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ORIGINAL ARTICLE

International Spinal Cord Injury Core Data Set (version 2.0)—including standardization of reporting

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Study design: The study design includes expert opinion, feedback, revisions and final consensus.
Objectives: The objective of the study was to present the new knowledge obtained since the International Spinal Cord Injury (SCI) Core Data Set (Version 1.0) published in 2006, and describe the adjustments made in Version 2.0, including standardization of data reporting.
Setting: International.
Methods: Comments received from the SCI community were discussed in a working group (WG); suggestions from the WG were reviewed and revisions were made. All suggested revisions were considered, and a final version was circulated for final approval.
Results: The International SCI Core Data Set (Version 2.0) consists of 25 variables. Changes made to this version include the deletion of one variable 'Total Days Hospitalized' and addition of two variables 'Date of Rehabilitation Admission' and 'Date of Death.' The variable 'Injury Etiology' was extended with six non-traumatic categories, and corresponding 'Date of Injury' for non-traumatic cases, was defined as the date of first physician visit for symptoms related to spinal cord dysfunction. A category reflecting transgender was added. A response category was added to the variable on utilization of ventilatory assistance to document the use of continuous positive airway pressure for sleep apnea. Other clarifications were made to the text. The reporting of the pediatric SCI population was updated as age groups 0–5, 6–12, 13–14, 15–17 and 18–21.
Conclusion: Collection of the core data set should be a basic requirement of all studies of SCI to facilitate accurate descriptions 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 standardize the collection and reporting of a minimal amount of information necessary to evaluate and compare results of published studies.[1] Therefore, published studies should, at minimum, include information on the age of the study population at the time of injury, the current age of the study population if different from age at injury, the length of elapsed time after injury when data are being collected, the calendar time frame during which the study was conducted, the gender of the study population, the causes of spinal cord dysfunction and the neurologic status of the study population.[1]

The first version of the International SCI Core Data Set[1] has been the adopted standard for collecting and reporting minimal data on study population characteristics and has demonstrated its applicability globally.[2–9]

All International SCI Data Sets are scheduled to undergo periodic review and revision when new knowledge and experience is gained to ensure continued relevance, acceptance and usage by the SCI clinical and research community.[10]

The revisions agreed upon by consensus are summarized in this manuscript.

MATERIALS AND METHODS

Comments have been received from the SCI community since the International SCI Core Data Set was first published. In addition, in 2015, the International SCI Data Sets Committee solicited comments from various committees in the International Spinal Cord Society (ISCoS) and the American Spinal Injury Association (ASIA), other organizations and individuals known to be interested, as well as a call on the ISCoS and ASIA websites. Furthermore, the relevance for pediatric SCI was evaluated.[11]

The suggestions and comments received were reviewed by the working group (WG) for the International SCI Core Data Set. When reviewing proposed revisions, the WG weighed the potential benefits of the proposal against the loss of continuity resulting from any revision. Ultimately, the WG adopted several

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changes to the International SCI Core Data Set[1] and accompanying analytic and reporting standards.[12]

After revision, further review was performed by the International SCI Data Sets Committee, the Executive and Scientific Committees of ISCoS and the ASIA Board, as well as interested organizations and individuals via targeted e-mails and the data set revisions were posted on the ISCoS and ASIA websites for at least 1 month. During the process, further revisions were adopted by the WG for the International SCI Core Data Set.

RESULTS

See all the variables in Appendix A. Changes made in the International SCI Core Data Set 2.0 are described here.

Dates to be registered when relevant

The variable 'Total Days Hospitalized for Acute Care and Rehabilitation' was deleted from the Core Data Set.

Language was added to clarify the instructions for coding the date of injury. For non-traumatic cases, the date of injury should be coded as the approximate date of the first physician visit related to symptoms of spinal cord dysfunction.

Date of admission to rehabilitation was added at the request of several clinicians and researchers due to the importance of being able to distinguish events that occur during acute care from those occurring during rehabilitation. Acute management and rehabilitation occurs in separated places in most settings. Even when not separated, there is typically a date when the patient is considered to be transferred from the acute to the rehabilitation program.

On the date of final inpatient discharge, patients will typically be discharged home (with no further planned inpatient admissions) or discharged to a long-term care facility. Outpatient rehabilitation or a home rehabilitation program may continue after this date, or limited rehabilitation therapy may continue in the long-term care facility. If there is a planned interruption in the inpatient hospitalization and the patient is readmitted for further care, then the date of final inpatient discharge is the date of discharge after the planned readmission. An example of this would be a patient who is discharged home temporarily until she/he is ready for further rehabilitation and then is brought back to the hospital for completion of inpatient rehabilitation. The date of inpatient discharge is the last date of discharge with no further planned hospitalizations. Subsequent admissions and discharges for the treatment of unplanned secondary medical complications such as infections or pressure sores are not to be coded in this variable.

'Date of Death' was added as a new variable, as previously just the occurrence of death was recorded for the variable 'Place upon Discharge/Current Residence'.

Gender

A new category reflecting 'transgender and other related' was added to the 'gender' variable, in recognition of some people identifying as transgender, transsexual, intersex or other similar gender affiliation.[13,14]

Thus the response categories are:

- Male
- Female
- Transgender or other-related category
- Unknown

Spinal cord injury etiology

Several new responses were added to the 'etiology' variable to allow basic categorization of non-traumatic cases and to include pediatric causes of SCI.

This variable identifies the etiology of the SCI. SCI is impairment of the spinal cord or cauda equina function resulting from the application of an external force of any magnitude or a dysfunction or disease process.

For traumatic spinal cord injuries, this variable includes response categories adapted from the International Classification of External Causes of Injuries (www.iceci.org). Because it is possible that an injury event may be classifiable into more than one of these categories, the following prioritization has been established for the coding:[1]

1. Sports and leisure
2. Assault
3. Transport
4. Fall
5. Birth injury or other traumatic cause, specify

Register birth injuries or all other known (specified) or unknown traumatic causes as other traumatic cause whenever sports, assault, transport or fall do not apply. Provision has been made in the data set to specify the cause. Paralysis secondary to surgical procedures when the patient does not have a neurological deficit prior to surgery would be registered in this category.

Non-traumatic causes for impairment of the spinal cord or cauda equina function are registered when this is not caused either directly or indirectly by an external event.

The most common non-traumatic causes as classified by the International SCI Non-Traumatic Data Sets classification to the second level[15] are included:

- Congenital or genetic etiology (for example, spina bifida)
- Degenerative non-traumatic etiology
- Tumor—benign
- Tumor—malignant
- Vascular etiology (for example, ischemia, hemorrhage, arteriovenous malformation)
- Infection (for example, bacterial, viral)
- Other non-traumatic spinal cord dysfunction, specify

The last option is for other or less common causes of non-traumatic spinal cord damage and cases of non-traumatic spinal cord damage where the exact etiology is unknown. It is possible to specify the cause, for example, with International Classification of Disease (ICD) code.

If more detailed information is needed pertaining to non-traumatic causes of SCI, additional levels of detail regarding etiology can be selected from the International SCI Non-Traumatic Data Set.[15]

Vertebral injury

This variable documents whether there was a spinal fracture and/or dislocation in addition to the SCI.[1]

If more detailed information is needed pertaining to vertebral injury, including information on non-continuous vertebral injuries, additional variables can be selected from the International SCI Spinal Column Injury Basic Data Set.[16]

Associated injury

Brachial plexus injuries were an additional category of injury that was added to the list of qualifying associated injuries.[1]

Table 1 Standardization of reporting for age at injury, time since injury, length of stay, calendar time and severity of SCI

Age at injury	Mean (s.d.) and for non-normal distributions median (IQR)
When grouped:	0–14, 15–29, 30–44, 45–59, 60–74 and 75+ years
For small sample size	0–29, 30–59 and 60+ years
For pediatric SCI:	0–5, 6–12, 13–14, 15–17 and 18–21 years
Time since injury	Mean (s.d.) and for non-normal distributions median (IQR)
When grouped:	<1, 1–4, 5–9, 10–14 and every 5 years thereafter
Length of stay	Mean (s.d.) and for non-normal distributions median (IQR)
Calendar time	Years during which the study is conducted
When grouped:	By either 5- or 10-year increments with years ending in 4 or 9
Severity of SCI	
When grouped:	C1–4 AIS A, B and C C5–8 AIS A, B and C T1–S3 AIS A, B, and C AIS D at any injury level Ventilator dependent at any injury level or AIS grade

Abbreviations: AIS, American Spinal Injury Association Impairment Scale; IQR, interquartile range; SCI, spinal cord injury.

This variable documents whether pre-specified major injuries occurred at the same time as the SCI.

Spinal surgery for traumatic spinal cord injuries

Under the heading 'spinal surgery for traumatic spinal cord injuries', the use of staples was added to the list of methods that may be used for internal fixation of the spine.[1]

If more detailed information is needed pertaining to surgical procedures, additional variables can be selected from the International SCI Spinal Interventions and Surgical Procedures Basic Data Set.[17]

Utilization of ventilatory assistance

The response category continuous positive airway pressure to treat sleep apnea was added to this variable.[1]

The variable response categories are:

- No
- Yes, <24 h per day at discharge
- Yes, 24 h per day at discharge
- Yes, unknown number of hours per day at discharge
- Continuous positive airway pressure for sleep apnea
- Unknown

Ventilatory assistance includes, but is not limited to, mechanical ventilators, phrenic nerve stimulators, diaphragmatic pacing, external negative pressure devices and bilevel positive airway pressure. Do not include routine administration of oxygen or periodic intermittent positive pressure breathing administration.

Place upon discharge or current residence

The 'place of discharge' was clarified to designate the location the individual was placed upon discharge or the current residence for post-discharge studies; the place upon discharge was also clarified to reflect the intended final disposition, rather than the location of a temporary stay in a hospital, rehabilitation setting or nursing home, for example, if the patient is discharged to a hospital or nursing home temporarily for custodial care only pending home renovations or for other reasons.

For post-discharge studies, this variable documents current place of residence. When the person is currently hospitalized on a temporary basis, the usual place of residence should be coded rather than 'hospital'.

Neurological status

Requirements for reporting the neurologic examination results were clarified. For post-discharge studies, the examination to be reported should be the most recent, and the unknown code should be used whenever an individual cannot engage in the examination due to age or condition.

For most studies, neurologic status should be reported either at initial acute care hospital examination or at discharge from the last inpatient hospital, and the examinations should be performed within 72 h of admission or discharge whenever possible.[1]

The neurologic examination should be performed by a health-care professional specifically trained to perform this examination, for example, by certification via the ASIA e-learning module InSTeP (http://asia-spinalinjury.org/learning/) in accordance with the most current version of the International Standards for Neurological Classification of SCI (ISNCSCI).[18] Of note, the ISNCSCI cannot be conducted in children of 5 years of age and younger.[19,20] Therefore, a specific e-learning module for children, WeeSTeP (http://asia-spinalinjury.org/learning/), has been developed.

The minimal information necessary to document neurologic status is the sensory and motor level on each side of the body and the ASIA Impairment Scale (AIS) (Appendix A) in accordance with the ISNCSCI.[18] Neurologic level of injury is then defined as the most caudal segment of the spinal cord with normal sensory and motor function, that is, the most cranial of the sensory and motor levels.[18]

Standardize reporting—including adjustments

Standard methods to analyze and report descriptive statistics that would facilitate comparisons across published studies were adopted in 2011.[12] See Table 1, which includes the adjustments made.

For continuous variables including age at injury, time since injury and length of stay, the mean and s.d. should be reported in all studies. The median and interquartile range should also be reported if the distribution is meaningfully skewed. Range should be reported when it is sufficiently narrow to raise concerns regarding generalizability of findings that are not represented in the study population.

Recognizing that the most general population data are published in 5-year increments of 0–4, 5–9, 10–14 years and so on, the recommended grouping for reporting and analyzing age has been changed to 0–14, 15–29, 30–44, 45–59, 60–74 and 75+ years. If necessary, as required to obtain a sufficient sample size in each grouping to permit adequate data analysis, the categories could be expanded to 30-year intervals to 0–29, 30–59 and 60+ years.

For studies of the pediatric SCI population, the current recommended grouping for age is 0–5, 6–12, 13–14, 15–17 and 18–21 years in order to correspond to anticipated milestones in the maturation process and to facilitate the merging of age groups to match the above reporting of 0–14 years.

Similarly, years post injury should now be grouped <1, 1–4, 5–9, 10–14 and every 5 years thereafter, doubling the years included in each interval with categories ending in 4 or 9, as required. The grouping '14

and below' and '15 and above' has been used in several studies and registries around the world, including Australia,[21] Canada,[22,23] Japan,[24] Norway[25] and Portugal.[26]

In addition, to allow differentiation between pediatric and adult populations with spinal cord damage included in global mappings (which used 15 years and older as the cut-off for adults) of traumatic[27] and non-traumatic SCI,[28] it is important to have a non-overlapping age cut-off.

The recommended calendar time intervals do not need to be changed (for example, 5-year intervals such as 1990–1994, 1995–1999, 2000–2004, 2005–2009 and so on, with the option of collapsing the number of categories by one-half, as needed). Each of these variables can be treated continuously in multivariate analyses. This change in the grouping should not substantially affect the ability to compare future data with previously collected data because the intervals captured will differ by only 1 year from the prior intervals that had been employed.

Neurologic level of injury and severity of the SCI is generally recommended to be reported in the following five categories: C1–4 AIS A, B and C; C5–8 AIS A, B and C; T1–S3 AIS A, B and C; AIS D at any injury level; and ventilator dependent at any injury level or AIS grade.[12] In case of few ventilator-dependent individuals, they should be grouped together with those in the C1–4 AIS A, B and C group. If the combined group is still too small, then the recommendation is to group them together with the C5–8 AIS A, B and C, that is, giving three groups C1–8 AIS A, B and C, T1–S3 AIS A, B and C, and AIS D at any level.[12]

DISCUSSION

The current update of the International SCI Core Data Set (version 2.0) is based on extensive collaboration with users and experts engaged with SCI clinical practice and research. Most suggestions have been adopted, but it has been imperative to keep this data set short and manageable in daily clinical practice and at the same time meaningful to research. The International SCI Core Data Set (Version 2.0) will often be used together with other International SCI Data Sets related to various SCI-specific topics, when relevant.

All of the International SCI Data Sets as well as the original publications may be downloaded for free from the ISCoS website: http://www.iscos.org.uk/international-sci-data-sets. In addition, the International SCI Data Sets are integrated with the National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (CDEs)[29,30], and can be downloaded from this website together with other NINDS CDEs, which may be helpful when planning SCI studies and clinical trials: https://www.commondataelements.ninds.nih.gov/SCI.aspx#tab = Data_Standards.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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APPENDIX A

INTERNATIONAL SPINAL CORD INJURY CORE DATA SET (VERSION 2.0)—DATA COLLECTION FORM

Dates (YYYYMMDD)

Birth date: __ __ __ __/ __ __/ __ __
Injury date: __ __ __ __/ __ __/ __ __
Acute admission: __ __ __ __/ __ __/ __ __
Rehabilitation admission: __ __ __ __/ __ __/ __ __
Final Inpatient discharge __ __ __ __/ __ __/ __ __
Date of death: __ __ __ __/ __ __/ __ __

Gender: □ Male □ Female □ Transgender and other related □ Unknown

Injury etiology:
□ Sports;
□ Assault;
□ Transport;
□ Fall;
□ Birth injury or other traumatic cause, Specify:_____;
□ Congenital or genetic etiology (for example, spina bifida);
□ Degenerative non-traumatic etiology;
□ Tumor—benign;
□ Tumor—malignant;
□ Vascular etiology (for example, ischemia, hemorrhage, arteriovenous malformation);
□ Infection (for example, bacterial, viral);
□ Other non-traumatic spinal cord dysfunction, Specify:_____;
□ Unspecified or Unknown

Vertebral injury: □ No □ Yes □ Unknown

Associated injury: □ No □ Yes □ Unknown

Spinal surgery: □ No □ Yes □ Unknown

Ventilatory assistance:
□ No;
□ Yes, <24 h per day at discharge;
□ Yes, 24 h per day at discharge;
□ Yes, unknown number of hours per day at discharge;
□ Continuous positive airway pressure (CPAP) for sleep apnea;
□ Unknown

Place upon discharge/current residence:
□ Private residence: includes house, condominium, mobile home, apartment or houseboat;
□ Hospital: includes mental hospital or other acute care hospital for management of continuing medical issues after spinal cord injury-related care and/or rehabilitation is completed;
□ Nursing home: includes skilled nursing facilities and institutions providing essentially long-term, custodial, chronic disease care;
□ Assisted living residence: includes residential non-institutional locations in which some level of support for activities of daily living is provided;
□ Group living situation: includes transitional living facility or any residence shared by non-family members;
□ Correctional institution: includes prison, penitentiary, jail, correctional center and so on;
□ Hotel or motel;
□ Homeless: includes cave, car, tent and so on;
□ Deceased;
□ Other, unclassified;
□ Unknown

Neurological Data

Acute admission

Date of examination

__ __ __ __/ __ __/ __ __

Sensory level

Left Right

__ __ __ __ __ __

Motor level

Left Right

__ __ __ __ __ __

ASIA Impairment Scale

__

Final inpatient discharge

Date of examination

__ __ __ __ /__ __/ __ __

Sensory level

Left Right

__ __ __ __ __ __

Motor level

Left Right

__ __ __ __ __ __

ASIA Impairment Scale

__