB, however they lack reliable clinical information such as stroke etiological diagnosis, risk factors, timing of stroke onsets and treatments (e.g, thrombolytic therapy) in the DAD, and reason of death in the RPDB. In addition, questions concerning the accuracy and completeness of administrative databases are frequent[9,10].

A hospital-based clinical registry is rich in clinical information by its very nature, which is an obvious advantage over administrative databases, but does not represent the generalizability of the entire stroke population. The stroke audit database contains clinical information which is richer than an administrative database and is population-based rather than hospital-based. Therefore, the stroke audit database is more suitable for health services researchers and care providers who are directly involved in quality monitoring and evaluation of stroke care.

## DISCUSSION

The Registry of Canadian Stroke Network has evolved over the past 10 years, and has become the largest Canadian database of stroke patients and one of the largest stroke registries worldwide. During this period of evolution, the RCSN data collection experienced challenging phases, from informed consent (Phase-1 and 2) to non-consent (Phase-3), from hospital-based clinical registry (Phase-1, 2 and 3) to population-based clinical audit (Phase-3 OSA). Also during this time, new privacy laws changed how personal health information would be collected for the RCSN.

We emphasize several lessons that we have learned. First, obtaining individual informed consent for participation in a stroke registry led to important selection biases, such that registry patients were not representative of the typical stroke patients[3].

Second, both administrative and clinical databases have limitations, such as former's lack of detailed clinical information and latter's lack of complete follow-up data. The clinical database can be enriched by linking it to the administrative database to trace patient outcomes and other clinical information, and/or socioeconomic status[8]. For example, the RCSN data analyses are strengthened by the linkage of registry database to administrative databases to capture mortality both during and after hospitalization, thus minimizing the outcome assessment bias potentially associated with the use of in-hospital data alone[11]. Therefore, majority of published RCSN papers or submitted manuscripts used the information from the administrative databases (Table 2), which supporting the idea that combination of clinical and administrative sources can improve the research

**Table 5.** Comparison between health care databases

| | Administrative database (e.g., DAD, RPDB) | Clinical Database | |
| --- | --- | --- | --- |
| | | Registry (e.g. Phase-1, 2 and 3) | Audit (e.g., Phase-3 OSA) |
| Patient selection | Population-based | Hospital-based | Population-based |
| Patient random Sampling | No | No | Yes |
| Hospital selection | Overall | Some | Overall |
| Expense | Inexpensive | Costly | Costly |
| Data collection and management | Easy | Complex | Complex |
| Sample size | Huge | Small (in general) | Small (in general) |
| Clinical information | Poor | Rich | Rich |
| Originally designed for clinical research | No | Yes | Yes |

capacity, and more importantly, increase the value of stroke registry database.

In Canada, all administrative databases used by the RCSN team are maintained by national-level or provincial-level organizations, not by the RCSN. Therefore, it is important to point out that Canadian clinical investigators have a great opportunity to easily and efficiently carry on their studies via linking the study cohort to the administrative databases, which benefit their clinical researches. However, investigators in other countries or areas may not be able to do the same thing as their Canadians colleagues, because there are no well-established administrative databases to link. Moreover, there may be strict policies preventing the data linkage, even if both clinical and administrative databases available[8].

In Taiwan, both clinical and administrative databases for stroke study are available. Many stroke registries have been done in Taiwan since 1980 (see details in a review article[12]), particularly the Taiwan Stroke Registry (TSR) launched in August 2006. The TSR is the first registry across Taiwan, and has enrolled more than 40,000 events from 39 academic and community hospitals[13]. Taiwan has an excellent public health insurance program that provides comprehensive medical services to its citizens. The National Health Insurance Research Database (NHIR, http://www.nhri.org.tw/nhird), provided by the Bureau of National Health Insurance and managed by the National Health Research Institutes, was launched in 1995. The NHIR is a population-based administrative database that contains patient-level demographic, diagnostic, and administrative information. The experience of RCSN can be applied in Taiwan, especially on the link of clinical data TSR with administrative data NHIR to improve the research level and stroke care quality.

Third, the baseline demographic and clinical characteristics of patients from hospital-based registry might be significantly different from the overall stroke population. The province-wide or nation-wide stroke care system can not be evaluated by the hospital-based registry like the RCSN Phase-3. Population-based audit like the Ontario Stroke Audit is essential to accomplish this task. Based on the baseline information of the 2002/03 OSA[6],

we revealed significant improvements in the use of evidence-based practices and interventions such as referral to stroke units, administration of thrombolysis, neuroimaging, secondary prevention drug therapy and referrals to secondary prevention clinics in fiscal year 2004/05[7].

The ongoing monitoring and evaluation performed through the registry are considered essential to ensure implementation of best practices and evidence-based stroke care. These clinical audits permit the examination of temporal trends in stroke care delivery and stroke outcomes across the province, which could not be substituted by the hospital-based clinical registry. Therefore, we must conduct the OSA data collection repeatedly. As of June 2010, we have finished the data collection for fiscal year 2008/09 OSA and started our data analyses. The fiscal year 2010/11 OSA is scheduled to be launched in early 2011.

## ACKNOWLEDGEMENTS

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