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Discussion Paper

International Spinal Cord Injury Core Data Set

M DeVivo[1], F Biering-Sørensen*[,2], S Charlifue[3], V Noonan[4], M Post[5], T Stripling[6] and P Wing[4] Executive Committee for the International SCI Data Sets Committees

[1]*Department of Physical Medicine and Rehabilitation, University of Alabama at Birmingham, Birmingham, AL, USA;* [2]*Clinic for Spinal Cord Injuries, Neuroscience Centre, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark;* [3]*Craig Hospital, Englewood, CO, USA;* [4]*Division of Spine, University of British Columbia, Vancouver, British Columbia, Canada;* [5]*Rehabilitation Centre De Hoogstraat and Rudolf Magnus Institute for Neuroscience, Utrecht, The Netherlands;* [6]*Paralyzed Veterans of America, Washington, DC, USA*

Study design: Survey of expert opinion, feedback, and development of final consensus.
Objective: Present the background, purpose, development process, and results for the International Spinal Cord Injury (SCI) Core Data Set.
Setting: International.
Methods: A committee of experts was established to select and define data elements to be included in an International SCI Core Data Set. A draft core data set was developed and disseminated to appropriate organisations for comment. All suggested revisions were considered, and a final version of the core data set was disseminated again for approval and adoption.
Results: The core data set consists of 24 variables, including basic demographic characteristics, dates of admission and discharge from initial acute and rehabilitation care, cause of injury, place of discharge, presence of vertebral fractures and associated injuries, occurrence of spinal surgery, and measures of neurological and ventilator status.
Conclusion: Collection of the core data set should be a basic ingredient of all future studies of SCI to facilitate accurate description of patient populations and comparison of results across published studies from around the world.
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Introduction

The purpose of the International Spinal Cord Injury (SCI) Core Data Set is to standardise the collection and reporting of minimal information necessary to describe a study population that would allow meaningful comparison of study results and assessment of study population representativeness and potential bias. This paper describes the background, purpose, development, and results of the International SCI Core Data Set, and provides suggestions for standardising the reporting of this minimal information in each published study.

Methods

An international working group was established to select and define data elements to be included in the International SCI Core Data Set.[1] The working group began by identifying minimal descriptive characteristics that would be worthwhile to know about any SCI study population. Priority was given to minimising the burden of data collection and ensuring that required data would be both meaningful and obtainable in diverse geographic and cultural environments. Once minimum data items were identified, the working group began drafting a syllabus that would include definitions, coding schemes, and instructions on how to collect each data item. The format and initial draft of the syllabus were based on the syllabus used successfully for many years by the Model SCI Systems in the United States.[2–5] The most current version of the Model SCI Systems data collection syllabus can be found at http://www.spinalcord.uab.edu/show.asp?durki=24480&site=1287&return=19775.[6–7] Review and revision of the draft core data set syllabus was accomplished through an iterative e-mail process and a series of executive

*Correspondence: F Biering-Sørensen, Clinic for Spinal Cord Injuries, Neuroscience Centre, Rigshospitalet, TH2091, Copenhagen University Hospital, Blegdamsvej 9, 25 Havnevej, DK-3100 Copenhagen, Denmark

committee telephone conference calls and open meetings.

Once completed, the draft core data set syllabus and background information were sent to numerous international professional organisations for review and comment in a manner similar to that used by the Paralyzed Veterans of America to develop SCI Clinical Practice Guidelines (http://www.pva.org/cgi-bin/pvastore/products.cgi?id = 1). Many comments were received. All comments were reviewed by the executive committee at an open meeting in Athens, Greece on 26 September 2004. A written response to each comment was prepared and the syllabus was revised as needed. The final draft of the syllabus was then approved by the executive committee and redistributed to all professional organisations along with a formal response to all comments. Each organisation was then asked to consider officially endorsing the core data set and begin promoting its use.

Results – the International SCI Core Data Set

It was agreed that the core data set should include information describing the age and gender of each study participant, the cause of the SCI, the time frame during which the injuries occurred, the length of hospital stay in acute care and rehabilitation, the place of discharge, whether a bony vertebral injury occurred, whether spinal surgery was performed, the presence of significant associated injuries, and the severity of SCI. For long-term cross-sectional or follow-up studies, additional necessary information would include the length of time postinjury and the dates during which the study was conducted. This information should be provided in either table or text format for the overall study population and for each study group.

A draft data collection form for the core data set appears as Appendix A. The following is a brief description of each of the data items contained in the core data set as well as the rationale for inclusion of each item. The complete data collection syllabus can be found at the web sites of ISCoS (www.iscos.org.uk) and American Spinal Injury Association (ASIA) (www.asia-spinalinjury.org).

Date of birth
Information on the age of study participants is critical to interpreting results and comparing results across studies. Collecting information on the date of birth is the most precise way to gather and store this information, because it allows for easy computation of age at injury as well as age at any future point in time when data might be collected. Conversely, if data were collected only reflecting age at injury, then subsequent age when outcomes are measured might be inaccurate by as much as 1 year. Knowing age precisely might be particularly important in studies of pediatric SCI where rapid maturation occurs. Information on date of birth is typically easy to collect and more reliable than current age or age at injury as it is usually documented on the hospital admission form.

Date of injury
Information on date of injury of study participants is also critical to understanding study results. This can be used to assess time postinjury for outcome measurement and is also useful for documentation of the calendar time frame of the study, as study results are often published long after the studies are conducted. Information on date of injury is typically easy to collect as it is usually documented in the initial history and physical report of the emergency room or hospital admitting physician.

Dates of first acute care hospital admission and final in-patient rehabilitation discharge
These dates should be collected in order to document the number of days between injury and admission to the hospital (and hence any delay in treatment that might have occurred) as well as the total amount of time from injury until completion of inpatient rehabilitation. Again, these dates should be readily available from the hospital admission and discharge forms or the admission and discharge notes written by the physician.

Total days hospitalised between injury and final inpatient rehabilitation discharge
Because patients may be discharged home between phases of care, or their initial care may have been delayed, it may not be possible to subtract the final date of discharge from the initial admission date to determine overall hospital length of stay. Therefore, the length of stay should be recorded separately by adding together the number of days spent in each hospital. This information should be obtained by examining the admission and discharge forms from each hospital. More detailed information on the dates of admission and discharge from each treatment phase and length of stay for acute care *versus* rehabilitation or other types of care may be included in a separate International SCI Data Set module to be collected for studies focused on those topics, but is not of sufficient routine importance to be included in the core data set.

Gender
Gender is an important study population descriptor, and most health outcomes are associated with gender. Therefore, this information should be provided in all published studies so that representativeness can be assessed and outcomes appropriately compared.

Aetiology of injury
Documenting the cause of SCI is worthwhile descriptive information for inclusion in reports of study results, both to assist in assessing study population

representativeness and because previous studies have documented health and social outcomes are often different for patients who have different causes of injury.[8–12] Therefore, this information is a necessary ingredient of any comparison of results across studies.

Many approaches to describing cause of injury have been used. For most studies, an approach that groups causes into a few categories will be sufficient. Therefore, the core data set requires only that causes be grouped into one of the following categories:

- sports and leisure activities,
- assaults,
- transport activities,
- falls,
- other traumatic causes,
- nontraumatic causes, and
- unknown.

Cause of injury should be obtainable from the hospital admission form or the history and physical written by the admitting physician. Reducing the number of categories to six should increase the reliability of cause of injury documentation. Because some overlap can occur in these categories, they have been ranked in order of priority as cited above from sports to nontraumatic. Therefore, if a patient falls from a horse while engaging in sports or leisure activity, the cause of injury would be documented as sports-related.

An additional International SCI Data Set module will be developed to provide guidelines for collecting more specific information on causes of injury and circumstances surrounding the injury that would be useful for studies of primary injury prevention. This module will likely be based on the multiaxial International Classification of External Causes of Injuries (ICECI). Details of the ICECI can be found at www.iceci.org.

Vertebral injury

Information on whether there was a spinal fracture and/or dislocation associated with the SCI is important because methods of treatment, length of stay, and treatment outcomes are typically related to the presence or absence of a concomitant vertebral column injury. Vertebral column injury is defined as any break, rupture, or crack through or between any part(s) of the vertebral column from the occiput to the coccyx, and is coded in the International SCI Core Data Set as follows:

- No (absent).
- Yes (present).
- Unknown.

A more detailed module on bony vertebral injury classification is being developed; however, for most studies, documenting whether there was a vertebral column injury should be sufficient to assess population representativeness and compare study results.

Spinal surgery

Information on whether spinal surgery was performed is useful for comparing study populations and treatment outcomes. Five common procedures are most important to document: laminectomy, neural canal restoration, reduction, spinal fusion, and internal fixation of the spine. For most studies, other than studies of types of spinal fractures, surgical interventions, and outcomes, it will only be necessary to document whether any of these procedures took place without specifying which procedures or how many procedures actually occurred. Therefore, for the International SCI Core Data Set, spinal surgery is classified as follows:

- No – none of these five procedures occurred.
- Yes – at least one of these five procedures occurred.
- Unknown.

Although other spinal or nonspinal surgeries might occur, limiting and standardising the description of spinal surgery to these five most common and important procedures should enhance reliability and facilitate comparisons of results. A module with detailed surgical information is being developed for studies where additional information is needed.

Laminectomy is defined as removal of normal intact lamina or foreign body at the site of spinal cord damage. Neural canal restoration is defined as the removal of bone or disk fragments, blood clots, or foreign bodies (such as bullet fragments) from the spinal canal. Reduction is defined as replacement of at least one dislocated, subluxed, or angulated vertebra into anatomic or near-anatomic alignment. Spinal fusion is defined as the addition of a bone graft to the vertebrae for the purpose of achieving intervertebral fusion or stability. Internal fixation of the spine is defined as attaching rods, plates, wires, etc to the spine (individually or in combination) to provide internal surgical stabilisation of the vertebral column. These procedures may be performed separately or in combination during a single operating room visit.

Associated injury

Information on other severe injuries that occur at the same time as the SCI is important because methods of treatment, length of stay, and treatment outcomes are typically related to the presence or absence of associated injuries.[13] This information is also important in assessing the comparability and representativeness of study populations.

The following associated injuries should be documented: moderate to severe traumatic brain injury (Glasgow Coma Scale of 12 or below at the time of final inpatient discharge), nonvertebral fractures requiring surgery, severe facial injuries affecting sense organs, major chest injury requiring chest tube or mechanical ventilation, traumatic amputations of an arm or leg (or injuries severe enough to require surgical amputation), severe haemorrhaging, or damage to any internal organ

requiring surgery. Injuries that pre-date the SCI should not be included.

For most studies other than those of injury aetiologies and associated injuries themselves, it will only be necessary to report whether any of these associated injuries took place without specifying which injuries or how many injuries occurred. Therefore, in the International SCI Core Data Set, associated injuries are classified as follows:

- No – none of the designated associated injuries occurred.
- Yes – at least one of the designated associated injuries occurred.
- Unknown.

Although other injuries might occur, limiting and standardising the description of associated injuries to these most common and important injuries should enhance reliability and facilitate comparisons across studies. A module with detailed associated injury information may be developed for studies where additional information is needed.

Ventilatory assistance

Another important injury severity measure is the need for ventilatory assistance. Ventilator-dependent patients have different methods of treatment, lengths of stay, and treatment outcomes compared to other persons with SCI.[14–16] Therefore, this information is very important for assessing study representativeness and comparing study results.

The International SCI Core Data Set requires documenting and reporting the use of any type of ventilatory assistance to sustain respiration on the date of final inpatient discharge. Use of ventilatory assistance during hospital stay but with successful weaning is not included in the reporting guidelines. A distinction should be made between 24 h/day and less than 24 h/day ventilator dependency. Therefore, in the International SCI Core Data Set, ventilatory assistance is categorised as follows:

- No.
- Yes – less than 24 h/day at discharge.
- Yes – 24 h/day at discharge.
- Yes – unknown number of hours per day at discharge.
- Unknown.

Ventilatory assistance includes but is not limited to mechanical ventilators, phrenic nerve stimulators, external negative pressure devices, and bilevel positive airway pressure. For purposes of these reporting guidelines, it does not include routine administration of oxygen, periodic intermittent positive pressure breathing administration, or continuous positive airway pressure.

Place of discharge

Information on either place of discharge or place of current residence should be provided for all studies. For studies and data collection that occur after discharge, current residence will likely be the more relevant factor, and could be similarly described. Places of residence to be distinguished include:

- private residence,
- hospital,
- nursing home,
- assisted living,
- group living,
- correctional institution,
- hotel,
- homeless,
- deceased,
- other unclassified, and
- unknown.

More complete definitions of each of these categories can be found in the core data set syllabus. These categories have been used reliably with slight modification for over 30 years in the USA Model SCI Systems database. This information is necessary because study results will typically differ by study setting or place of discharge.[9,17]

If the patient dies during hospitalisation prior to discharge, then the place of discharge would be coded as deceased, and the date of discharge cited above would reflect the date of death. This combination would allow studies of case fatality rates.

Neurological status

Information on injury severity is critical to understanding the representativeness of the study population, interpreting results, and comparing results across studies. Because neurologic status usually changes during the first few months postinjury, the date of neurologic exam should be documented so that time postinjury can be reported. For most studies, neurologic status should be reported either at initial acute care hospital examination or at discharge from the last inpatient hospital. Exams should be performed within 72 h of admission or discharge whenever possible. The neurologic exam should be performed by a physician or an appropriately trained designated person in accordance with the most current version of the International Standards for Neurological Classification.[18]

Minimal information necessary to document neurologic status is the sensory and motor level on each side of the body and the ASIA Impairment Scale. The sensory level is defined as the most caudal segment of the spinal cord with normal sensory function for both pinprick and light touch on both sides of the body. The motor level is defined by the lowest key muscle bilaterally that has a grade of at least 3, provided the key muscles represented by segments above that level are judged to be normal (grade 5). Neurologic level of injury is then defined as the most caudal segment of the spinal cord with both normal sensory and motor function, that

is, the most cranial of the sensory and motor levels. The ASIA Impairment Scale is described as either grade A, B, C, D, or E in accordance with the International Standards for Neurological Classification.[18]

It is usually helpful to stratify reported results by injury severity. Several standard strata have been used. One common approach is to report findings for four groups: (1) C1–C4 ASIA A, B, or C; (2) C5–C8 ASIA A, B, or C; (3) T1–S5 ASIA A, B, or C; and (4) ASIA D at any level. For studies with smaller sample sizes, groups 1 and 2 above are sometimes combined. An alternative approach is to report findings for the following four groups: (1) C1–C8 ASIA A (complete tetraplegia); (2) C1–C8 ASIA B, C, or D (incomplete tetraplegia); (3) T1–S5 ASIA A (complete paraplegia); and (4) T1–S5 ASIA B, C, or D (incomplete paraplegia). For multivariate statistical models, each ASIA grade can be considered separately, and high levels of tetraplegia can be considered separately from lower levels of tetraplegia and paraplegia.

Discussion and conclusions

At minimum, published studies should include information on study population age at the time of injury, current age if different from age at injury, length of time after injury when data are collected, calendar time frame of the study, gender, causes of SCI, and neurologic status. Health service and treatment outcome studies should also contain information on total number of days hospitalised, whether a bony vertebral injury was present, whether spinal surgery was performed, whether associated injuries were present, whether patients were ventilator-dependent, and place of discharge from inpatient care. Inclusion of more detailed information will depend on the research topic.

Some studies may have eligibility or exclusionary criteria that limit participation, and if so, that should be specified. Typical inclusion and exclusion criteria will include some combination of age, gender, aetiology of injury, neurologic status, location, and time postinjury. Other criteria can include spine fracture, spine surgery, associated injuries, and ventilator status, all of which are included in the International SCI Core Data Set.

It is extremely important that data be collected in a uniform manner. For this reason, each variable and response category have been specifically defined in a way that is designed to promote the collection and reporting of comparable minimal data.

As an exact coding scheme for each category of each variable is not essential to the purpose of the International SCI Core Data Set, one is not described. However, a standard coding scheme (assignment of numeric values to responses) and format is essential for combining data from multiple investigators and locations. Therefore, in the syllabus for the International SCI Core Data Set located at www.iscos.org.uk or www.asia-spinalinjury.org, all variable responses have been given numeric or alphabetic codes that can be used consistently at all locations. The exact coding scheme is merely a suggestion, and other formats and coding schemes may be equally effective and could be used in individual studies or by agreement of the collaborating investigators.

Additional modules of the International SCI Data Set will be developed by panels of experts in each area of research. These modules will identify the most critical variables for specific topics of research and provide recommended standards for collecting and reporting of that information.

In addition to the data collection form and syllabus, an identical set of several training cases is posted on the ASIA and ISCoS web sites. Before using the International SCI Core Data Set, individuals should review each training case, complete a sample data collection form, and compare it with the correct results that are also posted. There is also a link on the web sites to e-mail any questions that users may have concerning the training cases or any other questions that may arise, or seek any other technical assistance.

Organisations that have endorsed the International SCI Core Data Set as of 1 January 2006 include the American Spinal Injury Association (USA), International Spinal Cord Society (United Kingdom), Paralyzed Veterans of America (USA), American Academy of Physical Medicine and Rehabilitation (USA), National Spinal Cord Injury Association (USA), American Association of Spinal Cord Injury Psychologists and Social Workers (USA), American Association of Spinal Cord Injury Nurses (USA), North American Spine Society (USA), Rick Hansen Man in Motion Foundation (Canada), Ontario Neurotrauma Foundation (Canada), International Collaboration on Repair Discoveries (Canada), Quadriplegic Association of South Africa (South Africa), American Congress of Rehabilitation Medicine (USA), American Association of Orthopedic Surgeons (USA), Christopher Reeve Foundation (USA) and International Society for Physical and Rehabilitation Medicine (Belgium) and American Paraplegic Society (USA). Other organisations are reviewing the International SCI Core Data Set and will render endorsement decisions in due course. The most current list of endorsing organisations can be found at www.iscos.org.uk; www.asia-spinalinjury.org.

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Appendix A

International SCI Core Data Set Data Collection Form

Dates (YYYYMMDD)					
Birth date			– – – –/– –/– –		
Injury date			– – – –/– –/– –		
Acute Admission			– – – –/– –/– –		
Final Inpatient Discharge			– – – –/– –/– –		
Total Days Hospitalised	– – – –				
Gender	—				
Injury Aetiology	—	Vertebral Injury	—	Associated Injury	—
Spinal Surgery	—	Ventilatory Assistance	—	Place of Discharge	—

Neurological Data

Acute Admission Date of Exam – – – –/– –/– –			**Final Inpatient Discharge** Date of Exam – – – –/– –/– –	
Sensory level			Sensory level	
Left	Right		Left	Right
– – –	– – –		– – –	– – –
Motor level			Motor level	
Left	Right		Left	Right
– – –	– – –		– – –	– – –
ASIA Impairment Scale			ASIA Impairment Scale	
—			—	