Discussion Paper

International Spinal Cord Injury Data Sets

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Study design: Discussion and development of final consensus.

Objective: Present the background, purpose, and process for the International Spinal Cord Injury (SCI) Data Sets development.

Setting: International.

Methods: An international meeting on SCI data collection and analysis occurred at a workshop on May 2, 2002, before the combined meeting of the American Spinal Injury Association (ASIA) and the International Spinal Cord Society (ISCoS) in Vancouver, British Columbia, Canada. At this meeting, a process was developed for selection of data elements to be included in International SCI Data Sets.

Results: An overall structure and terminology has been developed following the format of the International Classification of Functioning, Disability and Health (ICF). This includes definitions of the Core Data Set, as well as Modules with Basic Questions or Data Sets and Expanded Data Sets. The Core Data Set has been developed and will be presented separately. Working groups for additional modules are being established as well as general guidelines for the development of the modules.

Conclusion: The presented format should help in developing data sets and modules within various topics related to SCI.

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Keywords: spinal cord injury; core data set; module; basic question; basic data set; expanded data set; ICF; registry; database

Background of the International Spinal Cord Injury Data Sets

Long-term survival with a reasonable quality of life has become an expected outcome worldwide for individuals with a spinal cord injury (SCI). As a result, there is an increased need for data pertaining to SCI. Such data should be in the form of a common international data set collected on individuals with SCI to facilitate comparisons regarding injuries, treatments, and outcomes between patients, centres, and countries.

Many countries have established SCI databases;[1–6] however, it is clear that it is necessary to have comparable data elements so that services affecting worldwide outcomes of people with SCI can be assessed and compared. For those countries that seek to develop or upgrade an SCI database, the ability to learn from the experience of others is critical. As data may be used to secure and/or maintain financial support for SCI services, data standards must be high and selection of data fields carefully examined.

History and objectives of the International SCI Data Sets

This process was initiated subsequent to an international meeting of selected experts in the field of SCI data collection and analysis. Forty-eight participants attended a 1-day pre-conference workshop on May 2, 2002, before the first combined meeting of the American Spinal Injury Association (ASIA) and the International Spinal Cord Society (ISCoS) in Vancouver, British Columbia, Canada.[7] This was the first international meeting to consider each data element that was collected at various SCI centres and to discuss the steps required

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to select and recommend the variables that should be included in future SCI data sets. The participants represented Australia, Canada, Denmark, India, Israel, Italy, Japan, The Netherlands, Sweden, Switzerland, United Kingdom, and United States.

The objectives of the workshop were to

- develop a common understanding of existing SCI databases worldwide; and
- establish partnerships for developing international data sets for SCI.

There was a consensus that guidelines for the recommended minimal number of data elements could provide a lowest common denominator and be the start of a common language among SCI centres worldwide. The guidelines should assist centres in developing new SCI databases and may enable researchers to be more consistent and effective in the design and publication of clinical research studies through the use of standard data elements that allow comparison between SCI populations worldwide.

In that workshop, five areas of focus for future development were identified:

- core clinical data set;
- expanded clinical data set;
- health and functional outcomes;
- participation outcomes; and
- life satisfaction outcomes.

The proposed next steps included

- formation of international working groups to continue work with the focus areas;
- circulation of the proposed data modules to relevant SCI organizations and societies requesting their review and feedback;
- achievement of consensus among the SCI organizations and societies on the data modules;
- presentation of the data modules to the ASIA and ISCoS governing bodies and general meetings;
- publication of each new data module in Spinal Cord; and
- posting instructions, data forms, and training materials on the web sites of ASIA and ISCoS for free downloading and use by all SCI researchers.

Organization

Following the workshop in Vancouver, the three outcome focus areas were combined into one. Three committees were formed for each of the remaining focus areas along with a supervising executive committee that consisted of the committee chairs and co-chairs. The executive committee remains as a steering committee with specific working groups created for developing each data set and module. The executive committee has also developed the structure and terminology for the various kinds of data sets to enable consistency in the future use and interpretation of recommendations.

International organizations and societies within the fields of neurosurgery, orthopaedic surgery, and rehabilitation are being invited to appoint members to join the review process for the creation and evaluation of the best possible international data set. When creating working groups on specific topics, several approaches are used, including

- contacting the organizations/societies within the relevant focus area to provide representatives;
- selecting additional individuals known to be reliable and knowledgeable within the area of interest for the specific topic;
- searching through Medline/PubMed to identify individuals who have published within the topic area within the last few years, and who, after being invited to participate in this process, express willingness to join the working group; and
- searching for established collaborations of individuals and groups who are developing evidence-based practice guidelines in the relevant areas.

Potential impact of International SCI Data Sets

The effort to develop internationally recognized and endorsed standard data sets builds on the experience and positive momentum of the worldwide dissemination of the ASIA and now ASIA/ISCoS International Standards for Neurological Classification of Spinal Cord Injury.[8] To be successful, it is important that the data sets are simple and perceived relevant to clinicians so that they will use them. In addition, it is imperative that these data sets be both easily retrieved and available for use at little or no cost and without any specific restrictions.

International Classification of Functioning, Disability and Health

In 2001, the World Health Organization (WHO) endorsed the International Classification of Functioning, Disability and Health (ICF).[9] As the ICF is an internationally accepted classification of consequences of disease, it is considered to be a useful conceptual framework for data sets related to consequences of SCI. In the ICF, a person's functioning or disability is conceived as a dynamic interaction between health conditions and environmental and personal factors (see Figure 1). In this classification scheme, disability is an umbrella term for any or all of the following:

- impairment of body function or structure,
- limitation in activities, or
- restriction in participation.

Components of the ICF are shown in Figures 1 and 2, and the key definitions are as follows:
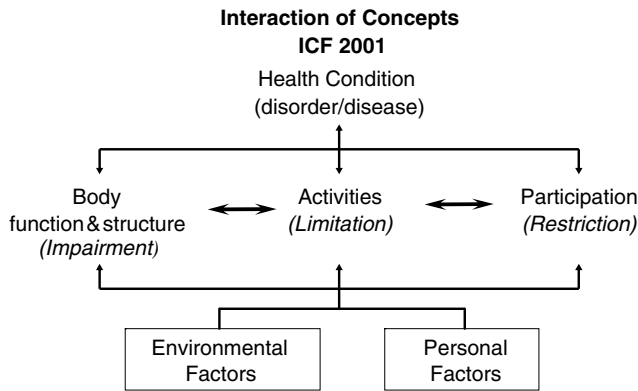*Body functions:* the physiological functions of the body systems (including psychological functions).

**Interaction of Concepts
ICF 2001**

Figure 1 Interactions between components of the ICF[9]

Body structures: anatomical parts of the body such as organs, limbs, and their components.

Impairments: problems in body functions and structures such as significant deviation or loss.

Activity: the execution of a task or action by an individual.

Activity limitations: difficulties an individual may have in executing activities.

Participation: involvement in a life situation.

Participation restrictions: problems an individual may experience in involvement in life situations.

Environmental factors: make up the physical, social, and attitudinal environment in which people live and conduct their lives. These are either barriers to or facilitators of the person's functioning.

The ICF makes it possible to link data across conditions or interventions. Tools such as ICF Core Sets are needed to make the ICF useful, and it is proposed that they be developed alongside the International SCI Data Sets.[10]

Structure and terminology for the International SCI Data Sets

Core Data Set
The Core Data Set is the recommended minimal data set that should be collected on all individuals with a new SCI during their initial in-patient period.[11] It is recommended that these data be included as a descriptive table in publications involving individuals with SCI. The Core Data Set includes basic questions (see below) as well as other elements.[11]

Basic question
This is a question that, with an affirmative answer, can be linked to one or more specific modules with more detailed information on the particular topic. There will not be basic questions for all modules.

Examples of basic questions include the following:

Vertebral injury: Yes/No/Unknown (from the Core Data Set[11])→Vertebral injury module

Spinal surgery: Yes/No/Unknown (from the Core Data Set[11])→Spinal surgery module

Aetiology of lesion: Transport/Fall/Assault/Sports/Other traumatic/Non-traumatic (from the Core Data Set[11])→Aetiology module

Basic data set
This is the minimal number of data elements, including the possible basic question that should be collected in daily clinical practice for a particular topic. One possible example would be a lower urinary tract function basic data set that might include a basic question such as 'method of bladder emptying', with possible responses including 'normal voiding; triggered reflex voiding; bladder-expression; intermittent catheterization; indwelling catheter; etc.' Another basic question for that same basic data set could be 'type of collecting appliances for urinary incontinence', with possible responses including 'none; condom catheter; diaper; ostomy bag; other'. Other possible examples of basic data sets include bowel management, pain, urodynamics, self-care, etc.

Expanded data set
This is a more detailed data set that may be optional for clinical practice but is recommended for specific research studies in a particular area. For example, a lower urinary tract function expanded data set might include questions such as 'what type of catheter is used for intermittent catheterization'? Any basic data set might have an expanded data set associated with it.

Module
A module may consist of related basic and expanded data sets as well as other appropriate data (eg specific scoring systems) that are appropriate for broader research studies. For example, a urological module might include

Urological module	Lower urinary tract function basic and expanded data sets
	Urinary tract imaging and function basic and expanded data sets
	Urodynamics basic and expanded data sets
	Urinary tract medical complications basic and expanded data sets

The overall framework for the International SCI Data Sets is illustrated in Figure 2.

Data set developments

The establishment of topic-specific expert working groups for each module is carried out by the Executive Committee in cooperation with relevant international societies and organizations. A member of the Executive Committee serves as a liaison on each working group to ensure that the modules are developed within the established framework.
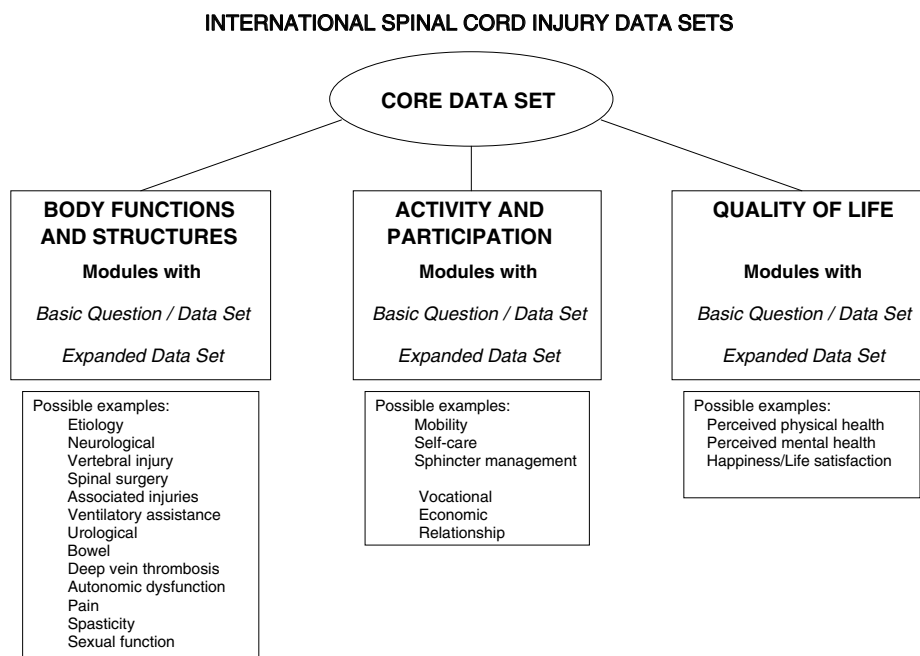
INTERNATIONAL SPINAL CORD INJURY DATA SETS

Figure 2 Structure of the International SCI Data Sets

The Core Data Set was the first data set to be developed.[11] Work has also begun on the development of basic questions and data sets in the following areas:

- Vertebral injury
- Spinal surgery
- Non-traumatic spinal cord lesions
- Aetiology/prevention, based on the WHO International Classification of External Causes of Injury[12] (ICECI – SCI)
- *Participation*. This group will initially survey the field and start with the development of basic questions for several possible modules within the area of participation.
- *Urology*. This group will initially describe the areas within the field and then determine basic questions or data sets, for example, bladder emptying, incontinence, urodynamics.

Data set presentation

As soon as new data sets and modules are developed in an iterative manner, consensus obtained, and a final draft approved together with an appropriate training programme by the relevant committees of ASIA and ISCoS, they will be disseminated at meetings, and published in international journals and web sites of ASIA/ISCoS and other endorsing organizations.

Training programmes

For each developed data set and module, the plan is to create an e-learning module accessible through the ASIA and ISCoS web sites, from which the data guidelines will be freely available. To facilitate ease and accuracy of use, training on the e-learning programme should precede downloading of particular data sets or modules. This training will provide examples on how to code the data set and will give a minimal introduction to those using the data sets in their own environment.

Epilogue

Development of International SCI Data Sets and standards is an imperative step that should lead to continual improvement of SCI examination, treatment, rehabilitation, and prevention programmes. It is unlikely that one centre alone will be able to recruit enough participants for break-through studies. Therefore, standardized international data sets are necessary for the many multi-centre trials and investigations that are going to take place in the years to come. During the years ahead, we hope that this process will be supported by all those involved with SCI.

Acknowledgements

References

1 Levi R, Ertzgaard P. Quality indicators in spinal cord injury care: a Swedish collaborative project. The Swedish

Spinal Cord Injury Council 1998. *Scand J Rehabil Med Suppl* 1998; **38:** 1–80.

2 O'Connor PJ. Development and utilisation of the Australian spinal cord injury register. *Spinal Cord* 2000; **38:** 597–603.

3 Biering-Sørensen F *et al.* Multidisciplinary electronic medical record and clinical database all in one. SCIBase. *Ugeskr Laeger* 2001; **163:** 3207–3212 (in Danish).

4 Walter JS *et al.* A database of self-reported secondary medical problems among VA spinal cord injury patients: its role in clinical care and management. *J Rehabil Res Dev* 2002; **39:** 53–61.

5 DeVivo MJ, Go BK, Jackson AB. Overview of the national spinal cord injury statistical center database. *J Spinal Cord Med* 2002; **25:** 335–338.

6 Pagliacci MC *et al.* Spinal cord lesion management in Italy: a 2-year survey. *Spinal Cord* 2003; **41:** 620–628.

7 Working Towards an International Spinal Cord Injury Data Set. Summary of Workshop Proceedings, May 2, 2002, Vancouver, British Columbia, Canada. The summary is available by contacting the workshop coordinator Vanessa Noonan by e-mail: vnoonan@vanhosp.bc.ca.

8 Marino RJ *et al.* International standards for neurological classification of spinal cord injury. *J Spinal Cord Med* 2003; **26**(Suppl 1)**:** S50–S56.

9 World Health Organization. *International Classification of Functioning, Disability and Health*. WHO: Geneva 2001.

10 Biering-Sørensen F *et al.* Developing Core Sets for persons with spinal cord injuries based on the International Classification of Functioning, Disability and Health as a way to specify functioning. *Spinal Cord* 2006; **44:** 541–546 (this issue).

11 DeVivo M *et al.* International Spinal Cord Injury Core Data Set. *Spinal Cord* 2006; **44:** 535–540 (this issue).

12 WHO International Classification of External Causes of Injury (ICECI). http://www.iceci.org/.