



# Development of an integrated, distributed clinical research database for spinal cord injury

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## **Accompanying documents to this report**

<b>Title:</b>	<b>Report number:</b>
<b>Draft Data Dictionary</b>	<b>0.9</b>
<b>ANZCOS 2012 Powerpoint presentation</b>	<b>1.0</b>

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## **Executive Summary**

### **Key messages**

In Victoria we have a high quality trauma service with comprehensive management of spinal cord injury (SCI) patients from accident for the rest of their lives through the Victorian Spinal Cord Service (VSCS) at Austin Health. The VSCS currently has no electronic register of its patients, and the current database run by the National Injury Surveillance Unit provides limited case registration and injury surveillance information. The existing data repositories and capacity are insufficient to facilitate collaborative research and maximise patient outcomes. The VSCS requires a collaborative, secure, web-based registry providing the necessary flexibility to facilitate a range of future research questions and programs. This project has successfully developed a comprehensive evidence-based dataset for the VSCS, and established processes for embedding data collection within usual care.

### **Purpose**

The long-term aim of this project is to develop an integrated, distributed clinical research database for spinal cord injury. It will draw data from clinical practice and activity, aggregate those data in a readily scalable manner and provide for security-oriented data linkage to local, national and internal registries and datasets.

This particular project was the first step towards achieving this goal. The aim of the project was to develop a local prototype of how nationally and internationally agreed spinal cord injury datasets could be collected, collated and analysed to facilitate research, quality improvement activities, and improved patient outcomes.

### **Rationale**

The need for clinical and research integration has been apparent for some time but only became urgent more recently. The TAC funded almost \$15 million across three program grants based at the VSCS that are all examining people living with SCI. The research groups have invested substantial resources into coordinating their clinical research such that the burden on the patients is minimized and the research outcomes maximized. This project has extended the collaboration by enabling the prospective collection of clinically relevant and research critical information by the clinical care staff.

### **Methods**

A number of processes were undertaken to achieve the project objectives. We firstly formed a multi-disciplinary working group which consisted of researchers, clinicians and service managers of the VSCS. In close collaboration with the working group, the research team undertook an iterative approach to collating the dataset, through careful mapping of the clinical pathway to available national and international datasets, benchmarking with other units, and examination of the literature.

The outcomes of these activities allowed the research team to assemble a comprehensive, parsimonious dataset for the VSCS, which was thoroughly documented in a data dictionary. Several workshops were held with VSCS clinicians to determine the process for collecting and auditing the data within the unit, specifically who, when and where each data item would be collected and verified.

We took great care to consider and reconcile the competing demands of a rigorous ontology with the day-to-day practical implications of data collection within usual clinical care. We

implemented many initiatives to “reward” clinical staff for their data entry efforts, to minimize double-handling of data and ensure data consistency across disciplines.

### **Research findings& implications**

The dataset developed for the VSCS consists of the Australian Spinal Cord Injury Register (ASCIR) items, the Australasian Rehabilitation Outcomes Centre (AROC) benchmarking fields; six of the International SCI datasets, five clinical indicators, time based information about the patient journey, and several patient outcome measures, including the ASIA impairment scale (AIS), the Functional Independence Measure (FIM) and the Spinal Cord Independence Measure (SCIM). These data fields were mapped to clinical care within the unit, and staff of the VSCS have developed a protocol for how these data will be embedded into routine clinical care. This project drove a thorough review of current assessment and data collection practice in the VSCS, and as a result meaningful changes to the way in which some of the clinical data are collected have already been made.

### **Use of the research**

The outcomes of this project are an essential step towards developing a robust, flexible registry for the VSCS which meets the needs of the local unit, and facilitates research collaboration with national and international partners. Specifically, the outcomes of this project will lead to better information about people living with SCI in Victoria. Effective service planning and quality improvement activities depend upon accurate information about the population. Similarly, good research proposals require accurate feasibility estimates and the VSCS will be in a much stronger position to provide this data as a direct outcome of this project. Similarly, community organizations, funders, health planners and government will enjoy more complete and accurate information about people living with SCI in Victoria.

### **Potential impact of the research**

Thankfully SCI is a rare injury, but with this low incidence come immense challenges in our searches for improvements in health status, clinical care and community participation. It is increasingly apparent that the key to achieving these improvements lies with affordable, scalable and effective collaboration. This project has established a template for local implementation of international data standards. The data platform that is under development will provide the opportunity for these international standards to be implemented in a similar fashion elsewhere at little cost. The research team at IBAS and the VSCS will continue to work with our collaborators worldwide to ensure that what we have learnt through this project is provided freely to those who can make use of that knowledge.



## Background

Spinal cord injury is a catastrophic injury that predominantly affects young men, most of whom then live for a further 50 years with substantial disability. Although thankfully the injury is relatively uncommon, the lifetime care costs are staggering. In 2010, Access Economics estimated the cost of spinal cord injury in Australia to be \$2.0 billion, \$5million per case of paraplegia (lifetime) and almost double that (\$9.5 million) for quadriplegia.<sup>1</sup> Over half of these people living with SCI in Victoria sustained their injury in a motor vehicle or workplace accident and as such much of their lifetime healthcare and disability costs are carried by the TAC or Workcover. Through the TAC in particular, significant funds have been made available for Neurotrauma Research in Victoria during the past decade. Significant advances in knowledge have been made, discovery continues and translation of this knowledge is ongoing. However, it is increasingly clear that better integrated clinical research data are necessary to maximise these investments.

The need for clinical and research integration became especially evident across the clinical research program centred at the Austin Hospital. The TAC funded almost \$15million across three program grants that are all examining people living with SCI. The research groups have invested substantial resources into coordinating their clinical research such that the burden on the patients is minimized and the research outcomes maximized. Our proposal was to extend that collaboration further through prospective collection of clinically relevant and research critical information by the clinical care staff.

This project was the first step in developing an integrated clinical research registry for traumatic spinal cord injury in Victoria. We have built on a number of recent local, national and international developments which, when taken together, suggested that there is a unique opportunity to be global leaders in clinical research registry development in SCI. These developments are outlined below.

Since the early 2000's, the international spinal community has been working collaboratively to examine the domains of disability in SCI and to express these in a manner consistent with the World Health Organization International Classification of Function (ICF).<sup>2, 3</sup> The first iteration of these, the International SCI Datasets, have been endorsed by key organisations including the International Spinal Cord Injury Society (ISCOS) and the America Spinal Injuries Association (ASIA). The International SCI Datasets cover 18 domains from case registration minimum dataset items to quality of life, respiratory function, bladder, bowel and sexual function. These items provide, for the first time, an international lingua franca for spinal cord injury functional outcome research.

The Rick Hansen Foundation is a Canadian charity and research organisation who support the Rick Hansen Spinal Cord Injury Register (RHSCIR). The RHSCIR began as a Canada-only register but has begun partnering with international SCI services. These collaborations include units in China, Israel and the Queensland Spinal Injuries Unit. In Canada, the model of data collection is expensive; RHSCIR directly funds data collection staff at each site and the dataset is very extensive. Although the international model is still being developed, it appears likely that it will involve little local direct funding and that data linkages will be centred on the Core Sets. In Canada, RHSCIR is an individual-client identified, aggregated dataset and this characteristic; along with issues surrounding governance and cost would likely limit implementation of RHSCIR in its current form in Victoria. Notwithstanding these issues, routine collection of International SCI Datasets during the acute and rehabilitation

episode at Austin Health would significantly increase opportunities for data linkage, multi-national collaboration and evaluation. Further linkage opportunities will be also be strengthened with existing, local datasets such as the Victorian Trauma (VSTORM) and the Australian Intensive Care registries.

The Australian Spinal Cord injury Register (ASCIR) is a long-standing, extensive registry that provides comprehensive case registration for SCI across Australia. <sup>4</sup> A project to review this registry and other aspects of SCI registration across Australia has recently been commissioned by the Spinal Cord Injury Network and undertaken by the Department of Epidemiology and Preventative Medicine, Monash University. Although the report is yet to be made publically available, it is anticipated that it will recommend closer national collaboration and suggest ways to extend ASCIR. Inclusion of the International SCI Datasets could be a key mechanism to support collaboration and a low cost, scalable platform would provide opportunities to strengthen ASCIR.

Through the TAC supported Spinal Research Institute (SRI), resources are allocated for the development of a research database that will provide vital infrastructure to our collective research efforts. As noted in the SRI's project plan, a database will be built because, "Developing appropriate clinical databases and interfacing them with national and international databases is essential to enable appropriate patients to be identified for the various studies and to ensure national and international collaborations can be undertaken successfully." This sentiment was echoed recently during the environmental scan of future Neurotrauma research needs conducted by the National Trauma Research Institute for the TAC in 2011.

## **The Research Question(s)**

The long-term aim of this project is to develop an integrated, distributed clinical research database for spinal cord injury. It will draw data from clinical practice and activity, aggregate those data in a readily scalable manner and provide for security-oriented data linkage to local, national and international registries and datasets.

This particular project is the first step towards achieving this goal. The aim of the project was to develop a local prototype of how data in the key internationally agreed domains of spinal cord injury care could be collected, collated and analysed to facilitate research and quality improvement activities.

The broad aims of the project were to develop a dataset for the VSCS that would:

- map to the International SCI Datasets
- be embedded in usual clinical care
- scale globally at little cost
- allow for data linkage locally and internationally while adhering to best international ethical and privacy practice
- engage people living with spinal cord injury as key partners in data collection and follow-up

The primary data we require to meet these aims and to improve patient outcomes are clinical. It is the information that nurses, doctors, allied health professionals and others accrue about people living with SCI as they pass through the continuum of care. This project therefore involved understanding these clinical processes and mapping the dataset to them. Thus the project has facilitated development of the critical interface between clinical care and the clinical dataset.

## Method

A number of processes were undertaken to achieve the project objectives. We firstly formed a multi-disciplinary working group which consisted of researchers, clinicians and service managers of the VSCS. The research team developed the first iteration of the dataset based on examination of the key elements of the ISCoS, ASCIR and AROC datasets. The role of the working group was to advise on the dataset to be implemented and the data collection processes. Initially, the working group reviewed existing data collection practices, specifically for ASCIR and AROC, and improved the way in which some of these data were collected in the unit.

We then re-mapped the the clinical pathway that SCI patients travel to the International SCI Datasets, and used this knowledge to select which of the ISCoS datasets would be included in the larger dataset. Following selection of the ISCoS datasets, the research team looked for overlap in the ISCoS, ASCIR and AROC datasets, removed any redundancy, and identified areas where more data items were required for the unit to effectively undertake quality improvement activities, monitor the outcomes its patients, and participate in national and international research projects.

As part of a wider national group aiming to update the current ASCIR dataset so that it meets the requirements of a safety and quality register, we surveyed all spinal unit directors in Australia and New Zealand to ascertain their thoughts on which clinical indicators and patient outcome measures should be included in the national register. We searched the scientific literature and identified other registries measuring similar areas to ensure that we selected valid, reliable and comparable measures of outcome and quality of care.

The outcomes of these activities allowed the research team to assemble a comprehensive, parsimonious dataset for the VSCS, which was thoroughly documented in a data dictionary. Several workshops were held with VSCS clinicians to determine the process for collecting and auditing the data within the unit, specifically who, when and where each data item would be collected and checked.

We took great care to consider and reconcile the competing demands of a rigorous ontology with the day-to-day practical implications of data collection within usual clinical care. Using the previous experience of the research team in large scale evaluation of chronic disease, we devised innovative methods to 'reward' the clinicians involved in data collection. The full (current) list of these "rewards" are in the Results, but briefly they included process enhancements such as the generation of interdisciplinary patient transfer and discharge summaries using the data collected by the clinicians in the register. These summaries minimize double-handling of data, ensure data consistency across disciplines and are able to be filed in the medical record.

## Results

The following key outcomes were achieved:

1. The project has been completed on time and on budget despite the significant delays associated with with negotiations around the intellectual property. In fact, the research team has achieved more than was planned initially. These additional achievements include better engagement with clinical stakeholders and research partners, a more comprehensive dataset and substantial national and international collaborations and partnerships .
2. Based on the successful completion of the processes outlined above, the VSCS dataset contains the following established datasets, outcome measures and areas of measurement:
  - the Australian Spinal Cord Injury Register (ASCIR) data
  - the Australasian Rehabilitation Outcomes Centre (AROC) benchmarking data;
  - six of the International SCI datasets
    - Core
    - Non-traumatic
    - Urodynamic
    - Lower urinary tract function
    - Bowel
    - Pulmonary
  - Clinical indicators, including the incidence of five highly relevant medical complications
  - Time based information about the patient journey (hospital transition)
  - ASIA impairment scale (AIS)
  - Functional Independence Measure (FIM)
  - Spinal Cord Independence Measure (SCIM)
3. The dataset was thoroughly documented in a data dictionary, which is a key output for this project. See Appendix 1.
4. All of the data items in the new dataset were mapped to clinical care within the unit, and several workshops were held with staff of the VSCS to develop a protocol for how these data will be embedded into routine clinical practice.
5. This project enabled a more thorough review of assessment and data collection practice in the VSCS, and as a result meaningful changes to the way in which some of the clinical data are collected have been made. The most significant change is to the ASIA impairment scale assessment. This vitally important piece of clinical information is now being assessed by the physiotherapist and registrar together and at three set timepoints during the patient admission. Previously this assessment was completed by the registrar alone and at ad-hoc timepoints.
6. The team developed “rewards” for the clinical staff nominated to collect and enter the data into the database. These include;
  - a. the purchase of three tablet computers for the VSCS to enable data collection to occur at the bedside. Adding the data to the database at the time and place of collection has obvious advantages for data integrity, timeliness of access to information and improved clinical care efficiency.
  - b. a generic, interdisciplinary discharge summary generated almost entirely from data entered into the database. Such a document will significantly reduce

- duplication, improve consistency and save time for busy clinicians. It will also form part of the medical record.
- c. Real time access to all collated data for all clinicians of the service. The data collected are owned by the service, and will be made freely available for clinical care, research and quality improvement activities.
  - d. Data completion and integrity reports will be routinely provided to the clinicians entering the data.
7. Ethics approval was sought and received from the Human Research Ethics Committee of Austin Health for opt-off consent and for the collection and storage of identified information.
  8. An important outcome of this project was the successful resolution of potential intellectual property complications. This project was built on collaboration. For us to successfully engage with and secure organisational buy-in from NISU, University of Sydney, University of Melbourne and others we needed to ensure that the research team at IBAS were fully empowered to distribute the research outputs freely to the widest possible audience.
    - a. We established a partnership with Melbourne University Department of eResearch led by Richard Sinnott, to build the web-based data platform, which is the natural extension of this project.
    - b. We partnered with the University of Sydney "Access to Care" project led by James Middleton, to jointly fund and share the platform developed by the eResearch team.
  9. The research team's leading role in practical data harmonization and efficient data accrual has been recognised internationally. Evidence for this recognition is the inclusion of David Berlowitz on the ISCoS Structured Medical Record Working Group (with Fin Biering-Sorensen, Marcel Post, Susie Charliefue, Vanessa Noonon and Yu-ying Chen), and the NINDS Common Data Element Committee, Care History/Comorbidity working group (with Fin Biering-Sorensen, Michael Fehlings, David Wright, Vanessa Noonan and James Harrop).
  10. The research team were invited to present the VSCS registry proposal at the ANZSCoS conference in Melbourne in October 2012. See Appendix 2 for presentation.
  11. As part of a wider national group aiming to update the current ASCIR dataset so that it meets the requirements of a safety and quality register, this research team led a small project to understand what clinical indicators and outcome measures were being collected by various spinal units in Australia and New Zealand, and which specific measures the units believe should be included in a redesigned ASCIR dataset. The results of this survey were presented at the SCIN Connections conference in August 2012, and have informed the development of the VSCS dataset in this project.

## Discussion / implications

The research team at IBAS has successfully achieved the specific aims of this project; to develop an integrated method of a clinically relevant and scientifically robust minimum dataset for the VSCS. The research outputs provide a strong platform upon which national and international collaboration around benchmarking, comparative effectiveness research and quality practice can be built. Successful completion of the project has provided the research team with the opportunity to leverage additional funding through the University of Sydney "Access to care" project and the Spinal Research Institute to continue to develop the VSCS register into SpinalCARE (Spinal Clinical And Research Excellence). This web-based data platform is in the final stages of testing and is expected to go live before end-2013.

The VSCS dataset is unique in its strong basis in already agreed international and national data items. Existing data registries such as the RHSCIR and ASCIR were developed at a time when international agreement from the SCI community about what was the "real" minimum dataset was lacking. Because of the unique timing of this project, we have largely avoided the risk of creating yet another silo of information about SCI. The VSCS dataset is internationally comparable at its core. Furthermore, the electronic data platform which will support the VSCS dataset into the future (SpinalCARE) is able to be easily modified and enhanced as the international standards inevitably evolve. The principles that have guided the development of SpinalCARE include the use of open source software and an intellectual property environment that facilitates open and generous access to these tools. These principles and the publication of the Data Dictionary should enhance the future clinical, research and community utility of SpinalCARE.

We envisage that the SpinalCARE database will also capture information beyond the initial definitive care episode so that people with SCI can be followed throughout their lives. Our vision is that SpinalCARE will engage the consumer as the source and custodian of their information, by providing a mechanism for people with SCI to input data around their health and function over time. While achievement of this aim was beyond the scope for the current project, the SpinalCARE dataset was compiled with this longer-term vision in mind. For example, there are valid and reliable self-report versions of the FIM and SCIM, and we have identified many items in the International SCI datasets that are suitable for self-report. Future research will be necessary to validate these measures, but as many of the International SCI datasets were developed with input from people living with SCI, there already exists a degree of face, context and construct validity in these measures.

Clinicians are busy. In many other clinical units where comprehensive data collection is undertaken, the only possible solution has been to employ additional staff who are responsible for data collection and entry. Although it is too early to be certain that our model is truly sustainable, we have specifically endeavoured to build a model of data collection that should reduce (or at the very least not increase) the administrative burden for clinicians as they go about their job of delivering excellent clinical care. Clinicians were involved with building the data system from the start because the data clinical researchers, epidemiologists, funders, administrations and government require is predominantly clinical in nature. We have substantial clinician "buy-in" for the project; they are excited about the prospect of good quality clinical information that they have generated and hence trust.

One of the important, unanticipated benefits of the project was the development of a better way to assess the AIS. The AIS is the single most important measure of neurological status

after SCI. The AIS measurement timepoints have been standardised during the definitive post-injury care period and the assessment is now being performed by the physiotherapist and registrar together. Previously the AIS was completed by the registrar alone and at ad-hoc timepoints which resulted in both incomplete and imprecise data in some people. The IBAS research team is continuing to assess the impact of this change in process in collaboration with the VSCS. We anticipate that the results of this evaluation will be available in early 2014.

We have an implementation evaluation plan that will extend beyond the period and scope of this project. This evaluation plan includes measures of data accuracy and completion, staff satisfaction, practice change, and research and quality improvement activity within the unit.

Academic outcomes of the project will include publication of papers in relevant, peer-reviewed scientific journals and presentation of results at local, national and international meetings. As with most scientific projects, these outputs will be delivered progressively over the next few years. For example, a publication with appropriate impact must wait until we have the evaluation results and the utility of the online SpinalCARE development is complete.

## **Conclusions**

Spinal Cord Injury (SCI) is an area of substantial research need through the continuum of new knowledge generation to research and knowledge translation. Importantly, SCI happens to ordinary people everyday and as such, clinician and scientists need to capture and understand information across multiple behavioural, physiological, genetic and investigational domains in multiple sites around the world and over extended time frames. Without these complex, rich data all of the impacts of injury on people are not able to be adequately explored, impeding the improvements in the quality of life of individuals and preventing the reduction of ongoing costs through better practice. This project has established the local foundation for such an endeavour.

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**Appendix 1: Victorian Spinal Cord Service Data dictionary, Version 0.9**

Please refer to attachment

## **Appendix 2: ANZSCoS 2012 presentation**

Please refer to attachment