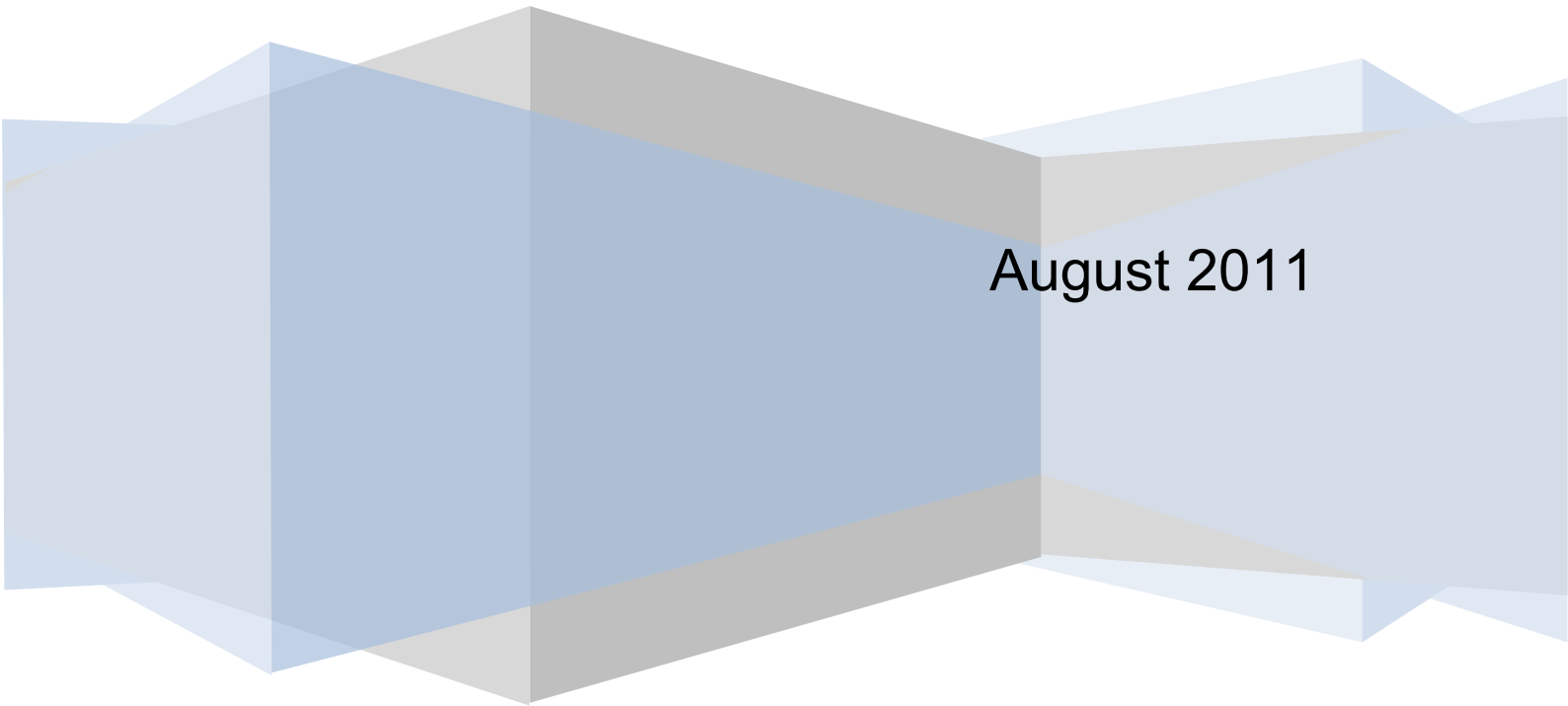
Scoping study to enhance spinal cord injury data connectivity within Australia and internationally

Phase One Report

Cameron Gosling
Belinda Gabbe
Paul Jennings
Peter Cameron



August 2011

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LIST OF ABBREVIATIONS

6MWT	6 Minute Walk Test
10MWT	10 Metre Walk Test
ACSQHC	Australian Commission on Safety and Quality in Health Care
AIHW	Australian Institute of Health and Welfare
AROC	Australian Rehabilitation Outcomes Centre
ASCIR	Australian Spinal Cord Injury Register
ASIA Impairment Scale	American Spinal Injury Association Impairment Scale
BMI	Body Mass Index
EMSCI	European Multicentre Study about Spinal Cord Injury
FIM	Functional Independence Measure
ISCoS	International Spinal Cord Society
LISAT – 11	Life Satisfaction Questionnaire [11 items]
MEP	Motor Evoked Potential
NACTN	North American Clinical Trials Network
NCV	Nerve Conduction Velocity
NISU	National Injury Surveillance Unit – Flinders University
SCI	Spinal cord injury
SCID	Spinal Cord Injury Database (NSW)
SCIM	Spinal Cord Independence Measure
SCIN	Spinal Cord Injury Network
SIU	Spinal Injury Unit
SSCIS	State Spinal Cord Injury Service (NSW)
SSEP	Somatosensory Evoked Potentials
TUG	Timed Up and Go
WISCI-II	Walking Index for Spinal Cord Injury

EXECUTIVE SUMMARY

Traumatic spinal cord injury affects 250 to 300 individuals directly every year. Monitoring and evaluating prevention and treatment programs in this important group of people has been seen as a high priority. Since the mid 1990's the Australian Spinal Cord Injury Register (ASCIR) has been the primary registry for recording incident cases of traumatic Spinal Cord Injury (SCI) in Australia. The ASCIR has been managed by the National Injury Surveillance Unit (NISU) at Flinders University and funded by the Australian Institute of Health and Welfare (AIHW) and the Department of Health and Ageing (DoHA). A funding crisis occurred in mid 2008 impacting on the function and utility of the registry. Subsequent to this issue, the ASCIR underwent a comprehensive review in 2008 culminating in the release of a technical briefing paper in May 2010. Two key conclusions were evident from this review. Firstly, funding issues have resulted in a reduction in the ability of the NISU to adequately support the registry in its current form. Secondly, the ASCIR needs to be redesigned into a clinical quality registry.

The Spinal Cord Injury Network (SCIN) commissioned a report and scoping project aimed at enhancing data connectivity and the development of a business case for a redesigned ASCIR. The brief from SCIN included reviewing how to implement the four key activities, identified by SCIN, ASCIR and NISU, into the new registry:

1. Continued data collection and analysis, as a unique epidemiological registry with over 25 years of data
2. Research focusing on the immediate access to care and pathways through care for people with traumatic spinal cord injury
3. Clinical trials of appropriate treatment and management protocols for people with spinal cord injury
4. Follow-up of people with spinal cord injury after their discharge from acute care and rehabilitation.

It is important that any clinical quality registry promotes, monitors and improves the quality of health care. Research using registry data can lead to significant improvements in safety and quality. Registries have the capacity to improve and promote research by utilising standard data definitions and collection methods, routine auditing of process of care and other outcomes of interest, linkage with other data sources, using routine data collection

processes and outcome measure to make research feasible, and providing engagement with the clinician and SIUs. The role of the registry is to generate hypotheses to be tested and specific research questions can be addressed by incorporating key outcome measures into the routine collecting of registry information.

The focus of this report was to develop recommendations on the implementation of a revised ASCIR and appropriate timelines for achieving this. This report is divided into three key sections including: the primary outcomes of interviews with key stakeholders identified by the SCIN; a comparison of spinal cord injury registries and databases (national and international) to identify common data items; and a mapping task matching the modifications required to the current ASCIR to conform to the operating principles and technical standards for Australian clinical quality registries as defined by the Australian Commission on Safety and Quality in Health Care (ACSQHC).

A number of fundamental issues were identified from these processes which will need to be addressed by the ASCIR stakeholders. These issues cannot be resolved solely by an external party without significant potential for loss of stakeholder engagement and clinical integrity. These issues identified are each linked to recommendations and timelines for adoption (Appendix 1). The primary question that needs to be addressed is: "What is the primary scope of the ASCIR?" Is it a registry for all spinal cord injury (i.e. traumatic, non-traumatic and paediatric) or should it be solely confined to adult traumatic spinal cord injury? All clinicians identified that the inclusion of non-traumatic and paediatric cases would be ideal, however problems implementing these groups into registry collection were clear. The recommendations for the continuation and development of the ASCIR are:

i. A revised governance structure is required including representation from clinicians (medical and allied health), researchers and associated peak bodies (e.g. SCIN) ensuring appropriate regional representation and the appointment of an independent chairperson – [0-3 months].
ii. Establish an appropriately constituted Steering Committee to oversee the governance of the ASCIR, including the development of strategic direction and ensuring deliverables are met for the registry and funding bodies – [0-3 months].
iii. Convene an appropriately constituted Management Committee to manage day-to-day aspects of the registry and ensure data quality measures are reported regularly – [0-3 months].
iv. Terms of Reference for the Steering Committee and Management Committee need to be developed, including meeting schedules and membership policies – [0-3 months].

v. The data access policy needs to be reviewed and updated as necessary – [3-6 months].
vi. Identify data reporting procedures including peer review processes, feedback to SIUs and dissemination of findings to the wider public – [3-6 months].
vii. Provide a detailed and agreed policy on the use of the registry for research purposes and the publishing of data through peer-reviewed publications – [3-6 months].
viii. The ASCIR capture only adult traumatic SCI cases until the issues with case identification of paediatric and non-traumatic cases are resolved – [0-2 years].
ix. A non-traumatic SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group – [6 months – 2 years].
x. A paediatric SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group – [6 months – 2 years].
xi. Formation of a working party to revise the minimum dataset. The working party should include representatives from each SIU, a database specialist (to streamline database changes and compatibility), clinical quality registry methodological expertise, and regional representation. Consideration should also be given to including international representation on this working party to improve the potential for international comparison and benchmarking – [0-6 months].
xii. Develop a revised data collection form, data dictionary and documentation supporting a standardised approach to data collection methodology – [3-9 months].
xiii. Establish a training protocol for the collection of the revised minimum dataset using flexible approaches to accommodate the geographical challenges of the ASCIR (e.g. online tutorials, teleconferencing, etc.) – [6-9 months].
xiv. ASCIR should adopt an opt-off method of consent to ensure complete case capture, minimise the potential for selection bias, and reduce administrative demands. Research sub-projects should seek individual ethics approvals as linked projects. While there is provision in the NHMRC National Statement on Ethical Conduct in Human Research for "unspecified" consent, the specific ethical issues for each project will need to be reviewed on a case-by-case basis – [0-3 months].
xv. Implementation of a secure database with web interface for data entry at site level – [0-6 months or on securing of funding].
xvi. Design system interfaces to allow data transfer from existing databases, and compatibility with other relevant registries – [0-6 months or on securing of funding].

xvii. Identify data quality assurance processes and build data audit and quality checks into the system to support the quality assurance protocols – [0-6 months or on securing of funding].

Ideally, the ASCIR would record all incident cases and follow-up for traumatic and non-traumatic SCI across all age groups. However, this would require the registry to include many non-specialist units and rehabilitation facilities increasing the complexity of the registry and the costs associated with registry function. Our recommendation is for the ASCIR to continue with the collection of traumatic SCI data for patients admitted to specialist SIUs, and enhancement of the minimum dataset to include additional clinical and outcomes data (including long-term follow-up). Extension of the registry to the collection of non-traumatic and paediatric cases should remain an aim of the ASCIR with working groups established to progress this extension. Uptake of the recommendations identified in this report would support the four core activities of the ASCIR. The recommendations made in this report for the ASCIR will require a collaborative effort involving spinal cord injury clinical experts, registry stakeholders, individuals with experience in the methodology, development, implementation and review of clinical quality registries.

ABOUT THIS REPORT

The Department of Epidemiology and Preventive Medicine at Monash University was engaged by the Spinal Cord Injury Network (SCIN), the Australian Spinal Cord Injury Register (ASCIR) board and the National Injury Surveillance Unit (NISU) to undertake a scoping study to enhance spinal cord injury data connectivity within Australia and Internationally. The ASCIR underwent a comprehensive review in 2008 culminating in the release of a technical briefing paper in May 2010. As such the information contained within this report should be read in conjunction with the Review of the Australian Spinal Cord Injury Register (ASCIR) (O'Brien et al. 2009) and the ASCIR Technical Briefing Paper (O'Brien et al. 2010).

The result of the 2008 to 2010 review process was the identification of four core activities for the ASCIR to achieve:

1. Continued data collection and analysis, as a unique epidemiological registry with over 25 years' data
2. Research focusing on the immediate access to care and pathways through care for people with traumatic spinal cord injury
3. Clinical trials of appropriate treatment and management protocols for people with spinal cord injury
4. Follow-up of people with spinal cord injury after their discharge from acute care and rehabilitation.

The current review addressed the following through community consultation, registry/database review and comparison with the Australian Commission on Safety and Quality in Health Care Operating Principles and Technical Standards for Australian Clinical Quality Registries (NHMRC Centre for Research Excellence in Patient Safety (CRE PS) and the National E-Health Transition Authority (NEHTA), 2008):

i. Determine information platform options, including interoperability requirements and opportunities for purchase/development of existing systems
ii. Specify data elements to be collected
iii. Specify data security requirements and quality assurance measures
iv. Identify opportunities for data linkage within Australia and internationally
v. Advise on required governance structure, partnerships and custodianship
vi. Advise on privacy and ethics issues and consent model options
vii. Advise on desired information output.

This report also addresses the expansion to include paediatric cases and non-traumatic spinal cord injury cases and the issues relevant to each of these groups.

This report is structured around three methods of information collection comprising interviewing of key stakeholders, a comparison of established registries/databases against the current ASCIR and benchmarking against the ACSQHC operating principles and technical standards for Australian clinical quality registries. Primary issues have been identified from these sources and will be discussed with recommendations for advancement of the ASCIR.

METHODOLOGY

Introduction

Data collection for this scoping study involved three methods; interviewing key stakeholders identified by the SCIN, identifying commonalities between registries and databases capturing data on SCI, and benchmarking the information collected from the interviews, registry/database comparisons and the ASCIR review (O'Brien et al. 2009) and technical briefing paper (O'Brien et al. 2010) against the ACSQHC Operating Principles and Technical Standards for Australian Clinical Quality Registries. The purpose of the interviews was to provide key stakeholders with the opportunity to express their vision for the registry, perceived changes necessary for the registry, and barriers to implementation of changes to the registry. The questions used in the interview were based on issues explored in the technical briefing paper (O'Brien et al. 2010) and the ACSQHC Operating Principles and Technical Standards for Australian Clinical Quality Registries.

Methodology - Interview

A list of key stakeholders (n=16) was generated by the SCIN for interview as part of Phase One of the scoping study. A further six participants were contacted to be interviewed using the "snowball" technique. Eighteen interviews were completed. Two stakeholders were unavailable, one declined to be interviewed, and one did not respond to email and phone requests for interview.

The list of stakeholders generated by SCIN to be interviewed as part of the study included:
Denzil O'Brien (Research Associate, Flinders University)
Professor James Harrison (Director, NISU)
Dr Ruth Marshall (Chair, ASCIR, Director SASCIS)
A/Prof James Middleton (Director, NSW SSCIS)
Dr Bonne Lee (Acting Director, POWH Spinal Unit, NSW)
A/Prof Doug Brown (Director, Victorian Spinal Cord Service, VIC)
Dr Andrew Nunn (Victorian Spinal Cord Service, Austin Health, VIC)
Dr Sridhar Atresh (Director, QLD SCIS)
Dr Ben Goss (Researcher, QUT)
Dr Sue Urquhart (QLD SCIS)
Mr John Ker (Director, Sir George Bedbrook Spinal Unit, WA)

Professor Brian Freeman (Professor and Head of Spinal Surgery, Uni of Adelaide)
Dr David Berlowitz (Lead investigator, Austin Health, VIC)
Professor Mary Galea (Professor of Clinical Physiotherapy, Uni of Melbourne, VIC)
Professor John Furness (Director, Centre for Neuroscience, Uni of Melbourne) or Dr Christopher
O'Callaghan (Department of Medicine, Repatriation and Austin Hospitals)
Dr Adrienne Epps (The Children's Hospital at Westmead, NSW)

The list of interviewees generated by the snowball technique included:
Dr Mary Clare-Waugh (The Children's Hospital at Westmead, NSW)
Professor Glen Davis (The University of Sydney, NSW)
Dr Grace Leong (Royal North Shore Hospital, NSW)
Dr Peter New (Spinal Rehabilitation Unit, Caulfield Hospital, Victoria)
Associate Professor Lisa Harvey (The University of Sydney, NSW)
Dr Ray Russo (Adelaide Women's and Children's Hospital, SA)

The interview schedule included questions on the proposed aim of the registry, inclusion criteria and case selection, minimum dataset items, data collection processes, data quality issues, performance indicators, ethics and privacy, registry governance and key barriers to the successful functioning of a clinical quality registry. The overarching theme of the interview questions was focused on revision, implementation and utility of the registry.

Methodology – Registry/Database Review:

Data dictionaries and/or case registration forms were collected from all known national and international spinal cord injury registries (see Table 1). Data items were assumed to be routinely collected where the item appeared on the case registration form or data dictionary. All data items were extracted from each dataset and were tabulated by registry and data item to assist in identifying common items and disparities. Data items were collapsed into one 'summary item', where: i) they collected like data; ii) it was logical to merge the items; and iii) where the items were very detailed and collected by only one registry.

Table 1 - Participating Spinal Cord Registries

Spinal Cord Registry	Location
Australian Spinal Cord Injury Register (ASCIR)	Adelaide, Australia
Queensland Spinal Injuries Unit Database	Brisbane, Australia
International Spinal Cord Society (ISCoS) datasets	United Kingdom
North American Clinical Trials Network (NACTN) data register	North America
Rick Hansen Spinal Cord Injury Registry	Canada
New South Wales State Spinal Cord Injury Service (SSCIS) Spinal Cord Injury Database (SCID)	Sydney, Australia
European Multicentre Study about Spinal Cord Injury (EMSCI)	Switzerland
SpineTango	Switzerland

Data items were then categorised, sorted and reported by data type (eg. demographic, socio-demographic, admission, injury, etc.). The ASCIR was used as the reference dataset, and data items contained within each registry were shaded in blue (See Appendices 2-15). Data collection time points were also identified.

Methodology – ACSQHC Operating Principle Benchmarking:

Information collected from the interviews, the registry/database evaluation and the technical briefing paper were benchmarked against the ACSQHC Operating Principles and Technical Standards. The identification of current ASCIR procedures and processes complying with the guidelines was completed in the benchmarking exercise.

FINDINGS

Interview Themes:

The discussion with participants was robust with positive and negative aspects of the current registry highlighted. The consistent response from participants was that while the current registry was generally good and provided useful epidemiological data on spinal cord trauma in Australia, aspects of the registry could be improved and there were variations in theme responses from individuals. The key themes to emerge from the interview process that require further consideration and reporting included: case identification and inclusion criteria, data items, governance and data access, ethics and privacy, future implementation barriers, and the role of the registry and its reporting.

1. Case identification and inclusion criteria:

Two separate issues were identified related to the inclusion of cases; the inclusion criteria, and case identification. Discussion with all interviewees included questions relating to the collection of data from non-traumatic injury and the inclusion of paediatric cases onto the registry. The non-traumatic cases were reported by 14 of the 18 interviewees as being of valuable to register due to the impact they have on unit resources and poor reporting of incidence data in this group. Paediatric cases were deemed important by most (12 interviewees) to record, especially the traumatic cases. However, the specialist paediatric rehabilitation physicians identified that modification of data items would be required to make them relevant to the clinicians involved in treating this sub-group. The interviewees reported that traumatic cases had clearly defined criteria, while non-traumatic cases are not always clear.

Difficulty ensuring inclusion of all eligible cases was another key theme identified from the interviews. State by state differences were reported regarding the capture of all eligible traumatic cases. As noted previously, non-traumatic cases were also recognised as important but potentially difficult to identify and ensure complete case capture. Reported reasons for incomplete case capture included treatment of traumatic cases at a medical facility other than one of the designated spinal units (e.g. ICU at another hospital), early recovery following spinal trauma (e.g. spinal concussion injuries), patient death in acute

care prior to reaching a specialised SIU, patient death before reaching hospital, and non-traumatic cases admitted to general rehabilitation hospitals.

2. Data items:

Most interviewees reported that the current minimum dataset of the ASCIR was useful for epidemiological reporting but lacked key clinical information. Ten of the 18 respondents identified that clinical problems and critical research questions should shape the data collected with an ideal model incorporating a core dataset with modules feeding into the data collection to answer questions of importance. Data collection by the current ASCIR is primarily epidemiologically based and expansion of the dataset is needed in more clinically related fields. The consensus view (12 of 18) was that additional pre-hospital and service transition (e.g. Emergency to ICU, ICU to specialised SIU) data items are required. Seven interviewees identified that linked pre-hospital medical service provider data and other hospital systems data would address the required information of pre-hospital service provision and hospital transition. The respondents noted that clearer identification of causation factors needs to be incorporated into the registry by utilization of the international classification of external cause of injury (ICECI) codes.

Another key theme identified through the interviews was that consideration should be given to the inclusion of relevant outcome measures, especially as part of long-term follow-up. All interviewees recommended that expansion to include long term follow-up of cases was required for the registry. Common time frames reported by respondents for follow-up included the time points of every year following the injury event for the first 5 years and then every 5 years thereafter.

A better system of recording and reporting complications related to admissions was identified as important. There was a view that the minimum dataset needs to be reviewed to identify redundant items which could be excluded. However, there was no clear consensus regarding data items, data collection time points (including acute, rehabilitation and long-term phases) and potential for linkage to other data sources such as the Australasian Rehabilitation Outcomes Centre (AROC).

3. Governance structure and data access:

Dissatisfaction with current governance processes was expressed by five participants, especially as it pertained to timely access to data. Sites maintaining their own databases generally did not report timeliness of data access as an issue, but they identified that a more structured process of gaining access to data and output reporting should be investigated. Seven of the 18 interviewees did not comment on the current governance structure due their unfamiliarity with the processes and policies of the current board. The formation of a strong governance structure with clearly defined policies for data access and reporting as well as adequate representation from all key stakeholders was identified as a priority for those that expressed dissatisfaction.

4. Ethics and Privacy:

Marked discrepancies were apparent when interviewees were asked about the role of ethics and privacy for the registry. Four options for consent were identified from these interviews and these included: (i) Informed consent (opt-in) including consent for other future registry roles such as follow-up contacts and research project registrations; (ii) opt-in informed consent to participate in the initial episode registry data collection only; (iii) opt-off consent where data held by the data custodians is de-identified but re-identifiable at the source; and finally (iv) opt-off consent for the provision of identifiable data to the data custodians. Themes related to individuals' rights, risk exposure and data security were common to all who expressed the desire to maintain and/or expand on the current opt-in consent method used by ASCIR.

5. Role of the Registry and Reporting:

The ASCIR to date has primarily reported epidemiological data as an annual report for the AIHW, site-specific reports, and a limited number of research outputs. Fourteen of the 18 respondents reported that the ASCIR needs to play a role as a platform for future research projects as well as being able to record information capable of reporting on current and changing clinical practice. The registry was also identified as a tool that could potentially inform health planning. It was for this reason that the same number of interviewees were in favour of the inclusion of non-traumatic and paediatric cases on the registry as they have an impact on the resource allocation for units. The recording of all SCI cases could allow for

benchmarking and quality assurance reviews identifying best practice for the treatment of all SCI across the population.

6. Future Implementation Barriers:

Three primary barriers for the continued role of the ASCIR were identified by the interview cohort. Firstly, all interviewees identified that an on-site data collector, and the financial resources to support this position, was necessary. While a number of units reported absorbing the cost of data collection by the unit, others identified this as a significant barrier to participation that warrants consideration in any external funding requests for the registry. Secondly, how the data is to be collected (including who collects the data at each site) and the standardisation of the collection procedures was an identified issue. The need for clear data standards and linkage to alternative data sources, where applicable, to minimise resource required and streamline the process was expressed by the interviewees. Finally, 16 of the 18 interviewees expressed a need for a secure database with a web interface to assist in overcoming the previous two barriers.

Spinal Cord Injury Registry/Database Comparison:

A total of eight registries were reviewed which yielded 376 independent data items. The number of data items per registry ranged from 38 items (SpineTango) to 190 items (ISCoS). The ASCIR currently contains 42 data items. Only four data items were consistent across all eight registries, and one item was consistent across seven of the eight registries. The five most consistently collected data items were:

i. Person identifier
ii. Sex
iii. Date of Birth
iv. Main cause
v. ASIA Impairment Scale.

The following data items are not collected by ASCIR, but are collected by both the Queensland and NSW registries:

i. Telephone contact details
ii. Income source
iii. Health fund
iv. Living arrangement
v. Referring institution
vi. Illicit drug involvement
vii. 'Sacral sparing' (although collected within ASIA 'Completeness' data-item)
viii. Community death / Date of community death.

The following data items are not collected by ASCIR, but are collected by both the Rick Hansen and ISCoS registries:

i. Height and Weight
ii. Smoking history
iii. Data relating to pain
iv. Detailed procedure information relating to surgery, interventions and ventilator/ventilation assistance
v. Total days hospitalised for acute care.

Demographics:

The ASCIR collects quite detailed demographic information in comparison to the international registries (Rick Hansen, ISCoS, EMSCI, NACTN, SpineTango). The Queensland and NSW registries collect data items in addition to that collected by ASCIR, including height and weight (Rick Hansen collects BMI in addition), language spoken and ethnicity. Several of the other registries (Queensland, NSW, Rick Hansen, NACTN) also collect more detailed socio-demographic data such as income source, health fund, household income and living arrangements (Appendix 2 and 3).

Admission information:

The admission information collected is consistent across the reviewed registries. The Queensland registry collects the most detailed admission data, including referrer's details, urgency of referral and information regarding admission delays (Appendix 4).

Injury information:

The ASCIR, Queensland and NSW registries collect more detailed injury information than the international registries. The ASCIR does not collect information regarding the involvement of illicit drugs at the time of injury where the other state-based registries and the ISCoS database do (Appendix 6).

Assessment information:

The ASIA Impairment Scale is the most commonly utilised assessment tool, recorded by all registries except for SpineTango. The following three instruments are recorded by two registries each:

i. Life Satisfaction Questionnaire [11 items] (LISAT – 11)
ii. The Spinal Cord Independence Measure (SCIM)
iii. Walking Index for Spinal Cord Injury (WISCI-II)

The EMSCI collect the greatest amount of assessment information, including neurological (ASIA), functional (10MWT, 6MWT, TUG, WISCI-II) and independence measures (SCIM3). In addition, some centres collect data items reporting the following assessments:

neurophysiological (MEP, SSEP, NCV); pain; hand function; and a urodynamic protocol. The FIM is collected by the ASCIR, Queensland and Rick Hansen registries on admission, and the ASCIR and Queensland registries at discharge (Appendix 7).

Other clinical and physiological information:

Some of the international registries, in particular the ISCoS database, collect additional detailed clinical (e.g. health history, specific medications, and results of laboratory tests such as lipid profiles) and physiological (e.g. endocrine function, vital signs, urodynamics) data not captured by the ASCIR, Queensland and NSW registries (Appendices 8-13). The additional clinical and physiological data collected by the international registries include:

i. Bowel and cardiovascular data items
ii. Endocrine, fertility and pulmonary data items
iii. Urological data items (QLD does collect some urological data)
iv. Pain data items
v. Sexual and physiological measurement data items.

Procedures information:

The ASCIR collects information relating to complications observed during surgery and the episode of care, and allows the date and International Classification of Diseases (ICD) code [or free text] to be collected. Several of the international registries collect detailed 'procedural' information, including the operation(s) performed, interventions (e.g. tracheostomy, nutritional feeding tubes, traction) and information relating to ventilator assistance (Appendix 14).

Discharge information:

The ASCIR collects mode of separation and discharge date/time. The Queensland, NSW and NACTN registry collect data relating to date and cause of death following discharge. In addition, the NACTN also collects the findings from autopsy. Queensland, NSW and the NACTN collect data on the discharge support services arranged following discharge. Several of the international registries (Rick Hansen, NACTN and SpineTango) utilise a data item labelled 'therapeutic goals achieved' (Appendix 15).

Data collection time periods:

Table 2 summarises the time periods where each registry collects data for the patients they include. Three registries follow-up patients beyond their acute or rehabilitation admission, and of those who do, the time periods for collection of follow-up data differ (Table 2).

Table 2 - Time periods of data collection by registry

ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	SpineTango
Admission Discharge	Admission Discharge (Limited thereafter)	Admission Discharge	Admission Discharge 1 Year 2 Years 5 Years Then every 5 years thereafter	Admission Discharge	0 – 15 days (Admission) 16 – 40 days 70 – 98 days 150 – 186 days 300 – 400 days	Admission Discharge	6 weeks 3 months 6 months 1 year 2 years

Clinical Quality Registry Operating Principles:

There are a number of similarities between the current ASCIR and the ACSQHC's guidelines as outlined in the technical report (O'Brien et al. 2010). This section of the report identifies the extent to which the current registry is compliant with the Operating Principles (OP).

a. Attributes of Australian Clinical Quality Registries OP1-OP7:

OP 1 – *The registry should be developed with clear and precisely defined purpose:* The ASCIR is partially compliant with this operating principle. The four core activities identified by the SCIN as the primary aims of the registry partially address this first principle.

OP 2 – *Collection of a core minimum dataset:* The ASCIR does currently collect a core dataset of 42 items. However, reservations have been expressed in the interview phase of the scoping study as to the adequacy of clinical and pre-hospital data collected as well as the absence of long term follow-up information. The interviewees also expressed that a number of these data items are poorly populated in the current registry.

OP 3 – *Data collected should be confined to items which are epidemiologically sound:* The current registry data items have been reported to be epidemiologically sound (O'Brien et al. 2010).

OP 4 – *Data collection methods should be systematic across sites:* ASCIR is not fully compliant with this operating principle. Current data collection methods are not consistent across sites. While all sites report on the ASCIR form and are collected from the clinical case notes, two states use their own electronic database systems which have been expanded from the ASCIR (Appendices 1-14). The immediacy of data collection was also raised as a concern during the interviews. Some ASCIR data items (e.g. ASIA scores) are time and patient dependent and, in some instances, using retrospective medical history data for collection purposes may not accurately reflect the outcome measured. There is also disparity in the training and consistency of data collectors between units, with some units using specially trained data collectors while others rely on registrars rotating through units at regular intervals. No formal ASCIR documentation on training of SIU data collectors was identified, with all sites relying on the data dictionary and data coding manual as reference material. As the collection of data processes varies across sites, there is the potential for loss of data integrity and reliability which could impact on the reporting and interpretation of data from the registry.

OP 5 – *Time to outcome assessment:* To date, outcome data assessments collected by ASCIR have been limited to information provided at admission and discharge to an SIU.

Post-discharge follow-up of SCI is not recorded by ASCIR. The clinical progress of a patient needs to be reflected in the data collected by the registry. From the interview and registry/database review it is clear that data collection time points need to be identified for all outcome information collected, including acute care outcomes (e.g. ICU length of stay, mortality, initial ASIA score), rehabilitation outcomes (e.g. admission and discharge FIM, complications) and long-term post-discharge follow-up. From the review of registries/databases, only half of the registries have any follow-up of patients and the time to follow-up differs across registries. The information collected, and instruments used, at follow-up also differs between registries.

OP 6 – *Outcome assessment considerations including burden, cost of data collection and loss to follow-up:* All interviewees identified that current ASCIR data collection requires dedicated collectors at each site and a database system with a web interface to enable direct data entry on site, thereby reducing the burden on SIUs and the central registry resources required. The only long-term follow-up currently recorded is readmission to a SIU (O'Brien et al. 2010). However, this data item does not appear in any reports generated from the registry.

OP 7 – *Complete registry data must be collected from the eligible population:* The O'Brien et al. 2010 briefing paper identified that almost all cases of traumatic (and some non-traumatic) admitted to any one of the specialist SIUs are recorded and confirmed by case audits. The cases captured by the ASCIR are a completed representation of cases admitted to SIUs but may under-report the true incidence of traumatic SCI given that transient cord injury cases (e.g. concussive injury) and deaths prior to admission to an SIU may not be completely captured. Using AROC discharge information, 30% of traumatic SCI cases were reported to be managed in either private or public non-specialist rehabilitation units (New et al. 2001). However, differentiation between patients who had acute care in a SIU and those that did not was not defined.

b. Data Collection OP8-OP14:

OP 8 – *Minimising data collection burden:* The burden of data collection varies between sites. Some sites have access to data collectors and data managers while others are reliant on the registrars, allied health practitioners or unit funding to support and complete data collection. The manner of documentation, admission time course, quality assurance and record keeping are the biggest obstacles in the data collection process. Data retrieval is time consuming as documentation is not standardised across institutions. Some sites have access to "in-house" database systems whereas others are reliant solely on paper-based data

collection. Data collection and entry processes were reported to be time consuming, especially when quality assurance processes are built into the process. For example, one site reported that data collectors verify data with clinicians prior to data entry. There are inconsistencies in resources available to retrieve and code the data across the units.

OP 9 – *Data capture performed as close as possible to the relevant care event and to the point of care by appropriately trained data collectors:* This OP is one of concern for the current registry (O'Brien et al. 2010) and some solutions, such as linking with emergency department data and ambulance records, have been offered as potential solutions. The time course of a SCI admission was identified as a problem for some data items in the ASCIR. This is especially true if patients move between acute care and rehabilitation care under the same episode admission.

OP 10 – *Data should be uniformly and easily accessible from the primary data source:* This OP is currently adhered to by the ASCIR.

OP 11 & 12 – *Standard definitions should be used and registries must use data dictionaries:* The ASCIR utilises a number of standard classification and definition conventions; predominately the National Health Data Dictionary (NHDD Version 12) for demographic data, the Australia Standard Classification for Social Statistics (ASCSS) for country of birth information, and the International Statistical Classifications of Diseases and Related Health Problems (ICD).

OP 13 & 14 – *Using existing data sources and data linkage:* ASCIR currently relies on manual registration of cases, collection of data by data collectors (registrars or dedicated data managers) and submission of information (electronic or paper-based) from the SIUs. The SIUs with their own electronic database have provided data to ASCIR electronically. While the ASCIR uses existing medical record information, the use of other data sources and comprehensive data linkage is not undertaken.

c. Data Elements OP15-OP17:

OP 15 – *Individually identifiable information:* ASCIR currently adheres to this principle as patient-level identifiable information is available for most cases. Due to the absence of informed consent for some patients, there are some de-identified cases that exist on the registry from the Queensland SIU. In the absence of a national unique health identifier, the capacity to link with other data systems relies on the collection of identifiable data. Identifiable data also allows for the easier identification of duplicates on the system. The issue of ethics and privacy was raised extensively in the interviews with varied responses from participants.

OPs 16 – *Process of care measures:* No consistent data are currently collected by ASCIR on process of care. Interviewees identified a number of process of care measures such as time to SIU admission, hospital care transitions, timing of surgical interventions and timing of traction application that are not collected by the current registry. Process of care measures will need to be incorporated into the registry.

OP 17 – *Use of objective outcome measures:* The ASCIR only requires assessment\function using ASIA and FIM, both measured at SIU admission and discharge. The objectivity and validity of these measures was questioned by interviewees. The value of using the FIM for spinal cord injury populations and inter and intra-rater reliability of the ASIA were the key points highlighted by the interviewees.

d. Risk Adjustment OP18:

OP 18 – *Collection of objective, reliable co-variates for risk adjustment:* The ASCIR currently collects data for use in risk adjustment. However, the review of registries/databases has identified that the number of items recorded for patient demographics, socio-economic items, admission details, medical history, injury event information and medical assessment are not as comprehensive as other sources.

e. Data Security OP19-OP21:

OPs 19 to 21 – *Secure access controls, electronic transfer and electronic messaging; Collection, storage and transmission of clinical registry data should be in line with relevant legislation and guidelines; Institutional policy principles set out in Part B: technical standards should be met:* The current data security for the ASCIR is ensured by the AIHW Act 1987, however the model used is based on a Level 1 system as outlined in Part B: Technical standards from the ACSAQHC. A Level 1 system is a stand-alone registry, usually paper-based with individual data entry to the system for analysis and reporting purposes. The current transfer of data from the SIUs does not comply with the ACSAQHC technical standards. The current registry does adhere to the current NH&MRC National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

f. Ensuring data quality OP22-OP26:

OP 22 – *Report as a quality measure the percentage of eligible patients recruited to the registry:* The ASCIR capture almost all eligible patients with traumatic SCI. The main populations identified by the interview and technical briefing report as exceptions to this are paediatric cases of traumatic SCI, patients who die prior to hospital admission and some cases of spinal concussion injury. The percentage of eligible cases is currently not reported by ASCIR.

OP 23 – *Quality control and ongoing monitoring:* No uniform monitoring of data currently occurs. Review of cases by the data custodians only occurs where errors are potentially identified or rely on feedback of SIU data reports back to the individual units.

OP 24 – *Data audited against a sample of case records:* The registry is not compliant with this operating principle.

OP 25 – *Inbuilt data range and validity checks:* Current data checks incorporate the clerical review of the electronic and paper-based data submitted, visual scrutiny of information as it is manually entered, error checks and feedback to the SIUs, periodic (year by year) review and statistical level screening. Data collection forms are then archived by the NISU.

OP 26 – *Reports should be produced according to strict timelines and should be appropriately funded:* The reporting process has currently been suspended by the ASCIR and the SIUs reported difficulty in obtaining timely unit-level data. While SIUs with their own database were able to generate reports, the funding issues faced by ASCIR and its data custodian have hampered this function of the registry.

g. Organisation and governance OP27-OP28:

OP 27 and 28 – *Formal Governance Structures; Policies for contingencies:* The ASCIR currently operates under a board comprising SIU Clinical Directors, an AIHW representative and several other people with relevant knowledge and expertise (O'Brien et al. 2010). No governance documentation of policies and procedures were provided for this review. The membership of the current ASCIR board partially complies with OP 27. The membership does not yet include a consumer representative, a representative from key professional organisations or policy developers. There are currently no policy documents relating to OP 28.

h. Data custodianship OP29-OP31:

OP 29 to 31 – *Data access and custodianship:* These criteria are met by the current registry and governing board. A well defined document was provided as part of this review and clearly defines the data access policies. However, this is at odds with some of the interviews conducted where participants expressed concern about data access and the timeliness of this access.

i. Ethics and Privacy OP32-OP35:

OPs 32 to 35 – *Ethics approval; Familiarity of personnel with privacy and ethics legislation and guidelines; Participants/Next of kin aware of registry data collection; Ethics approval for sub-projects:* The current registry adheres to each of these OPs.

j. Information output OP36-OP41:

OPs 36 to 41 – *Quality care and benchmarking; Timely reporting; Peer review; Ad hoc site analysis; Annual reporting; Reporting procedures:* The technical briefing report (O'Brien et al. 2010) identified that the annual reporting of registry information (OP 40) is the only principle currently adhered to. Current ASCIR processes do not allow for the adherence to the remaining OPs. SIUs without access to a local database system also identified that ad hoc site analysis was difficult due to current data access regulations, and benchmarking of performance is not a function able to be performed from the current ASCIR.

k. Resources and funds OP42:

OP 42 – *Appropriate funding of registry activities:* As reported in the technical briefing paper (O'Brien et al. 2010) the ASCIR reached a funding crisis in 2008 leading to limited data collection and processing. The AIHW provided funding to bring the registry up to date, but most SIUs rely on self-funding to complete data collection.

Technical standards:

The current technical standard operated by the ASCIR is Level 1 according to the guidelines of the ACSQHC Technical Standards for Australian Clinical Quality registries. The current database does not meet the key OPs relating to data quality and only partially meets data

security OPs, mainly identified in the technical briefing paper (O'Brien et al. 2010) as the adherence to the AIHW Act 1987. The ACSQHC technical standards are based on the National E-Health Transition Authority (NEHTA) recommended standards. Using these guidelines as a base standard will allow for future linking with other national registries (e.g. National Death Index) optimising the utility of information gathered by the registry.

A Level 1 registry is the first of four types of registry architecture and standards developed by NEHTA. A Level 1 registry comprises:

i. A stand-alone registry.
ii. Paper-based submission of data to the registry.
iii. Data entry into a stand-alone computer system for analysis and reporting.

The ASCIR is currently a Level 1 system as submission of data for central processing still requires data entry into the stand-alone computer system.

RECOMMENDATIONS:

The previous sections have summarised: key issues and themes identified through the stakeholder interviews; content and data items of spinal cord injury registries from around the world, and; compliance of the ASCIR with the ACSQHC Operating Principles and Technical Standards for Australian Clinical Quality Registries. This section collates the collected information and provides recommendations for revision and development of the ASCIR.

Governance structure and custodianship:

Clinicians reported that the current governance structure appeared to be adequate but were content to be guided by the outcomes of this report. Other individuals interviewed felt that the governance structure was limited and should be expanded to be more inclusive of allied health, researchers and other potential stakeholders. To date the information output has been restricted to annual reports and a limited number of peer-reviewed research publications. Some concern was expressed about the data reports and NISU identified that due to funding issues, and a backlog of data entry (O'Brien et al. 2010), the provision of data summaries to units has been limited. Units without access to their own databases have also expressed concern over data access. Currently the AIHW Act 1987 covers aspects of data security and data custodianship. However with the current limitations in funding experienced by the ASCIR many reports and data validation processes have been reduced or suspended. The governance structure of the ASCIR requires revision to comply with the ACSQHC Operating Principles and Technical Standards for Australian Clinical Quality Registries. The specific recommendations for the governance structure and processes of the registry include:

Recommendations:

i. A revised governance structure is required including representation from clinicians (medical and allied health), researchers and associated peak bodies (e.g. SCIN) ensuring appropriate regional representation and the appointment of an independent chairperson.

ii. Establish an appropriately constituted Steering Committee to oversee the governance of the ASCIR, including the development of strategic direction and ensuring deliverables are met for the registry and funding bodies.
iii. Convene an appropriately constituted Management Committee to manage day-to-day aspects of the registry and ensure data quality measures are reported regularly.
iv. Terms of Reference for the Steering Committee and Management Committee need to be developed, including meeting schedules and membership policies.
v. The data access policy needs to be reviewed and updated as necessary.
vi. Identify data reporting procedures including peer review processes, feedback to SIUs and dissemination of findings to the wider public.
vii. Provide a detailed and agreed policy on the use of the registry for research purposes and the publishing of data through peer-reviewed publications.

Case Identification:

The inclusion of only traumatic SCI has consistently been described by the interview participants and registry documentation as clearly definable, identifiable and easy to capture as most are admitted to the specialist SIUs. The inclusion of non-traumatic cases and paediatric cases are identified as more problematic. Maintaining a traumatic injury only registry would allow for comparisons with other data sources (e.g. Rick Hansen Spinal Cord Injury Registry), however the inclusion of the other key patient groups (non-traumatic and paediatric) should be strongly considered as it provides greater opportunity to expand funding sources, lead the world on information collected about SCI and ensure a more comprehensive description of the extent of the problem in Australia.

In a recent cohort study, New et al. (2010) reported that of the 3610 patients with SCI discharged from AROC affiliated hospitals nearly two-thirds had a non-traumatic SCI. While it was generally agreed that non-traumatic cases would be a valuable addition to the registry, clear inclusion criteria need to be developed. The inclusion of non-traumatic SCI cases would also impact on funding models as the inclusion of non-traumatic cases would require the incorporation of non-specialised spinal rehabilitation facilities into the ASCIR.

Paediatric cases pose a similar problem with an almost identical proportion of traumatic to non-traumatic cases to those previously reported in an adult population (New et al. 2010). Paediatric cases would also require significant modification of data items to ensure the registry is clinically useful for physicians working in the area.

The advantages of maintaining a specialised SIU traumatic case registry only are a clearly defined case registration criterion, assuring nearly complete capture and minimising cost implications. To ensure continuity of the ASCIR, it is recommended that capture of traumatic cases be continued immediately and the criteria for the inclusion of non-traumatic and paediatric cases be developed.

Recommendations:

i. The ASCIR capture only adult traumatic SCI cases until the issues with case identification of paediatric and non-traumatic cases are resolved.
ii. A non-traumatic SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group.
iii. A paediatric SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group.

Data Items:

The project brief of the scoping study included the identification of data elements to be collected. The findings from the interviews and registry comparisons have identified significant limitations in the current ASCIR dataset and the need for a comprehensive structured review of data items. The current ASCIR is consistent with other registries with respect to demographic, injury event and assessment details, and admission to SIU information. Compared to other registries, the ASCIR is limited with respect to clinical and physiological data items, pre-hospital and acute phase of care data, procedures information and post-discharge follow-up of registered cases.

The minimum dataset needs to be revised to include items relevant to all phases of care and the data dictionaries of the registries reviewed in this scoping study provide the ideal platform for revision of the ASCIR minimum dataset. The recommendation of specific data items on the basis of the review of registries undertaken for this scoping study is not appropriate as the revision of the minimum dataset must be feasible and supported by the registry stakeholders. The revision of the minimum dataset should engage all relevant

stakeholders and be undertaken using a detailed and structured process. If this is not undertaken, relevance, uptake and compliance cannot be assured.

The potential for data linkage to pre-hospital emergency providers, hospital administrative systems, other state and national trauma registries and the future e-health record has been identified in the interview sections and the previous technical briefing document. The level of data linkage required for the registry will be largely dependent on the final determination of the minimum dataset. Once the minimum dataset has been reviewed and revised, a determination of the best source for each data item can be identified and then incorporated into the data collection.

As a critical component of any clinical registry, long-term follow-up is required of SCI patients. There are a number of issues that were identified from the interviews and registries review related to the long-term follow-up of SCI patients including the reliability and validity of outcome measurement tools, variance in data collection time points, data collection methods and patient accessibility. Patient distance from the SIU in some states, training of multiple data collectors at multiple sites and cost were also identified as barriers to the implementation of long-term follow-up, especially with the inclusion of non-traumatic and paediatric cases. A centralised process administering a combination of generic and specialised survey tools by telephone interview could be adopted to minimise costs.

Time to follow-up also varied among respondents and between registries. A common timeframe reported was at 1, 2, and 5 years post injury and then every 5 years thereafter. These time points are consistent with the Rick Hansen Spinal Cord Injury Registry. The data item review working party should also identify appropriate long-term follow-up time points. Based on the work undertaken for this scoping study, the recommendations for the dataset development are as follows.

Recommendations:

i. Formation of a working party to revise the minimum dataset. The working party should include representatives from each SIU, a database specialist (to streamline database changes and compatibility), clinical quality registry methodological expertise, and regional representation. Consideration should also be given to including international representation on this working party to improve the potential for international comparison and benchmarking.

ii. Develop a revised data collection form, data dictionary and documentation supporting a standardised approach to data collection methodology.
iii. Establish a training protocol for the collection of the revised minimum dataset using flexible approaches to accommodate the geographical challenges of the ASCIR (e.g. online tutorials, teleconferencing, etc.).

Ethics & privacy:

Four options for consent were identified from the interview process and these included:

1. Informed consent (opt-in) with additional consent for other future registry roles: The opt-in consent was the most consistent model across all registries although the level of consent varied according to the scope and nature of the registry. This model is used by the Rick Hansen Spinal Cord Injury Registry whereby individuals provide consent for the level of information or involvement they wish to contribute to the registry. In this model, a patient would consent to various levels of commitment including primary identification and case registration details; to receive information; to allow for data to be used; to be involved in research; and to be followed-up. This model allows the individual to specify the level of involvement they wish to have with registry functions.

2. Informed consent (opt-in) to participate in the initial episode registry data collection only: This model is a variation of the previous, where a patient provides consent for inclusion onto the registry but opts-out of any further contact by the registry for follow-up or research purposes. The benefits and limitations are comparable to those identified for Option 1.

3. Opt-off consent where data is de-identified but re-identifiable at the source: This model relies on the transmission of de-identified data to the central database with the patient identifiers maintained by the individual units.

4. Opt-off consent for the provision of all identifiable data to data custodian: This approach allows the data custodian to monitor all aspects of the registry, easily identify cases across multiple data sources, prevent duplication of cases and allow enhanced auditing of the data.

The benefits and limitations of each informed consent option are outlined in Table 3. All national and international registries/databases use the informed consent (Opt-in) model to various degrees. While less than 10% of SCID cases (4 out of 50 patients) did not provide consent in the previous year, it is possible that the cases declining inclusion systematically differ to those who do consent. Complete case capture is required for clinical quality registries to ensure the data are representative of all eligible cases. Given the problems with availability of staff to consent cases and collect data expressed by several centres, an opt-in approach will increase the resources required to maintain the registry and increase the risk of incomplete case capture.

Table 3: Befits and limitations of each informed consent option identified through the scoping interviews of key stakeholders.

Informed Consent Option	Benefits	Limitations
Opt-in with additional consent for future registry roles. Opt-in to participate in initial episode registry collection only.	- Allows easy transfer of patient level data across borders. - Provides traceable information on patients using multiple data sources. - Conduct an extensive data collection interview at time of consenting if required.	- Complete case identification may not be achievable (i.e. limits participation). - Introduction of selection bias into the registry. - Time to consent patients and collect data. - Individual research projects will still require ethical review of consent processes.
Opt-off consent where data is de-identified but re-identifiable at source	- Complete case identification.	- Increased workload for local site data collectors/managers. - May impact on the ability to link to other data sources.
Opt-off consent for the provision of all identifiable data to data custodian	- Complete identification of cases is achieved through this model. - Reduces administrative demands. - Allows data collection for patients who die or are discharged prior to consenting. - Level of information provided to patients can be adapted to include additional registry functions.	- Perceived issues with privacy and information disclosure.

The consent and registration of patients is a fundamental issue in the development of the ASCIR. Based on the results of this scoping study, the recommendations for the ASCIR are as follows.

Recommendations:

i. ASCIR should adopt an opt-off method of consent (Option 4 from Table 3) to ensure complete case capture, minimise the potential for selection bias, and reduce administrative demands.
ii. Research sub-projects should seek individual ethics approvals as linked projects. While there is provision in the NHMRC National Statement on Ethical Conduct in Human Research for "unspecified" consent, the specific ethical issues for each project will need to be reviewed on a case-by-case basis.

Technical Standards:

Data collated from the three methods used in this project and from the technical briefing report strongly support a move to a central secure database with a web interface. The adoption of the complete ACSQHC technical standards recommendations is complex and costly, especially when paired with the perceived requirement of data collectors at each site. Another option, suggested in the interview phase, was to identify cheaper data storage and interface options, however this option may have data security issues related to "best practice" and limit the potential to interface with the national e-health record when it commences.

Implementation of a secure database with web interface for data entry at the site level will allow for:

1. Direct entry of data potentially reducing the requirement for registry resources at site and centrally.
2. Electronic transfer from sites with their own databases minimising data handling and data entry resource usage centrally.
3. The potential to utilise electronic extraction of data items held in hospital administration systems which could be uploaded to the ASCIR on a regular basis – reducing data collection resource and also improve registry efficiency.

4. The electronic transfer or linkage of data to ASCIR for those with their own site-specific databases to minimise resource, decrease data handling and improve data validity.

The options available to the ASCIR include; a "custom build" of a secure database with a web interface that complies with the ACSQHC's Technical Standards, the use of a commercial database product, or uptake of an existing database such as the Rick Hansen Spinal Cord Injury Registry database. The latter would involve international transfer and storage of data and would require consultation with ethics committees and legal representatives before considering this option. Commercial database products are often less expensive than a custom-built database in the short term but are less flexible with respect to database changes, expensive to modify, and may not meet the detailed needs of the ASCIR. A custom-built database will ensure the needs of the registry users and stakeholders are met, the Technical Standards and adhered to, compliance with the developing E-Health agenda incorporated, and will allow the database to be built with international and state-based registry connectivity in mind. Finalisation of the revised minimum dataset will be necessary to inform the best approach to database development and estimated cost options will be provided in the Phase II report of this scoping study.

Recommendations:

i. Implementation of a secure database with web interface for data entry at site level.
ii. Design system interfaces to allow data transfer from existing databases, and compatibility with other relevant registries.
iii. Identify data quality assurance processes and build data audit and quality checks into the system to support the quality assurance protocols.

Funding:

Funding has been identified as a problem facing the ASCIR. Funding of the ASCIR should incorporate models based on expanded data collection procedures, the utilisation of a web-based system and a larger eligible population of cases. Funding models will be addressed in the Phase II report.

Conclusion:

This review has provided an overview of the current SCI registry as it compares to other national and international registries/databases, its alignment with the operating principles designated by ACSQHC, and feedback provided by key stakeholders from the SCI community. Recommendations for the necessary steps to progress the ASCIR from an epidemiological registry to a clinical quality registry are made. It is clear that the revised ASCIR will require significant "buy-in" from all key stakeholder groups including specialist SIUs, researchers and funding bodies. ASCIR requires the development of a web-based registry, incorporating individual patient level data submission and data linkages with external systems. A review of data items and then mapping to the best available data source is required. This scoping study has also identified the underlying issues that require resolution by the SCI registry stakeholders before the recommendations can be fully implemented.

REFERENCES

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APPENDICES

Appendix 1: Implementation timeline

Recommendation	0-3 months	3-6 months	6-9 months	9-12 months	12-18 months	18-24 months
Governance Structure and Custodianship:						
i. A revised governance structure is required including representation from clinicians (medical and allied health), researchers and associated peak bodies (e.g. SCIN) ensuring appropriate regional representation and the appointment of an independent chairperson.						
ii. Establish an appropriately constituted Steering Committee to oversee the governance of the ASCIR, including the development of strategic direction and ensuring deliverables are met for the registry and funding bodies.						
iii. Convene an appropriately constituted Management Committee to manage day-to-day aspects of the registry and ensure data quality measures are reported regularly.						
iv. Terms of Reference for the Steering Committee and Management Committee need to be developed, including meeting schedules and membership policies.						
v. The data access policy needs to be reviewed and updated as necessary.						
vi. Identify data reporting procedures including peer review processes, feedback to SIUs and dissemination of findings to the wider public.						
vii. Provide a detailed and agreed policy on the use of the registry for research purposes and the publishing of data through peer-reviewed publications.						
Case Identification:						
viii. The ASCIR capture only adult traumatic SCI cases until the issues with case identification of paediatric and non-traumatic cases are resolved.						
ix. A non-traumatic SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group.						
x. A paediatric SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group.						

Data Items:

xi. Formation of a working party to revise the minimum dataset. The working party should include representatives from each SIU, a database specialist (to streamline database changes and compatibility), clinical quality registry methodological expertise, and regional representation. Consideration should also be given to including international representation on this working party to improve the potential for international comparison and benchmarking.

xii. Develop a revised data collection form, data dictionary and documentation supporting a standardised approach to data collection methodology.

xiii. Establish a training protocol for the collection of the revised minimum dataset using flexible approaches to accommodate the geographical challenges of the ASCIR (e.g. online tutorials, teleconferencing, etc.).

Ethics and Privacy:

xiv. ASCIR should adopt an opt-off method of consent to ensure complete case capture, minimise the potential for selection bias, and reduce administrative demands. Research sub-projects should seek individual ethics approvals as linked projects. While there is provision in the NHMRC National Statement on Ethical Conduct in Human Research for "unspecified" consent, the specific ethical issues for each project will need to be reviewed on a case-by-case basis.

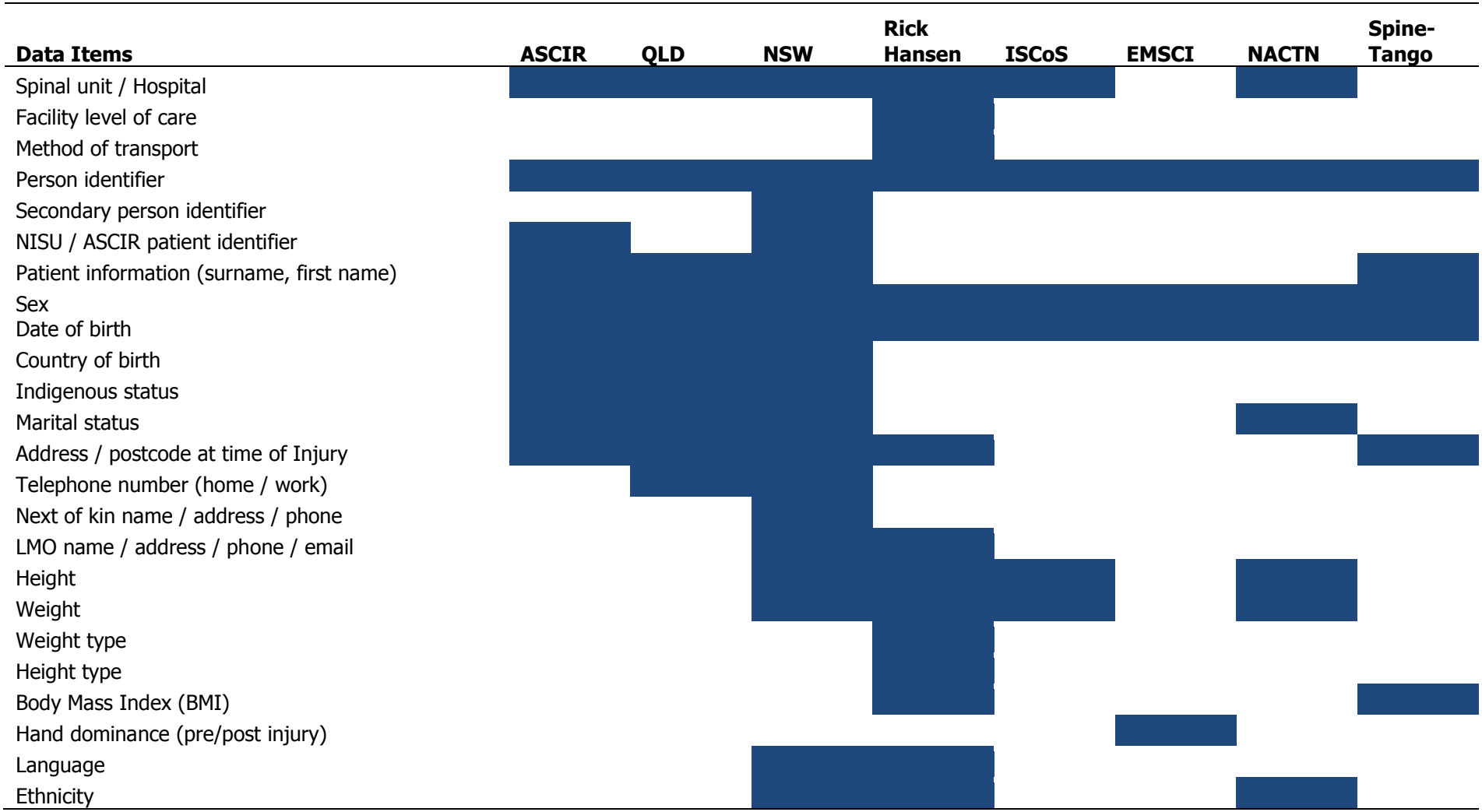
Technical Standards:

xv. Implementation of a secure database with web interface for data entry at site level.

xvi. Design system interfaces to allow data transfer from existing databases, and compatibility with other relevant registries.

xvii. Identify data quality assurance processes and build data audit and quality checks into the system to support the quality assurance protocols.

Appendix 2: Demographic data items



Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Spinal unit / Hospital	■	■	■	■	■		■	
Facility level of care				■				
Method of transport				■				
Person identifier	■	■	■	■	■	■	■	■
Secondary person identifier			■					
NISU / ASCIR patient identifier	■		■					
Patient information (surname, first name)	■	■	■					■
Sex	■	■	■	■	■	■	■	■
Date of birth	■	■	■	■	■	■	■	■
Country of birth	■	■	■					
Indigenous status	■	■	■					
Marital status	■	■	■				■	
Address / postcode at time of Injury	■	■	■	■				■
Telephone number (home / work)		■	■					
Next of kin name / address / phone			■					
LMO name / address / phone / email			■	■				
Height			■	■	■		■	
Weight			■	■	■		■	
Weight type				■				
Height type				■				
Body Mass Index (BMI)				■				■
Hand dominance (pre/post injury)						■		
Language			■	■				
Ethnicity			■	■			■	

Appendix 3: Socio-demographic data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Education level								
Employment status								
Occupation								
Compensable status (admission and discharge)								
Compensable type								
Income source								
Health fund								
Medicare Number / Social Security Number								
Household income								
Living arrangement								
Living setting								

Appendix 4: Admission data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Reason for this admission	■		■					■
Admission date	■	■		■	■		■	■
Admission time	■	■		■			■	
Spinal diagnoses on acute admission	■	■	■	■	■			
Referral date		■						
Referrers name / occupation / phone		■						
Referring institution or service		■	■					
Referral type		■						
Urgency		■						
Referral region		■						
Admission delay		■						
Admission registered as			■	■				
Hospital ward details			■	■				■

Appendix 5: Medical history data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Additional diagnoses / associated injury / comorbidity	■	■		■	■	■	■	■
Allergies			■					
Drug use			■	■			■	
Previous laminectomy, detail				■				■
Previous fusion, detail				■				■
Neurological level of pre-existing SCI				■				
ASIA Impairment scale of pre-existing SCI				■				
Family history of cardiovascular disease, Specify					■			

Appendix 6: Injury data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Main external cause A	■	■	■	■	■	■	■	■
Main external cause B - Intent	■		■					
Place of injury occurrence - sub-type	■	■	■					
Activity when injured - type	■	■	■					
Date of injury	■	■	■	■	■		■	
Time of injury	■	■	■	■			■	
Time of evacuation from injury site							■	
Traumatic SCI event - narrative	■	■	■					
Transferred to this hospital from							■	
Transport related injury items	■							
Address / postcode where injury occurred	■	■		■				
Penetrating / blunt injury	■				■		■	
Single or multiple level spinal column injury(ies)					■			
Disc and posterior ligamentous complex injury					■			
Traumatic translation					■			
Alcohol involved, BAC level	■	■	■		■			
Drugs involved		■	■					
Traumatic / non-traumatic			■					
Brain injury			■					
Mechanism: energy				■				
Injury work related				■				

Appendix 7: Assessment data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Limitations in activities (ICF classification)				■				■
Patient Classification (magnitude of symptoms)				■				
Functional assessment measure (FIM) at admission	■	■	■	■				
Date of functional assessment measure (FIM)	■	■	■				■	
Functional assessment measure (FIM) at discharge	■	■	■	■	■	■	■	
ASIA impairment scale	■	■	■	■	■	■	■	
ASIA evaluator				■			■	
ASIA Motor Index scores (Left / Right)	■			■		■	■	
Voluntary anal contraction		■		■			■	
Bulbocavernosis reflex status				■		■	■	
Cauda Equina syndrome / other neurological deficit				■			■	
Neurological deficit on discharge	■	■						
Primary means of mobility		■					■	
Neuroprofile on admission		■						
Barthel score on admission		■						
Sensory score / function		■		■	■	■	■	
Motor score / function		■		■	■	■	■	
Zones of Partial Preservation (ZPPS)	■	■	■				■	
Date of neurological examination					■			
General quality of life					■			
Rating of physical health					■	■		
Satisfaction with psychological health					■			
AIS (by anatomical grouping)				■			■	
Injury Severity Score				■				
SF-36 (by component and PCS/MCS)				■				

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
LISAT-11								
SF-Craig Hospital Inventory of Environmental Factors (CHIEF)								
SCI Health Questionnaire								
SCIM evaluation								
WISCI II								
Is the patient on paralytics								
Is the patient sedated								
6 Minute Walk Test (6MWT) (abort / time / distance)								
10 Metre Walk Test (10MWT) (max / assist)								
Timed Up and Go								
Hand Function								
Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)								
Motor Evoked Potential (MEP)								
Oswestry Low Back Pain Disability Index 2.1								
EuroQol ED-5D								
Somatosensory Evoked Potentials (SSEP)								
Nerve Conduction Velocity (NCV)								

Appendix 8: Diagnosis data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Principal diagnosis	■	■					■	■
Sacral sparing		■	■					
Vertebral injury					■		■	
Neurological level				■		■	■	■
Type of spine diagnosis (Prim / Sec / Tertiary)				■				
Spine diagnosis: Location general / detail				■			■	■
Imaging, date, time and detail							■	

Appendix 9: Bowel and cardiovascular data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Bowel: 36 data items relating to bowel function					■			
Bowel: Position for bowel care						■		
Cardiac pacemaker (Pre Injury / Post Injury)					■		■	
Cardiac pacemaker date (Pre Injury / Post Injury)					■		■	
Cardiac surgery , Specify					■		■	
Cardiac surgery date					■		■	
Other cardiac disorders, Specify					■		■	
Hypertension					■			
Hypotension					■		■	
Orthostatic hypotension					■			
Deep vein thrombosis (Pre Injury / Post Injury)		■			■		■	
Deep vein thrombosis date (Pre Injury / Post Injury)					■		■	
Neuropathy					■			
Diabetes					■			
Hyperlipidemia					■			
Myocardial infarction (Pre Injury / Post Injury)					■			
Myocardial infarction date (Pre Injury / Post Injury)					■			
Stroke (Pre Injury / Post Injury)					■			
Stroke date (Pre Injury / Post Injury)					■			
Other, Specify (Pre Injury / Post Injury)					■		■	
Other events date (Pre Injury / Post Injury)					■		■	
Pulmonary embolism		■			■			
Dependent oedema					■			
Autonomic dysreflexia		■			■			

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Anticholinergics								
Antihypertensives								
Antihypotensives								
Cardiac medications								
Other medications, specify								
Fasting Serum Lipid Profile within the last year: During anti-lipid therapy?								
Fasting Serum Lipid Profile within the last year: Total cholesterol, Triglycerides, HDL & LDL cholesterol								

Appendix 10: Endocrine, Fertility and Pulmonary data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Endocrine: 18 Data items related to endocrine function								
Fertility: 8 Data items relating to fertitlity								
Pulmonary conditions present before spinal cord lesion-Asthma								
Pulmonary conditions present before spinal cord lesion-Chronic obstructive pulmonary disease (COPD)								
Pulmonary conditions present before spinal cord lesion-Sleep apnea								
Pulmonary conditions present before spinal cord lesion-Other								
Pulmonary conditions present before spinal cord lesion-Other, Specify								
Smoking history (current or past)								
If a former smoker, which year did you quit smoking?								
If a former or current smoker, for how many years did (have) you smoked?								
If a former or current smoker, on average how many cigarettes do (did) you smoke on a daily basis?								
If a former or current smoker, on average how many cigars do (did) you smoke on a daily basis?								
If a former or current smoker, on average how many pipe bowls do (did) you smoke on a daily basis?								
For former or current cigarette smokers only, the number of pack-years of smoking								
[(average number smoked daily)/ 20] x (number of years smoked)= __ pack-years								
Pulmonary complications and conditions after the spinal cord lesion within the last year - Pneumonia								

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Pneumonia - number of episodes treated with antibiotics								
Pneumonia - number of episodes requiring hospitalization								
Pulmonary complications and conditions after the spinal cord lesion within the last year - Asthma								
Pulmonary complications and conditions after the spinal cord lesion within the last year - COPD								
Pulmonary complications and conditions after the spinal cord lesion within the last year - Sleep Apnea								
Pulmonary complications and conditions after the spinal cord lesion within the last year - Other								
Mechanical Ventilation: Invasive / non-invasive								
Current Utilization of Ventilatory Assistance - Diaphragmatic pacing								
Diaphragmatic pacing: Date inserted								
Current Utilization of Ventilatory Assistance - Phrenic nerve stimulation								
Phrenic nerve stimulation: Date inserted								
Current Utilization of Ventilatory Assistance - Bi-level Positive Airway Pressure (BiPAP)								
BiPAP: Date commenced								
Current Utilization of Ventilatory Assistance - Other								
Current Utilization of Ventilatory Assistance - Other, specify								
Pulmonary Function Tests - Forced vital capacity (FVC)								
Pulmonary Function Tests - Forced expiratory volume in one second								
Pulmonary Function Tests - Peak expiratory flow (PEF)								
Respiratory: Arterial Blood Gases								
Respiratory: Independent breathing time								

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Respiratory: Neck circumference								
Respiratory: Overnight oximetry readings, min, mean, % time < 90%								
Respiratory: CPAP, value								

Appendix 11: Urological data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Bladder management method								
Urological status								
Urological: Test date								
Urological: Test type								
Urological: Test complications								
Urological: Next review date								
Urological: Next test type								
Urological: Urinary tract impairment related to SCI								
Urological: Awareness of the need to empty bladder								
Urological: Main bladder emptying method								
Urological: Other bladder emptying method								
Urological: Av. Number of voluntary bladder emptying during last week								
Urological: Any involuntary urine leakage within the last three months								
Urological: Collecting appliances for urinary incontinence								
Urological: Drugs for the urinary tract within the last year								
Urological: Surgical procedures on the urinary tract								
Urological: Any changes in urinary symptoms within the last year								
Prostate Specific Antigen (date)								
Prostate Histopathology								
Prostate Gleason 1, 2 and Sum								
Urodynamic: Bladder sensation during cystometry								
Urodynamic: Detrusor function								
Urodynamic: Bladder compliance during filling cystometry								

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Urodynamic: Urethral function during voiding								
Urodynamic: Detrusor leak point pressure during filling cystometry								
Urodynamic: Maximum detrusor pressure during filling cystometry								
Urodynamic: Cystometric bladder capacity during filling cystometry								
Urodunamic: Post void residual volume								
Urinary imaging: Method used								
Urinary imaging: Imaging findings								

Appendix 12: Pain data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Medications: NSAID, AntiDepres, AntiEpileptic, Opiods, AntiSpasmodics						■		■
Have you had any pain during the last seven days including today?					■			
If yes, how many different pain problems did you have?					■	■		
Pain problem: worst, second worst or third worst (Select Sites)				■	■	■		
Type of pain - Nociceptive		■		■	■	■		
Type of pain - Neuropathic		■		■	■	■		
Pain intensity now						■		
Methods for acheiving pain relief						■		
Average pain intensity in the last week				■	■	■		
Date of onset for pain					■			
Number of days with pain in the last seven days including today					■			
How long does your pain usually last?					■			
When during the day is the pain most intense?					■			
How much do you limit your activities in order to keep your pain from getting worse?					■			
How much has your pain changed your ability to take part in recreational and other social activities?					■			
How much has your pain changed the amount of satisfaction or enjoyment you get from family-related activities?					■			
In general, how much has pain interfered with your day-to-day activities in the last week?				■	■			
In general, how much has pain interfered with your overall mood in the past week?					■			

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
In general, how much has pain interfered with your ability to get a good night's sleep?								
Are you using or receiving any Treatment for your pain problem?								
Pre-exisiting pain? (nature)								
Description of pain								

Appendix 13: Sexual and physiological measure data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Sexual: 11 questions relating to sexual functioning					■			
Objective Measures: Time performed					■		■	
Objective Measures: Position during testing					■			
Objective Measures: Devices in use during testing - Abdominal binder					■			
Objective Measures: Devices in use during testing - Pressure stockings					■			
Objective Measures: Pulse (bpm)					■		■	
Objective Measures: Evaluation of Pulse					■			
Objective Measures: Blood pressure systolic				■	■		■	
Objective Measures: Blood pressure diastolic					■		■	
Objective Measures: Unassisted respiratory rate				■				
Glasgow Coma Scale (Field, Facility)				■			■	
Temperature on arrival							■	

Appendix 14: Procedure data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Therapeutic goals								
Complications during surgery / episode of care								
Operations / Surgery								
Utilisation of ventilator assistance								
Methylprednisolone / Corticosteroids								
Operation date / time								
Spinal surgical progression								
Was the sugery done in stages								
Spine procedures: location general / detail								
Spine procedures: Type of intubation								
Spine procedures: Estimated blood loss								
Spine procedures: Decompression of neural elements date / time								
Spine procedures: Surgeon								
Spine procedures: Type of anaesthetic								
Spine procedures: Type of approach								
Spine procedures: Operative type, code, description								
Spine procedures: Procedure notes								
Interventions: Skeletal traction								
Interventions: Detailed variables related to traction								
Interventions: Outcome of attempted reduction								
Interventions: Date / time reduction achieved								
Interventions: Intubation > 24 hours								
Interventions: Tracheostomy								
Interventions: Nutrition tube feeds								
Interventions: Spine surgery in non-participating facility								
Interventions: Equipment								

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Interventions: Health services other				■				■
TURP (Yes/No, Date, Histo)						■		
prostatectomy (Yes/No, Date, Histo, Gleason 1,2 and Sum)						■		
Intubation code				■			■	
Therapist credentials				■			■	■

Appendix 15: Discharge and reporting data items

Data Items	ASCIR	QLD	NSW	Rick Hansen	ISCoS	EMSCI	NACTN	Spine-Tango
Therapeutic goals achieved				■			■	■
Mode of separation	■	■		■	■		■	■
Discharge date (and / or time)	■	■		■	■		■	■
Was the spinal cord decompressed during acute care							■	
Was decompression confirmed by radiology							■	
Acute discharge support services organised		■		■			■	
Mobility outcome		■						
Deceased		■	■				■	
Death date		■	■				■	
Cause of death		■					■	
Was an autopsy performed							■	
Total days hospitalised for acute care / rehabilitation				■	■			■
Annual report category	■	■						
Consent	■	■	■	■			■	