Developing a national registry of veterans with spinal cord dysfunction: experiences and implications

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We describe the development of a registry of veterans with spinal cord dysfunction who have been treated within the Department of Veterans Affairs health care facilities. The registry departs from the function and structure of traditional registries by a more extensive utilization of advances in computer technology; in particular, by its reliance upon computerized record linkage and by its association with a set of computer-based clinical management and reporting tools. We discuss some of the applications of the registry to research for persons with spinal cord dysfunction as well as implications that our experiences provide for developing other registries of persons with disabilities.

Keywords: spinal cord injury; spinal cord dysfunction; registry; data base

Introduction

A registry is 'a file of documents containing uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a predetermined purpose.'¹ Disease registries—for example, the registry operated by the United States Model Spinal Cord Injury (SCI) Systems program,²—have greatly contributed to our knowledge regarding the prevalence, natural history, cost, and sequelae of diseases. With continued advances in computer technology, the capability for obtaining and managing information for registries has vastly increased, and the potential applications for registries have multiplied.

We recently developed and implemented an ongoing national registry of American veterans with spinal cord dysfunction (SCD) who receive care at Department of Veterans Affairs (VA) facilities. The VA registry departs from the design of traditional registries by a more extensive utilization of advances in computer technology; in particular, by its reliance upon computerized record linkage and by its association with a set of computer-based clinical management and reporting tools. We first describe our experiences in developing a SCD registry within

the VA. Then, we discuss some of the distinctive features and applications of computer-based registries.

Background

Terminology

Spinal cord dysfunction can be caused by either traumatic events (eg, injury), or by non-traumatic events (eg, diseases such as multiple sclerosis). SCD denotes spinal cord dysfunction regardless of cause. SCI denotes SCD of traumatic cause. SCD of nontraumatic cause is referred to as such.

Organization of care for veterans with SCD

In the VA, care for persons with traumatic SCI is organized through the Spinal Cord Injury Service, which has designated 22 VA Medical Centers (VAMCs) as specialized SCI Centers. SCI Centers handle approximately two-thirds of inpatient visits for persons with SCI.³ Some SCI Centers also care for veterans with SCD regardless of cause, while others care for persons with SCI only.

At the approximately 150 VAMCs without a specialized SCI Center, care is typically provided by an SCI Primary Care Team which includes a physician, a nurse, and an SCI Coordinator. The

SCI Coordinator, who is usually a social worker, is responsible for most contact and follow-up.

VAMCs have similar hospital data management systems, all of which are based upon the VA's Decentralized Hospital Computer Program (DHCP). All hospital computer systems maintain a standard set of data elements, which are supplemented by local additions as desired.

Registry development process

Historically, planning for veterans with SCD has been hampered by inadequate information. ICD-9 diagnostic codes used to identify persons with SCD were often applied inconsistently, as was a special data field that purportedly identified persons with SCI.⁴ Administrative files did not record basic information about SCD (eg, date of onset or injury, injury level and completeness), functional status variables (eg, activities of daily living) or information about met and unmet needs. A standardized information resource was needed.

Registry development began with an agreement about the registry's basic design and inclusion criteria. The registry is intended to include all veterans who (a) have SCD of either traumatic or non-traumatic cause, and (b) utilize VA health care services. All VAMCs have local registries that follow SCD veterans treated at those facilities. Local registries can upload information into a national database linked to other VA national databases. Registry development was predicted upon the premise that having computer-based tools for clinical management linked to local computer systems would give providers an incentive to populate local registries, which in turn would help ensure the comprehensiveness of the national database.

An expert panel, which includes SCI physicians, SCI nurses, SCI coordinators, VA administrators, software developers, and patient advocates, was convened and began by identifying the operational goals of the registry. One goal was to provide clinicians with a means to more easily track persons with SCD and to more easily organize clinical information on individual patients. A second goal was to provide administrators, policy makers, and advocates with population-level data to aid in procuring and organizing services for SCD veterans. A final goal was to provide researchers with an easily accessible list of patients from which to draw nationally representative samples.

In order to proceed expeditiously, programmers modified software created for another VA registry. The initial version of SCD registry software had modules for case registration and reporting. The case registration module supported the input of identifying information (eg, social security number) and basic SCD-specific clinical data (eg, date of injury or onset of disease). The reporting module linked the case registration module with the much more extensive data maintained on local hospital computer systems.

Modifying existing software facilitated creation of a generic registry within constraints of time and budget. However, the initial version of registry software was not widely used. Barriers to use included inadequate communication with users, overly technical training manuals, some data elements that were either difficult to collect or not in a format desired by clinicians, and reporting formats which were not sufficiently specific to patients with SCD. The expert panel recommended modifications to the software intended to increase ease of use, to increase clinical relevance, and to obtain information which the SCI Service could use as performance measures. The case registration and reporting modules were modified, and functional status and clinical modules were added. Training materials were redesigned.

Developers also noted that users such as SCI Coordinators had little time for case finding. Accordingly, we 'seeded' local registries through an independent case-finding operation. Registry developers used information from VA administrative files (eg, ICD-9 codes, visits to SCI bed sections) to identify approximately 50 000 veterans thought likely to have SCD and mailed surveys to each. Approximately 25 000 surveys were returned, of which approximately 18 000 reported SCD. Surveys were keyed at a central location and the results were then electronically transferred to local registries. Case finding is ongoing through local initiatives.

Membership criteria

The registry's inclusion criteria (Appendix 1) are based upon diseases or conditions whose pathophysiology either primarily or secondarily affects the spinal cord, spinal canal, or cauda equina. Classification of traumatic SCI is straightforward. For non-traumatic SCD, diagnoses are divided into two groups. The first group, which includes conditions such as multiple sclerosis, contains all persons with that diagnosis regardless of level of impairment. (This decision was made because impairment level tends to change over time – for example, the impairment attributable to multiple sclerosis could at any time be high, minimal or even absent). In the second group of diagnoses, which includes conditions such as malignant neoplasms that have metastasized to the spine and spinal cord, impairment is required as a condition for registry membership.

Data elements

The registry's case registration module is divided into two components – basic registration and basic health care data. The basic registration component includes elements such as name, social security number, date and cause of SCD, injury level and completeness, and multiple sclerosis subtype (Appendix 2). The basic health care data component includes information about providers, site of initial rehabilitation, and annual

rehabilitation visits. Some data elements offer the option of simplified reporting. For example, injury level may be reported as tetraplegia/paraplegia, and completeness may be reported as complete/incomplete.

The functional status module (Appendix 2) allows the local user to select among various measures. While most measures are applied in the usual fashion, we have modified the Functional Independence Measure (FIM)⁵ in order to be based upon either observer- or patient-report. That is, the FIM may be performed in the traditional manner by a clinician or clinicians, using the full FIM scale with 18 items (13 motor items and five cognitive items), each having seven levels. Alternatively, functional status may be based upon patient self-report, which includes only the 13 motor items of the FIM and utilizes four rather than seven response categories. Initial validation studies of the above self-reported measure have been encouraging.⁶

Reports

The above data elements can be uploaded to a national database linked with other national VA databases. In addition to the above, local users can make use of almost every data element maintained on their local DHCP system. For example, the registry's reporting capability can be used to identify patients who have not visited the SCI clinic as expected, who have received urgent care, who have been admitted to the hospital with pressure sores, who have out-of-range laboratory values, who have received prosthetic devices, who have future clinic visits scheduled, and so forth. Reports can pertain to individual patients (eg, a schedule of clinic appointments combined with selected laboratory results) or groups of patients (eg, total inpatient hospital days at a facility).

Comment

We have described our experiences in developing a national VA registry of veterans with SCD. Although by no means trivial, our registry development task was simplified by a number of considerations. First, the VA has a strong organizational commitment to improving the care of persons with SCD. Second, despite local modifications, each VAMC has essentially the same computer system, thus simplifying software design and record linkage. Third, the VA's computerized administrative files already maintain much of the data required for a registry focused on utilization and planning, thus reducing the need for prospective data collection. Finally, the registry is linked with a clinical reporting tool, thus increasing receptivity by clinical users.⁷ Despite these favorable circumstances, and despite the systematic approach to registry development described above, the initial version of the registry did not fully meet its users needs and required significant redesign. The Model Systems Registry underwent a similar redesign.² One implication for future registry developers is the importance of

including all users – especially data collectors – in the design process as early as possible. Another implication is the need for timetables and budgets to include the possibility of modification and redesign.

Appendix 3 contains a checklist of questions we considered during the registry development process. Most are self-explanatory and can be applied to registry development in general.

To briefly comment on some of the items in Appendix 3, registries may have various goals including identification of individuals, surveillance, general epidemiology, evaluating services, evaluating treatments, research and patient and provider education.⁸ While all of these were important to the VA, its registry's primary goals were identifying individuals, facilitating planning, and increasing the amount of information easily accessible to the clinician.

Accurate case definition and comprehensive case finding are crucial to the validity of a registry. At its most basic, a registry is a list of cases. However, not every list of cases is a registry. For example, a list of patients having the diagnosis of multiple sclerosis on an administrative file is not a registry because diagnoses on administrative files tend to be inaccurate and incomplete. This list of cases would become a registry with the adoption of a formal protocol for identifying and verifying cases.

The number of data elements which can be collected reliably is limited. Appendix 4 describes the criteria we used to determine whether or not to collect a data element. Whenever possible, registry data are collected as part of ongoing clinical or administrative processes. For example, FIM measurements can be made by clinicians as part of their usual assessment procedures, or might instead be based upon a self-report which can be filled out by the patient while he or she is waiting to see the clinician. Our ability to link local registries with other VA databases was a crucial factor allowing us to limit the number of data elements requiring primary data collection. Thus, although the registry itself contains only a sparse set of variables, it is effectively equivalent to a much larger database because of the large number and variety of data elements already maintained in the local DHCPs and the VA's national administrative files.

Applications

One noteworthy property of computer-based registries lies in their ability to support multiple types of research. The VA SCD Registry supports research in a number of ways. First, it facilitates recruitment of patients into randomized trials (eg, a randomized trial comparing treatments for multiple sclerosis) by providing a nationally representative list of patients from which to sample. Second, it supports outcomes research by automating follow-up of patients' health service utilization, mortality, and functional status. Third, it supports basic epidemiological research into the natural history of SCD by providing the ability to

follow changes in functional status over time. (This can be done by forming cohorts to be prospectively followed through the registry, and/or by using the registry to create a representative group of cases to be included in case-control designs). Fourth, the registry plays a crucial role in supporting quality improvement research. For example, the VA's SCI Service uses the registry to measure quality improvement indicators such as the percentage of SCD veterans who have a primary physician, the percentage of SCD veterans who are offered an annual rehabilitation evaluation, the percentage of SCD veterans who have had a functional assessment, and so forth. Not only is the registry used to identify potential quality problems, but it can also track the success of interventions intended to address these problems. Finally, the Registry's ability to link patients with resource utilization helps support research on the cost of care for veterans with SCD. Without a population-based denominator available from a registry, estimates of the cost of care can be biased – for example, because patients using little or no services tend to be overlooked.

A future application of computer-based registries is to accelerate the process of developing comprehensive national and international data bases pertaining to persons with SCD. This was considered in a recent conference,⁹ one of the conclusions of which is that the most feasible way to develop comprehensive international registries involves developing separate computer-based registries that can subsequently be linked. We have demonstrated the ability to successfully link registry data across approximately 170 hospitals, albeit within a single health care system. As computer technology continues to improve, we anticipate that computerized record linkage could be expanded to include multiple health care systems and eventually multiple nations. Furthermore, we anticipate that registry designs based upon record linkage will become increasingly cost-effective in comparison with more traditional registry designs.

The continuing advance of computer technology will change the focus, change the design, and broaden the applicability of registries pertaining to persons with disabilities. One of the challenges of the 21st century will be translating the additional information available from registries first into improved clinical practice and ultimately into improved outcomes.

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Appendix 1 Membership Criteria

045	acute poliomyelitis
094.0	Tabes dorsalis
138	late effects of poliomyelitis
192.2	malignant neoplasm of spinal cord
192.3	malignant neoplasm of spinal meninges
198.4	secondary malignant neoplasm of meninges
225.3	secondary benign neoplasm of spinal cord
225.4	secondary benign neoplasm of spinal meninges
324.1	intrapinal abscess
334.0	Friedreich's ataxia
334.1	hereditary spastic paraplegia
334.8	other spinocerebellar diseases
334.9	spinocerebellar disease, unspecified
335.2	motor neuron disease
336	other diseases of spinal cord
340	multiple sclerosis
334.0	quadriplegia
344.1	paraplegia
344.2	diplegia of upper limbs
344.6	cauda equina syndrome

721.41	thoracic spondylosis with myelopathy
721.42	lumbar spondylosis with myelopathy
721.91	unspecified spondylosis with myelopathy
722.7	intervertebral disc disorder with myelopathy
806	fracture of vertebral column with SCI
907.2	late effects of SCI
952	SCI without evidence of spinal bone injury

Notes: These were the ICD-9 codes used to screen administrative files. Other diagnoses may be included by the provider as warranted. Some of the above diagnoses (eg, quadriplegia) require evidence of disability due to SCI.

These criteria were developed by a neurologist and reviewed by the registry's expert panel.

Appendix 2 Data Elements

Registration module: Basic registration

Name
Social security number
Vital status
SCI/SCD indicator
SCI network
Registration status
Date of registration
Date of last update
Cause(s) of SCD
Date of SCD onset
Highest level of injury
Completeness of injury
Multiple sclerosis subtype

Registration module: Basic health care data

Site(s) of medical care – SCI Center, VA medical center where care is primarily received, other VA providers, other non-VA providers
Primary care provider
SCI coordinator
Referral source
Site of initial rehabilitation
Date of discharge from initial rehabilitation
Annual rehabilitation evaluation offered – date
Annual rehabilitation evaluation received – date
Next annual rehabilitation evaluation scheduled – date
Bowel care reimbursement program membership
Bowel care reimbursement program certified
Bowel care reimbursement program provider

Functional module

Activities of daily living–basic
Activities of daily living–instrumental
Need for personal assistance (yes/no, per 24 h, per 2 weeks)
Method of ambulation–walking
Method of ambulation–wheelchair
Functional Independence Measure (FIM)–self-report
Functional Independence Measure (FIM)–observer-based
Functional Assessment Measure (FAM)
Craig Assessment and Reporting Technique (CHART)
Duke University Severity of Illness Index (DUSOI)
Diener Quality of Life Index
Kurtzke Functional Systems Scale (FS)
Kurtzke Expanded Disability Status Scale (EDSS)

Clinical module

ASIA impairment score
ASIA motor score

ASIA sensory score
ASIA neurological levels
ASIA partial preservation – sensory
ASIA partial preservation – motor
Specific body parts affected
Extent of movement
Extent of feeling
Amputation
Head injury

Data from other DHCP components available for reports

Patient demographics (eg, address, telephone, date of birth, age, gender, race, insurance)
Inpatient (eg, date of admission, date of discharge, patient location, admission diagnoses, discharge diagnoses, discharge location)
Outpatient (eg, clinic stops)
Pharmacy
Laboratory
Radiology

Appendix 3 Registry Development Checklist

- * Have all stakeholders been identified?
- * Have all stakeholders participated in defining registry goals?
- * Have all stakeholders agreed to registry goals?
- * Have registry goals been clearly defined?
- * Have registry goals been clearly communicated to data collectors?
- * Has the content of registry reports been defined?
- * Have end users been given the opportunity to comment on the format and content of registry reports?
- * Do all stakeholders receive reports and/or other products from the registry?
- * Do the registry's data elements use standard definitions?
- * Have explicit membership criteria been set?
- * Does an explicit process exist to assist data collectors in determining the membership criteria of uncertain cases?
- * Have all potential sources of cases been identified?
- * Will case finding be an ongoing process or a one-time event?
- * Has the target population been explicitly identified?
- * Have the personnel responsible for case finding been identified?
- * Do case finders and other data collectors have an incentive to collaborate?
- * Do the personnel responsible for case finding have adequate resources to do so?
- * If selected within an existing organization, do case finders have approval to perform case finding?
- * Does the registry collect extraneous data elements?
- * Are data elements collected as efficiently as possible? (eg, as a by-product of existing clinical or administrative processes)
- * Have personnel responsible for quality assurance and oversight been identified?
- * Have general functional specifications been received by stakeholders for consistency with registry goals?
- * Have technical specifications been reviewed by programmers to ensure consistency?
- * Have technical specifications been reviewed by end users to ensure completeness and appropriateness?
- * Have the goals and content of training for data collectors been defined?
- * Have end users had the opportunity to comment on the form and content of training materials?

- * Is information about data quality fed back to data collectors?
- * Does a written data collection protocol exist?
- * Has the data collection protocol been pilot tested?
- * Do data collectors receive a copy of the data collection protocol?
- * Does a written data management protocol exist?
- * Has the data management protocol been pilot tested?
- * Do data management personnel receive a copy of the data management protocol?
- * Do development timetables and budgets provide adequate leeway for testing and redesign if necessary?
- * Does the registry have a stable organizational home?
- * Does the registry have sufficient development funds?
- * Have functions such as data collection, data management, data analysis, quality assurance, coordination, training, and clinical consultation been adequately funded?
- * Does the registry have sufficient funds for long-term maintenance?
- * Has the registry been adequately publicized?

Note: General specifications describe users and uses; for example, 'the registry will assist clinicians by increasing the amount of patient-specific information which is easily accessible'. Technical specifications involve individual data

elements, including possible values, protocols for collection, and responsible individuals. For example, 'date of onset will be collected by the SCI Coordinator at the time of registration and is defined as the date of injury for persons with traumatic injury and the date of diagnosis for persons with non-traumatic SCD. If day and month are unknown, these should be reported as missing.'

Appendix 4 Criteria for Determining the Importance of a Data Element

Does the data element satisfy all of the following?

- * The data element must be associated with an explicitly stated clinical issue, hypothesis, or research question.
- * The data element should be well enough defined to allow a formal data collection protocol to be written.
- * A means should exist to accurately collect the data element.
- * Data collectors should have an incentive for accurate data collection.
- * The data element should not be recorded on another computer-accessible file.
- * If clinical, the data element should be sufficiently important to require collection on all patients.