

ORIGINAL ARTICLE

The International Spinal Cord Injury Pain Basic Data Set

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Objective: To develop a basic pain data set (International Spinal Cord Injury Basic Pain Data Set, ISCI-PDS:B) within the framework of the International spinal cord injury (SCI) data sets that would facilitate consistent collection and reporting of pain in the SCI population.

Setting: International.

Methods: The ISCI-PDS:B was developed by a working group consisting of individuals with published evidence of expertise in SCI-related pain regarding taxonomy, psychophysics, psychology, epidemiology and assessment, and one representative of the Executive Committee of the International SCI Standards and Data Sets. The members were appointed by four major organizations with an interest in SCI-related pain (International Spinal Cord Society, ISCoS; American Spinal Injury Association, ASIA; American Pain Society, APS and International Association for the Study of Pain, IASP). The initial ISCI-PDS:B was revised based on suggestions from members of the Executive Committee of the International SCI Standards and Data Sets, the ISCoS Scientific Committee, ASIA and APS Boards, and the Neuropathic Pain Special Interest Group of the IASP, individual reviewers and societies and the ISCoS Council.

Results: The final ISCI-PDS:B contains core questions about clinically relevant information concerning SCI-related pain that can be collected by health-care professionals with expertise in SCI in various clinical settings. The questions concern pain severity, physical and emotional function and include a pain-intensity rating, a pain classification and questions related to the temporal pattern of pain for each specific pain problem. The impact of pain on physical, social and emotional function, and sleep is evaluated for each pain. *Spinal Cord* (2008) 46, 818–823; doi:10.1038/sc.2008.64; published online 3 June 2008

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Introduction

Pain is one of the most frequently reported reasons for reduced quality of life following spinal cord injury (SCI).¹ The clinical picture of pain associated with SCI is highly complex in that multiple pains with different characteristics may be experienced simultaneously in different regions of the body. SCI pain taxonomies^{2,3} classify pain as neuropathic or nociceptive, and according to level of injury. Neuropathic pain following SCI is often associated with evoked pain, such as allodynia or hyperalgesia⁴ and examination of sensory abnormalities is therefore an

important complement to the verbal assessment.^{5,6} However, it is presently not possible to accurately link particular pain features to specific mechanisms. Because many of the pain types experienced after an SCI are relatively refractory to treatments, pain often persists and can even worsen over time⁷ and interfere with cognitive, emotional and physical functioning.⁸

In the clinical setting, information is collected that provides a basis for treatment decisions concerning pain. Although physicians who treat patients with SCI routinely collect clinical information, a standardized way to collect pain data is lacking. The use of standardized sets of outcome measures in clinical practice and in clinical trials would facilitate research collaboration between clinical centers and the translation, interpretation and application of results to improve the management of SCI-related pain.

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The purpose of the International Spinal Cord Injury Pain Data Set (ISCIPDS) is to standardize the collection and reporting of pain in the SCI population. The ISCIPDS contains basic (ISCIPDS:B) and extended (ISCIPDS:E) components. The ISCIPDS:B, which is presented here, contains a basic amount of clinically relevant information concerning pain. The information is intended to be collected by health-care professionals with expertise in SCI at the initial evaluation and at regular follow-up sessions. The information described below should be collected as an interview and each question read to the patient or research subject as worded. In addition, the evaluation should be logistically feasible across various settings and in different countries. The ISCIPDS:E (not yet developed), on the other hand, may primarily be used for research purposes. The overall purpose of the ISCIPDS is consistent with the purpose and vision of the International Spinal Cord Injury Data Sets⁹ and should be used in conjunction with the International SCI Core Data Set¹⁰ that includes information on date of birth and injury, gender, the cause of the SCI and neurological status including positive and negative sensory signs.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) has recommended that clinical pain trials should consider including a core set of outcomes¹¹ including pain severity, and physical and emotional functioning to capture the multidimensional nature of pain. After SCI, a decrease in physical function may be more related to the physical impairments of SCI rather than to pain; therefore, a decrease in function due to pain, that is, pain interference should be assessed.

The questions in the ISCIPDS:B are based on the IMMPACT recommendations above, but adapted to the special issues related to SCI (that is, several simultaneous different pain problems, physical impairments). Therefore, a pain-intensity rating, a classification of pain and questions related to temporal pattern for each specific pain are recommended. The impact of pain on physical, social and emotional function, and sleep is also addressed.

Materials and methods

An initial version of the ISCIPDS:B was prepared by an interdisciplinary working group. All members in this group had published on the topic of SCI-related pain and were appointed by four major organizations with a significant interest in this area (International Spinal Cord Society, ISCoS; American Spinal Injury Association, ASIA; American Pain Society, APS and International Association for the Study of Pain, IASP). Efforts were guided by the need to prepare a basic pain data set that could be used by clinicians without cost in various settings and countries without the need of advanced technical equipment. The data collected would provide a minimal amount of standardized information necessary for arriving at a probable diagnosis of pain type. To ensure consistency in the data collection and facilitate interpretation, detailed information is provided in a syllabus for each specific variable and response category.

The development of the final version of the ISCIPDS:B followed the steps briefly outlined in Table 1.

Table 1 Outline of the development of the final version of the ISCIPDS:B

<i>Steps</i>	
1	The working group of the International Spinal Cord Injury Pain Basic Data Set prepared the first version of the ISCIPDS:B during a 3-day meeting in Copenhagen in May 2006. This version was further developed and a set of instructions (syllabus) was prepared by the members of the subcommittee via e-mail correspondence.
2	The ISCIPDS:B was reviewed by members of the executive committee of the International SCI Standards and Data Sets. The suggestions from the committee members were discussed in the working group and appropriate changes were made to the ISCIPDS:B.
3	The ISCIPDS:B was reviewed by members of the ISCoS Scientific Committee and ASIA Board. The comments from the committee/board members were discussed in the working group and further adjustments of the ISCIPDS:B were made.
4	The ISCIPDS:B was reviewed by members of the APS Board and the NeuPSIG of the IASP. The comments from the Board and committee members were discussed in the working group and further adjustments of the ISCIPDS:B were made.
5	Organizations and Societies and individuals with an interest in SCI-related pain were also invited to review and comment on the data set. The data set was also posted on the ISCoS and ASIA websites for 2 months to allow additional comments and suggestions. The suggestions provided were discussed by the working group and adjustments to the data set were made.
6	To finalize the ISCIPDS:B, members of the ISCoS Scientific Committee, Council and ASIA Board review the data set for final approval.
7	Endorsement of the data set will be sought by the relevant Organizations and Societies.

Abbreviations: APS, American Pain Society; ASIA, American Spinal Injury Association; IASP, International Association for the Study of Pain; ISCIPDS:B, International Spinal Cord Injury Basic Pain Data Set; ISCoS, International Spinal Cord Society; NeuPSIG, Neuropathic Pain Special Interest Group; SCI, spinal cord injury.

Results

The ISCIPDS:B data sheet is included in the Appendix and the data sheet and syllabus are available on the respective websites of ISCoS (www.iscos.org.uk) and ASIA (www.asia-spinalinjury.org). Training cases are under development and will also be available on these websites. Listed below are the variables included in the ISCIPDS:B.

Date of data collection

This variable provides a way to relate the collected data to other data collected from the same individual at various time points.

Have you had any pain during the last 7 days including today?

This question evaluates any present, chronic and intermittent pain. The 7-day interval was chosen to capture both constant and intermittent current pain. This question can also be used as a basic pain question in other questionnaires, that is, gate question to the Pain Basic Data Set.

If yes, how many different pain problems do you have?

This variable defines the number of different pain problems an individual perceives that he/she has experienced during the last 7 days. The answer to this question can range from 'one pain problem' to 'five or more pain problems'.

Description of the three worst pain problems

Each person is asked to describe the three worst pain problems he/she is currently experiencing. We had two

reasons for limiting this assessment to three problems. First, most people with SCI experience three or fewer pain problems.¹² Second, describing the details of more than three different simultaneous pain problems may induce errors in the data collection due to increased assessment burden. Although the intent of the ISCI-PDS:B is to evaluate each separate pain problem, it may also be used to evaluate the only most significant or 'worst' pain problem if there are severe time constraints.

Location(s) of pain. This variable defines where the pain is located and can be used to follow pain at subsequent visits. The eight pain areas are: (1) head, (2) neck/shoulders, (3) arms/hands, (4) frontal torso/genitals, (5) back, (6) buttocks/hips, (7) upper legs/thighs and (8) lower legs/feet. Within each of these pain locations, further divisions into more precise locations can be made. Each individual is asked to describe the location of all present pain. The descriptions of the pain locations are based on each individual's report of where pain is located. Therefore, the delineations of these areas are not defined with precise anatomical landmarks.

Types of pain. Seven broad types of pain are specified based on pain types identified in previous SCI pain taxonomies.^{2,3,13,14} The pain classification is based on the criteria below and in combination with the ASIA Impairment Scale (AIS).¹⁵ For a neuropathic pain to be classified as SCI-related pain, a lesion or disease affecting the spinal cord or nerve roots must be present and the pain must fall within an expected anatomical location for that lesioned or diseased spinal cord or nerve roots. Neuropathic pain that cannot be attributed to a lesion or disease affecting the spinal cord or nerve roots should be classified as 'other' (neuropathic).

Musculoskeletal (nociceptive) pain refers to pain occurring in any region where there is at least some preserved sensation above, at or below the neurological level of injury and which is believed to be arising from musculoskeletal structures. The presence of this type of pain is suggested by pain descriptors such as dull or aching, pain related to movement, tenderness of musculoskeletal structures on palpation, response to anti-inflammatory medications and evidence of skeletal pathology on imaging consistent with the pain presentation. Examples include spinal fractures, muscular injury, shoulder overuse syndromes and muscle spasm.^{2,3,13,14}

Visceral (nociceptive) pain refers to pain usually located in the thorax or abdomen and believed to be generated in visceral structures. The presence of this type of pain is suggested by characteristics such as dull, aching or cramping and a relationship to visceral pathology or dysfunction, for example, infection or obstruction.^{2,3,13,14} Examples include urinary tract infection, ureteric calculus and bowel impaction.

Other (nociceptive) pain refers to nociceptive pains that may be present but do not fall into the musculoskeletal or visceral categories.³ Examples include pain associated with ulceration of the skin and headache.

At-level (neuropathic) pain refers to neuropathic pain presenting in a segmental pattern. It is perceived anywhere within the dermatome of the level of neurological injury and

three dermatomes below this level. It is often characterized as burning, electric or shooting. Sensory changes such as allodynia or hyperalgesia within the pain distribution are often found. The pain may be unilateral or bilateral.^{2,3} Note neuropathic pain associated with cauda equina damage is radicular in nature and therefore defined as at-level (neuropathic) pain regardless of distribution.

Below-level (neuropathic) pain refers to neuropathic pain present in the region more than three dermatomes below the neurological level of injury. It has typical characteristics such as burning, electric or shooting qualities and a diffuse, regional distribution. Sensory changes such as allodynia or hyperalgesia may be present. If the pain is present in the region within three dermatomes below the neurological level of injury as well as more than three dermatomes below the level, the pain is classified as at- and below-level (neuropathic) unless the person is able to distinguish a separate at-level (neuropathic) component. If two separate pains are distinguishable, the two pain types, that is, at-level (neuropathic) and below-level (neuropathic) must be classified and documented as two different pains.

At- and below-level (neuropathic) pains refer to the case when a person with below-level neuropathic pain also has neuropathic pain within the region three dermatomes at or below the neurological level of injury but is unable to distinguish two separate pain problems.

Other (neuropathic) pain refers to neuropathic pains that are present above, at or below the neurological level of injury but are not thought to arise from a lesion or disease affecting the spinal cord or nerve roots. Examples include postherpetic neuralgia, pain associated with diabetic neuropathy, central post-stroke pain and compressive mononeuropathies.^{2,3}

'Unknown' should be used when it is not possible to classify the pain into one of the categories listed above.

Average pain intensity in the last week. Pain intensity is the most common pain domain assessed in research and clinical settings. Although different rating scales have proven to be valid for assessing pain intensity, including the Numerical Rating Scale (NRS), the Verbal Rating Scale and the Visual Analogue Scale, the 0–10 NRS has the most strengths and fewest weaknesses of available measures.¹⁶ Moreover, the 0–10 NRS, and specifically the 0–10 with the end points listed, has been recommended by the IMMPACT consensus group for use in pain clinical trials,¹¹ and by a National Institute on Disability and Rehabilitation Research (NIDDR)-sponsored consensus group regarding SCI-related pain.¹⁶

Date of onset. This variable specifies the date this particular pain problem started.

Number of days with pain in the last 7 days including today. This variable specifies the total number of days with pain during the last 7 days, including today.

How long does your pain usually last?. This variable provides an estimate of the duration of pain and the response categories range from 'one minute or less' to 'constant or continuous.'

The duration of pain can be defined when a specific pain follows a predictable pattern. If no predictable pattern for a specific pain exists, the answer 'unknown' is given.

When is the pain most intense? This variable identifies the diurnal peak in pain intensity. The response categories are 'morning,' 'afternoon,' 'evening,' 'night' and 'unpredictable'.

Pain interference. This section contains three items from the Life Interference (LI) subscale of the Multidimensional Pain Inventory SCI version (MPI-SCI)¹⁷ evaluating impact of pain on activities in general and on recreational, social and family-related activities, and three items specifically asking about pain interference with general activities, mood and sleep.

The MPI-SCI LI subscale is recommended for assessing pain interference in SCI.¹⁸ The validity and reliability of the MPI-SCI LI subscale have been established for the SCI chronic pain population.¹⁹ This includes convergent construct validity, that is, strong correlation ($r=0.61$) with a measure of a similar construct (that is, the Pain Disability Index),²⁰ excellent internal consistency ($r=0.90$) and test-retest ($r=0.81$) values. In addition, a multiple regression analysis showed that LI significantly predicted satisfaction with life in persons with SCI and pain.¹⁹ The three selected questions had high factor loadings on the LI factor.¹⁷ The internal consistency of these three items is 0.80 and test-retest is 0.78.

The three additional interference items were written for and included in the data set given the need for (1) the availability of a single item that could be used to assess the general domain of pain interference; and (2) the need to ensure assessment of pain interference on mood and sleep (not assessed by the MPI-SCI LI), two additional key interference domains.

Discussion

The ISCI-PDS:B presented in this paper is an effort to provide a standardized way of evaluating and reporting the diverse pains in persons with SCI. The ISCI-PDS:B is designed to contain a minimal amount of the most critical clinically relevant information concerning pain that can be collected in the daily practice of health-care professionals with expertise in SCI. In addition, the evaluation should be logistically feasible across various settings and countries including the developing countries. The ISCI-PDS:B should be used in combination with the AIS¹⁵ to determine extent of neurological injury and to determine the location of pain relative to injury (that is, above, at and below).

In summary, the basic pain data set is intended to be used to evaluate pain in the daily clinical practice at both in- and outpatient SCI clinics around the world. In a specialized pain clinic managing patients with SCI, more sophisticated methods including quantitative sensory assessments would add diagnostic precision. Similar to the other international SCI data sets, the ISCI-PDS:B should be viewed as a work in progress. Therefore, as knowledge increases regarding the factors that are responsible for causing and maintaining the various pains after SCI, the evaluation of pain in this

population will have to be modified to be consistent with this new knowledge. It is our intention to continue to update and improve the ISCI-PDS:B and the working group (through the corresponding author) welcomes additional suggestions and comments for further improvement. We hope that by publishing the data set studies evaluating stability and reliability of the basic pain data set will be undertaken.

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Appendix

International spinal cord injury data sets

Please note that the syllabus and data set forms are posted on the *ISCoS* (www.iscos.org.uk) and *ASIA* (www.asia-spinalinjury.org) websites.

PAIN BASIC DATA SET—FORM

Date of data collection: YYYY/MM/DD

Have you had any pain during the last 7 days including today?

- No Yes

If yes, how many different pain problems did you have?

- 1; 2; 3; 4; >5

Please describe your three worst pain problems:

Pain locations/sites (can be more than one, so check all that apply): right (R), midline (M), or left (L)	R	M	L	Type of pain (check all that apply)	Intensity and temporal pattern of pain
Head					Average pain intensity in the last week: 0 = no pain; 10 = pain as bad as you can imagine 0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10 Date of onset: YYYY/MM/DD Number of days with pain in the last 7 days including today: none; 1; 2; 3; 4; 5; 6; 7; unknown How long does your pain usually last: ≤ 1 min; > 1 min but < 1 hr; ≥ 1 hr but < 24 hrs; ≥ 24 hrs; constant or continuous; unknown When during the day is the pain most intense: morning (06.01-12.00); afternoon (12.01-18.00); evening (18.01-24.00); night (00.01-06.00) unpredictable; pain is not consistently more intense at any one time of day
Neck/shoulders				Nociceptive <input type="checkbox"/> Musculoskeletal <input type="checkbox"/> Visceral <input type="checkbox"/> Other	
throat					
neck					
shoulder					
Arms/hands				Neuropathic <input type="checkbox"/> At-level <input type="checkbox"/> Below-level <input type="checkbox"/> At- and below-level pain (one pain) <input type="checkbox"/> Other <input type="checkbox"/> Unknown	
upper arm					
elbow					
forearm					
wrist					
hand/fingers					
Frontal torso/genitals					
chest					
abdomen					
pelvis/genitalia					
Back					
upper back					
lower back					
Buttocks/hips					
buttocks					
hip					
anus					
Upper legs/thighs					
Lower legs/feet					
knee					
shin					
calf					
ankle					
foot/toes					

Please note that the time period during the last week apply to all pain interference questions.

How much do you limit your activities in order to keep your pain from getting worse?

Not at all 0 – 1 – 2 – 3 – 4 – 5 – 6 Very much

How much has your pain changed your ability to take part in recreational and other social activities?

No change 0 – 1 – 2 – 3 – 4 – 5 – 6 Extreme change

How much has your pain changed the amount of satisfaction or enjoyment you get from family-related activities?

No change 0 – 1 – 2 – 3 – 4 – 5 – 6 Extreme change

In general, how much has pain interfered with your day-to-day activities in the last week?

No interference 0 – 1 – 2 – 3 – 4 – 5 – 6 Extreme interference

In general, how much has pain interfered with your overall mood in the past week?

No interference 0 – 1 – 2 – 3 – 4 – 5 – 6 Extreme interference

In general, how much has pain interfered with your ability to get a good night's sleep?

No interference 0 – 1 – 2 – 3 – 4 – 5 – 6 Extreme interference

Are you using or receiving any treatment for your pain problem?

No Yes