ORIGINAL ARTICLE

The International Spinal Cord Injury Pain Extended Data Set (Version 1.0)

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Objectives: The objective of this study was to develop the International Spinal Cord Injury Pain Extended Data Set (ISCIPEDS) with the purpose of guiding the assessment and treatment of pain after spinal cord injury (SCI).

Setting: International.

Methods: The ISCIPEDS was reviewed by members of the International SCI Data Sets Committee, the International Spinal Cord Society Executive and Scientific Committees, American Spinal Injury Association and American Pain Society Boards, and the Neuropathic Pain Special Interest Group of the International Association for the Study of Pain, individual reviewers and societies.

Results: The working group recommended four assessment domains for the ISCIPEDS: (i) Pain symptoms including variables related to pain type, temporal course, severity, unpleasantness, tolerability of pain and questionnaires assessing pain type and symptom severity; (ii) Sensory signs to detect and quantify sensory abnormalities commonly associated with neuropathic pain, including dynamic mechanical and thermal allodynia, and hyperalgesia; (iii) Treatments (ongoing and past 12 months); and (iv) Psychosocial factors and comorbid conditions.

Conclusion: The ISCIPEDS was designed to be used together with the International SCI Pain Basic Data Set and provide a brief yet thorough assessment of domains related to chronic pain in individuals with SCI. The data set includes pain-relevant self-reported assessments, questionnaires and sensory examinations. The recommendations were based on (i) their relevance to individuals with SCI and chronic pain, (ii) the existence of published findings supporting the utility of the selected measures for use in individuals with SCI, and to the greatest extent possible (iii) their availability in the public domain free of charge.

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INTRODUCTION

Persistent and severe pain is common after a spinal cord injury (SCI),^{1,2} and most individuals experience neuropathic and/or musculoskeletal pain at 1 year after injury.³ The persistence of pain after SCI often leads to higher levels of depression,⁴ significant psychosocial impact^{5–8} and reduced quality of life⁹ by interfering with sleep, mood and daily activities including social activities and work.¹⁰

Pain in people with SCI is classified in the broad categories *nociceptive*, *neuropathic* (at or below level of injury), *other* or *unknown*.¹¹ The neuropathic pains are often associated with various sensory abnormalities including allodynia and hyperalgesia,^{12,13} and research suggests that assessment of these can help define phenotypes and/or predict pain development or treatment responses.^{3,14,15}

The multidimensionality of pain is emphasized by the dynamic interaction between biological factors, psychological status, and social and cultural factors; this makes the pain experience highly individual and unique. Although biological factors may cause, maintain and modulate pain after SCI, psychological factors can exert a powerful influence on the perception and impact of pain, and social factors may

modulate the impact and responses to these perceptions.^{16,17} Thus, the interrelationships between persistent pain, psychosocial factors, and physical and functional impairments underscore the importance of a multimodal approach to the assessment, treatment and rehabilitation of individuals who experience chronic pain after their SCI.^{18,19} The chronicity of pain associated with SCI also suggests that personal adaptation and coping skills are critical for achieving optimal quality of life after SCI.^{20,21}

The International Spinal Cord Injury Pain Data Sets (ISCIPDSs) consist of a *basic* (ISCIPBDS) and an *extended* (ISCIPEDS) data set. The information collected in the ISCIPEDS should be considered supplemental to the information collected in the ISCIPBDS. The ISCIPBDS v2.0²² contains a minimal amount of clinically relevant information concerning pain (for example, pain interference, probable pain diagnosis, location, intensity and duration of pain) that can be collected in the daily practice of health-care professionals with expertise in SCI. The ISCIPBDS v2.0 was shortened from its original format²³ to increase its clinical utility and to reflect the new SCI pain taxonomy.¹¹ The ISCIPBDS was adopted by the National Institute of

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Health, National Institute of Neurological Disorders and Stroke (NINDS) and Common Data Elements (CDEs) as a supplemental/highly recommended data set to be collected in clinical SCI pain research (www.commondataelements.ninds.nih.gov/SCI.aspx#tab=Data_Standards).²⁴

The organization of the *extended* data set is directly based on the pain problems identified in the *basic* data set and is intended to be used in research studies and be collected by researchers or health-care professionals familiar with SCI. Data should be collected by interview (or the recommended mode of administration for a specific instrument) and by clinical examination. The ISCIPEDS was designed to evaluate the following domains: (i) *Pain symptoms* (for example, temporal course, severity, unpleasantness, tolerability and pain type). Pain symptoms are particularly important to evaluate in populations such as SCI, where pain is typically heterogeneous, persistent and often severe; (ii) *Sensory signs* to detect and quantify common sensory abnormalities associated with clinical pain (for example, abnormal responses to light touch, pinprick and cold sensation). The sensory measures were intentionally selected to be appropriate for bedside examination to facilitate their use. Identification of symptoms and signs associated with neuropathic pain may not only facilitate a better understanding of the clinical condition but may also provide a foundation for subgroup analyses in clinical trials and thus facilitate future mechanism-based treatment interventions;^{25,26} (iii) *Treatments* used currently or in the past 12 months (for example, dose (if appropriate), frequency, adverse effects and the person's rating of global impression of change).²⁷ Information regarding a person's previous and current experience with various treatment interventions is vital for the planning of clinical studies and screening of potential participants for a clinical trial; (iv) *Psychosocial domains and comorbid conditions* including outcomes (for example, quality of life, satisfaction with life), mediating factors or comorbid conditions (for example, depression, anxiety).

Presently, the evidence base in the SCI pain research field does not strongly support the use of specific instruments above others. Therefore, the selection of specific instruments for a research study should primarily reflect a study's purpose and aims. The ISCIPEDS includes multiple measures for each domain with similar purposes and equivalent psychometric properties. However, for future revisions and updates of the ISCIPEDS, the utility of specific domains and instruments will be reevaluated as new evidence becomes available.

The overall purpose of the ISCIPEDSs is to standardize the collection and reporting of pain in the SCI population and to encourage

investigators in this field to assess several critical pain-related domains in research studies. Moreover, the use of comparable sets of outcome measures in research studies will increase efficiency and facilitate collaborations, translation, interpretation and application of results.

MATERIALS AND METHODS

The members of the interdisciplinary ISCIPEDS working group have extensive experience in both the clinical management and the clinical research of pain associated with SCI. Each member was appointed by one of the four major organizations with a significant interest in this area of research (that is, International Spinal Cord Society (ISCoS), American Spinal Injury Association (ASIA), American Pain Society (APS) and International Association for the Study of Pain (IASP)). For the ISCIPEDS, one additional psychologist (ER) specializing in medical/clinical psychology and public health was added to the group.

The recommendations of instruments and methods were based on the criteria including (i) their relevance to individuals with SCI and chronic pain, (ii) the existence of published findings supporting the utility of the measures selected in samples of individuals with SCI, and to the greatest extent possible (iii) their availability in the public domain. Consistent with the development of the ISCIPEDS,²² the guiding principle was to prepare a data set that could be used without added cost by clinicians in various settings and countries and without the need of advanced technical equipment. 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 process of the ISCIPEDS followed the steps briefly outlined in Table 1.

RESULTS

The ISCIPEDS includes several important assessment domains that are divided into four sections.

Pain symptoms

This section is intended to assess individual variables related to the temporal course, severity, unpleasantness, tolerability of pain, as well as questionnaires related to the pain type and symptom severity.

Overall pain. These measures are not only intended to provide an overall assessment of pain (including all pain problems) but can also be used for individual pain problems (previously identified by the ISCIPEDS), if appropriate (Appendix A). This section includes the following items:

Number of days with pain in the last 7 days including today. This variable evaluates the constancy of pain by specifying the total number of days with pain during the last 7 days, including today, and the

Table 1 Outline of the development of the final version of the International Spinal Cord Injury Pain Extended Data Set

Steps	
1	The working group of the International Spinal Cord Injury (SCI) Pain Data Set prepared the first version of the ISCIPEDS and a set of instructions (syllabus) primarily via e-mail discussions and also in face-to-face meetings at national and international meetings.
2	The ISCIPEDS was reviewed by members of the International SCI Data Sets Committee. The suggestions from the Committee members were discussed in the working group and appropriate changes made.
3	The ISCIPEDS was reviewed by Members of the International Spinal Cord Society (ISCoS) Executive and Scientific Committees and the American Spinal Injury Association (ASIA) Board. The comments from the Committees and Board members were discussed in the working group and further adjustments were made.
4	Organizations and Societies and individuals with an interest in SCI-related pain were also invited to review and comment on the ISCIPEDS. 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 were made.
5	The ISCIPEDS was reviewed by members of the American Pain Society (APS) Board and the Neuropathic Pain Special Interest Group (NeuPSIG) of the International Association for the Study of Pain (IASP). The comments from the Board and committee members were discussed in the working group and further adjustments were made.
6	To finalize the ISCIPEDS, members of the ISCoS Executive and Scientific Committees, and the ASIA Board reviewed the data set for final approval.

response categories range from 0 = none to 7 = seven days. 'Today' is the day the individual answers the question regardless of the time of day. The duration of pain during the day is not relevant to this question.

Worst 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 Analog Scale, the 0–10 NRS has the most strengths and fewest weaknesses of available measures.²⁸ Moreover, the 0–10 NRS has been recommended by the IMMPACT consensus group for the use in pain clinical trials²⁹ and by the 2006 NIDRR SCI pain outcome measures consensus group.³⁰

The 7-day time frame was selected to balance the need to assess pain over a long enough epoch to capture usual pain, against the need to keep the time frame short enough to maximize recall accuracy. The instruction and end points used were designed to differentiate between pain intensity and pain unpleasantness.³¹ For example, the intensity of pain is related to how strong the pain feels and the unpleasantness of pain is related to how disturbing the pain is. To better understand the difference between pain intensity and unpleasantness, one can substitute the word 'sound' for 'pain'. Pain intensity is analogous to the loudness of a sound, whereas unpleasantness is analogous to the aversiveness of a sound not necessarily related to its loudness.

The worst pain intensity experienced during the last week is rated on a 0–10 NRS (ranging from 0 = 'No pain' to a maximum of 10 = 'The most intense pain imaginable'). Please note that 'last week' specifically refers to *the last 7 days including today*.

Average pain unpleasantness in the last week. Pain is a result of sensory, cognitive and affective dimensions, and the emotional dimension can be evaluated separately from intensity.³² The average pain unpleasantness is rated on a 0–10 NRS (ranging from 0 = 'Not at all unpleasant' to a maximum of 10 = 'The most unpleasant pain imaginable'). Please note that 'last week' specifically refers to *the last 7 days including today*.

Number of days with manageable/tolerable pain in the last 7 days including today. Manageable or tolerable pain is a construct reported by Zelman *et al.*³³ and not specific to pain after SCI. Focus group methodology has suggested that manageable or tolerable pain is pain that permits concentration on something other than the pain, perhaps by using a treatment or self-remedy that 'takes the edge off' pain and allows performance of daily activities or 'getting something done.' Other factors associated with manageable pain are lower levels of negative mood, feeling well enough to socialize and not experiencing excessive adverse effects of ongoing treatments including medication.

This variable specifies the total number of days with pain during the last 7 days, including today, and the response categories ranges from 0 = none to 7 = seven days. 'Today' is the day the individual answers the question regardless of the time of day. The duration of manageable/tolerable pain during the day is not relevant to this question.

Individual pain problems. These measures are intended to be performed for each separate pain problem identified in the ISCI-PBDS (Appendix A).

Pain intensity in present moment. The present pain intensity for (up to) three pain problems (the three worst pain problems respondents experience) is rated on a 0–10 NRS (ranging from 0 = 'No pain' to a maximum of 10 = 'The most intense pain

imaginable'). Please note that 'present' specifically refers to this moment.

How long does your pain usually last? This variable provides an estimate of the duration of pain. Some pain types are very brief and may be felt several times per day. This question refers to the duration of each separate pain event. Response categories are the following: 1 min or less; more than 1 min but less than 1 h; at least 1 h but less than 24 h; at least 24 h but not continuous; constant or continuous; and unknown. 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 during the day is the pain most intense? This variable identifies the diurnal peak in pain intensity. Response categories are the following: Morning, Afternoon, Evening, Night and Unpredictable; pain is not consistently more intense at any one time of day. 'Morning' is between 6.01 am and Noon (06.01 and 12.00); 'Afternoon' is between Noon and 6.00 pm (12.01 and 18.00); 'Evening' is between 6.01 pm and Midnight (18.01 and 24.00); 'Night' is between Midnight and 6.00 am (00.01 and 06.00).

Recommended questionnaires. These questionnaires are intended to provide supplemental information as appropriate for a specific purpose or interest (Table 2).

Sensory signs

These assessments are intended to detect and quantify common sensory abnormalities in a painful area at or below the level of injury (Appendix B). The sensory bedside assessment includes abnormal responses to light touch, pinprick and cold sensation compared with a non-affected control area above the level of injury. The sensory measures were intentionally selected to be appropriate for bedside examination and to detect and quantify sensory abnormalities, that is, *mechanical allodynia* (pain in response to an innocuous mechanical stimuli), *mechanical hyperalgesia* (exaggerated response to a painful mechanical stimulus) and *thermal allodynia* (pain in response to an innocuous thermal stimuli) commonly associated with neuropathic pain types.

Dynamic light touch. Dynamic light touch can be assessed by light stroking the skin with an innocuous moving stimuli, for example, a cotton wisp, cotton wool tip or a brush (for example, Smedic standardized brush, Sweden), of approximately 2 cm with a speed of 1–2 cm s⁻¹.³⁴ Sensation is rated as *normal* (compared with a control area in a non-affected skin area), *absent* (no sensation felt), *hypoesthesia* (decreased sensation compared with control area), *hyperesthesia* (increased sensation compared with control area), *allodynia* (light touch provokes pain) or *other* (changed sensation that cannot be categorized otherwise). If allodynia is present, the pain is rated on a 0–10 NRS (ranging from 0 = 'No pain' to a maximum of 10 = 'Pain as bad as you can imagine').

Pinprick. Pinprick sensation can be assessed by pricking the skin with a disposable safety pin or calibrated monofilaments, for example, Semmes-Weinstein monofilaments or other custom-made weighted pinprick stimuli (Rolke *et al.*³⁴). Pinprick is a nociceptive stimulus that normally evokes pain. Sensation is rated as *normal* when pain evoked in the painful area is no different than in the control area, *absent* when there is no evoked pain sensation, *hypoalgesia* when pain evoked in the painful area is less intense than in the control area, *hyperalgesia* when pain evoked in the painful area is more intense than in the control

Table 2 Pain symptoms: recommended questionnaires for the assessment of pain type or pain symptom severity

<i>Domain</i>	<i>Instrument</i>	<i>Construct measured</i>	<i>Intended population</i>	<i>Mode of administration</i>	<i>Length</i>	<i>References</i>	<i>Availability</i>
Pain type (screening only—not for individual assessment)	Douleur Neuropathique 4 questions (DN4)	Neuropathic pain type	General	Self or Examiner	7 items for Self; 10 items for Examiner	Bouhassira, <i>et al</i> . ⁴⁰	Free for non-funded academic users. Visit: www.proqolid.org/instruments/neuropathic_pain_4_questions_dn4
	Spinal Cord Injury Pain Instrument (SCIPI)	Neuropathic pain type	SCI	Self or Examiner	4 or 7 items	Norbrink ⁴¹	Free for use. Items can be found in the article by Bryce <i>et al</i> .
Pain quality	Pain Quality Assessment Scale (PQAS)	Pain symptom severity	General	Self	20 items	Bryce <i>et al</i> . ⁴²	Free for non-funded academic users. Visit: www.proqolid.org/instruments/pain_quality_assessment_scale_and_revised_pain_quality_assessment_pqas_r
	Short form McGill Pain Questionnaire 2 (SF-MPQ-2)	Pain symptom severity	General	Self	22 items	Jensen <i>et al</i> . ⁴³	Free for non-funded academic users. Visit: www.proqolid.org/instruments/pain_quality_assessment_pqas_r
	Neuropathic Pain Symptom Inventory (NPSI)	Pain symptom severity	Neuropathic pain	Self	12 items	Dworkin <i>et al</i> . ⁴⁴	Free for academic users if used in studies not funded by commercial companies. Visit: www.proqolid.org/instruments/short_form_mcgill_pain_questionnaire_sf_mpq_2?fromSearch=yes&text=yes
	Neuropathic Pain Questionnaire (NPQ)	Pain symptom severity	Neuropathic pain	Self	12 items	Bouhassira <i>et al</i> . ⁴⁵	Copyrighted. Free for non-funded academic users. Visit: www.proqolid.org/instruments/neuropathic_pain_symptom_inventory_npsi
	painDETECT (PD-Q)	Pain symptom severity	Neuropathic pain	Self	10 items	Krause and Backonja ⁴⁶	Free for use. Items can be found in the article by Krause and Backonja.
						Freyhagen <i>et al</i> . ⁴⁷	Copyrighted. Free. Visit: www.pfizerpatientreportedoutcomes.com/therapeutic-areas/pain/neuropathic-pain

Abbreviation: SCI, spinal cord injury.

Table 3 Psychosocial domains and comorbid conditions: recommended questionnaires

Domain	Instrument	Construct measured	Intended population	Mode of administration	Length	References	Availability
Depression	Patient Health Questionnaire-9 (PHQ-9)	Depression symptoms	Primary care; core measure in SCI model system	Self	9 items; 8-item and 2-item versions available	Spitzer <i>et al.</i> ⁴⁸ Kroenke <i>et al.</i> ⁴⁹	Free via Pfizer: www.phqscreeners.com
	PROMIS Depression-Short Form	Depression; minimizes somatic confounds	General	Self	8 items	Amtmann <i>et al.</i> ⁵⁰ Amtmann <i>et al.</i> ⁵¹	Commercial users and corporations (for-profit and not-for-profit) are expected to pay distribution fees for the use of PROMIS measures. However, PROMIS can be used cost-free by academic researchers. Academic Researchers interested in accessing PROMIS measures without cost can contact PROMIS for more information (www.nihpromis.org). Free via Pfizer: www.phqscreeners.com
Anxiety	Generalized Anxiety Disorder-7 (GAD-7)	Anxiety symptoms	Primary care	Self	7 items	Spitzer <i>et al.</i> ⁵²	Free via Pfizer: www.phqscreeners.com
	PROMIS Anxiety-Short Form	Anxiety symptoms	General	Self	8 items	Amtmann <i>et al.</i> ⁵⁰	Commercial users and corporations (for-profit and not-for-profit) are expected to pay distribution fees for the use of PROMIS measures. However, PROMIS can be used cost-free by academic researchers. Academic Researchers interested in accessing PROMIS measures without cost can contact PROMIS for more information (www.nihpromis.org). Items can be found in the article by Vlaeyen <i>et al.</i>
Quality of Life/ Satisfaction with Life	Tampa Scale of Kinesiophobia (TSK)	Fear of pain/re-injury	Developed for low back pain by Miller, Kopri, and Todd, in 1991 (unpublished report); used across chronic pain populations	Self	17 items	Vlaeyen <i>et al.</i> ⁵³	
	PTSD Checklist Civilian Version (PCL-C)	PTSD symptoms	General	Self	20 items	Weathers <i>et al.</i> ⁵⁴	To obtain this scale, visit the VA National Center for PTSD website to complete the online request form: www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp To obtain licensing, visit: www.sf-36.org
	Short-Form-36 (SF-36)	Perceived functional health and well-being	General medical	Self or Examiner	36 items; 8 sub-scales	Ware <i>et al.</i> ⁵⁵	
	EuroQoL-5 Dimension Questionnaire (EQ-5D)	Health-related quality of life	General medical	Self	5 items	EuroQoL Group ⁵⁶	To register study and submit licensing fees (if applicable), visit: www.euroqol.org For direct access, visit: www.uic.edu/orgs/qli/questionnaires/questionnaire-home.htm Items can be found in the article by Charlifue <i>et al.</i>
Resilience	Quality of Life Index-SCI version (QLI-SCI)	Satisfaction and quality of life	Spinal cord injury	Self or Examiner	37 items	May and Warren ^{57,58}	
	International SCI Basic Data Set-QoL items	General quality of life; satisfaction with physical and mental health	Spinal cord injury	Self	3 items	Charlifue <i>et al.</i> ⁵⁹	
Mood	Connor Davidson Resilience Scale (CD-RISC)	Psychological resilience	General	Self	25 items; 10-item, 2-item versions available	Connor and Davidson ⁶⁰	To obtain any version of the scale, a request form can be found at: www.cd-risc.com
	Positive and Negative Affect Schedule (PANAS)	Positive and negative affect	General	Self	20 items	Watson <i>et al.</i> ⁶¹	Item can be found in the article by Watson <i>et al.</i>
Participation	Craig Handicap Assessment and Reporting Technique (CHART)-SF	Community integration and independence	Variety of physical rehabilitation populations	Self or Examiner	19 items for CHART-SF	Whiteneck <i>et al.</i> ⁶²	Available via Craig Hospital, visit: www.craighospital.org/uploads/CraigHospital.CHART-Manual.pdf

area, and *other* (changed sensation that cannot be categorized otherwise). If hyperalgesia is present, the pain is rated on a 0–10 NRS (ranging from 0 = ‘No pain’ to a maximum of 10 = ‘Pain as bad as you can imagine’).

Cold. Cold sensation can be assessed using a cold thermoroller (Somedic Sweden) of 20 or 25 °C, a piece of cold metal or an acetone droplet. For determination of cold detection and cold pain thresholds, thermal tests can be performed using thermodes (TSA, Medoc, Israel or MSA, Somedic, Sweden); see Rolke *et al.*³⁴ Sensation rated as *normal* (compared with a control area in a non-affected skin area), *absent* (no sensation felt), *hypoesthesia* (decreased sensation compared with control area), *hyperesthesia* (increased sensation compared with control area), *allodynia* (an innocuous cold stimuli provokes pain) or *other* (changed sensation that cannot be categorized otherwise). If allodynia is present, the pain is rated on a 0–10 NRS (ranging from 0 = ‘No pain’ to a maximum of 10 = ‘Pain as bad as you can imagine’). Because environmental temperature may affect skin temperature and thus thermal testing it is important to record the room temperature when testing.

Treatments

Information regarding a person’s previous and current experience with various treatment interventions is important both for the planning of clinical studies and facilitates screening of potential participants for a clinical trial (Appendix C). The ISCIPEDES is designed to capture information regarding both past (last 12 months) and current treatments. Because of possible recall biases, the effectiveness of past treatments are not captured in detail but only whether a person has had the treatment in the past 12 months and if it was helpful or not, or unknown. For current, ongoing treatments, more details are captured, including the dose (if appropriate), frequency of treatment, any adverse effects and a rating of the person’s global impression of change.²⁷

Past treatment. This variable specifies treatments for pain received in the past and treatment response. The respondent is to indicate (‘Check’) each treatment that they have received in the past for their pain. Where possible, the respondent also indicates whether it was helpful (‘Yes’) or not helpful (‘No’). If the respondent cannot remember or is uncertain about effectiveness, they indicate ‘Uncertain’. This section can be completed on one form to indicate treatments and responses for overall pain or on multiple forms for each specific pain type. Because of the fact that the management of pain in SCI is challenging with a wide range of treatments being tried that include *pain medications*—such as opioids, non-steroidal anti-inflammatory drugs, acetaminophen, tricyclic antidepressants and anticonvulsants—*physical therapy and alternative treatment approaches*—such as massage, marijuana, acupuncture and hypnosis,^{35–37} *self-management*,³⁸ *relaxation and psychotherapy*—and *procedural and surgical interventions*, the list provided is very long to cover the most common options.

Current treatment. This variable specifies the current treatments for pain, timing of treatment, response and side effects. The respondent is to indicate current treatments for pain including dose (‘Dose’), if a medication, and frequency (‘How often’). Effectiveness is assessed using the Patient Global Impression of Change (‘PGIC’).^{27,30} Any side effects or adverse events (‘Side effects/adverse events’) related to the treatment are also to be noted. This section can be completed on one form to indicate treatments and responses for overall pain or on multiple forms for each specific pain.

Psychosocial domains and comorbid conditions

This section is intended to assess outcomes, mediating factors or comorbid conditions (for example, depression, anxiety, quality of life) (Table 3). The psychosocial domains that researchers should consider assessing in their studies of SCI pain include outcome variables, mediating variables and comorbid conditions that would be of interest to those seeking to develop, test or expand biopsychosocial models of SCI-related pain. The ISCIPEDES working group selected those domains and identified potential measures of those domains, as a function of (i) their relevance to individuals with SCI and chronic pain and (ii) the existence of published findings that support the utility of the measures selected in samples of individuals with SCI, and as much as possible (iii) their availability in the public domain.

DISCUSSION

There is a vast array of outcomes measures that have been recommended for use in neuropathic pain research³⁹ and in SCI pain research specifically.³⁰ A systematic review of all such measures is beyond the scope of the ISCIPEDES. Although not all of the recommended measures included in the ISCIPEDES were developed specifically for individuals with SCI, it was the consensus of the expert panel that the measures selected are those that would be most useful in SCI populations. More research will be needed to help establish their psychometric properties in individuals with SCI, and, pending the findings from this research, future recommendations may differ somewhat from our current ones. We recommend that researchers carefully examine the appropriateness of any measure they might consider using with respect to utility in the SCI chronic pain population. For example, standard measures for pain-related outcomes may have content that can be inappropriate for people with SCI (for example, pain intensity with walking) or that can be misleading if endorsed (for example, unusual sensory experiences). The instruments in the ISCIPEDES were selected in part to minimize that problem. The reader is also referred to the SCIRE (www.scireproject.com) and NINDS CDEs (www.commondataelements.ninds.nih.gov/SCI.aspx) websites where an extensive number of outcome measures are evaluated with respect to their applicability and psychometric properties. Although the measures reviewed in these loci are not focused only on pain per se, they offer other resources for SCI researchers who want to use the most valid scales, particularly those that are being proposed for adoption across studies.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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APPENDIX A

PAIN SYMPTOMS

A. Overall pain

Number of days with pain in the last 7 days including today

none; 1; 2; 3; 4; 5; 6; 7; unknown

Worst pain intensity in the last week

0 = no pain; 10 = the most intense pain imaginable:

0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Average pain unpleasantness in the last week

0 = not at all unpleasant; 10 = the most unpleasant pain imaginable

0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Number of days with manageable/tolerable pain in the last 7 days including today

none; 1; 2; 3; 4; 5; 6; 7; unknown

B. Individual pain problems

Pain intensity in present moment

0 = no pain; 10 = the most intense pain imaginable:

0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

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)

APPENDIX B

SENSORY SIGNS

Dynamic light touch

At level of injury

Normal

Absent Hypoesthesia Hyperesthesia Allodynia Other _____

If allodynia, rate the intensity: 0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Below level of injury

Normal

Absent Hypoesthesia Hyperesthesia Allodynia Other _____

If allodynia, rate the intensity: 0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Notes: Left or right side can be noted here

Pinprick

At level of injury

Normal

Absent Hypoalgesia Hyperalgesia Other _____

If hyperalgesia, rate the intensity: 0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Below level of injury

Normal

Absent Hypoalgesia Hyperalgesia Other _____

If hyperalgesia, rate the intensity: 0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Notes: Left or right side can be noted here

Cold

At level of injury

Normal

Absent Hypoesthesia Hyperesthesia Allodynia Other _____

If allodynia, rate the intensity: 0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Below level of injury

Normal

Absent Hypoesthesia Hyperesthesia Allodynia Other _____

If allodynia, rate the intensity: 0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10

Notes: Left or right side can be noted here

APPENDIX C

TREATMENTS

Past treatments

This section can either be filled out for overall pain or for each separate pain component.

Please indicate previous treatments (over the last 12 months) and whether the treatment was helpful.

Please indicate all treatments you have had (over the last 12 months)		Was the treatment helpful?		
Check		Yes	No	Uncertain/ Unknown
	Physiotherapy			
	Aerobic exercise (low to moderate intensity)			
	Passive exercise (non-weight bearing or against resistance, e.g., stretching)			
	Resistance exercise (strength building, e.g., weight training)			
	Position adjustment (in wheelchair, bed, etc.)			
	Joint mobilisation/manipulation (incl. chiropractic, osteopathic)			
	Other, specify			
	Passive and stimulation therapy			
	Massage			
	Acupressure			
	Transcutaneous electrical nerve stimulation (TES, TNS, TENS)			
	Ultrasound			
	Laser			
	Heat therapy (incl. heat-packs, shortwave)			
	Other, specify			
	Relaxation and Psychotherapy			
	Bio-feedback/relaxation training			
	Relaxation (relaxation techniques, e.g., muscle relaxation or deep breathing)			
	Meditation (meditation techniques, e.g., concentrative, religious)			
	Mindfulness meditation (meditation using mindfulness technique)			
	Hypnosis			
	Cognitive/Behavioural therapy			
	Other psychotherapy			
	Other, specify			
	Oral and topical medication			
	Antidepressants (e.g., amitriptyline, nortriptyline, duloxetine)			
	Antiepileptics (e.g., pregabalin, gabapentin, carbamazepine)			
	Tramadol			
	Opioids (e.g., morphine, oxycodone, buprenorphine, fentanyl)			
	Cannabinoids (e.g., marijuana)			
	Acetaminophen/paracetamol			
	NSAIDs/aspirin e.g., ibuprofen, naproxen, celecoxib, meloxicam			
	Benzodiazepines e.g., diazepam			

	Antispasticity drugs e.g., baclofen, tizantidine			
	Topical anaesthetics e.g., lidocaine/lignocaine			
	Topical capsaicin			
	Other, specify			
	Procedural interventions			
	Trigger point injection/Dry needling			
	Acupuncture			
	Peripheral nerve/motor point block (incl. alcohol, phenol, steroid, anaesthetic blocks, botulinum toxin injection)			
	Joint injections (incl. shoulder, knee, facet joint, ilio-sacral)			
	Intravenous lidocaine			
	Intravenous ketamine			
	Epidural block			
	Intrathecal pumps (incl. morphine, ziconotide, clonidine, baclofen)			
	Spinal cord stimulator			
	Transcranial brain stimulation (tDCS or rTMS)			
	Percutaneous Peripheral Nerve Stimulation			
	Other, specify			
	Surgical interventions			
	Dorsal root entry zone lesion			
	Spinal surgery (e.g., stabilization, rod removal, untethering of cord, shunt)			
	Deep brain stimulation (implanted brain electrodes)			
	Other, specify			
	Other treatments			
	Specify			

Current treatments: For examples of treatments please see previous section (*Past treatments*)

Treatment	Dose	How often	PGIC*	Side effects/adverse events

***PGIC - Patient Global Impression of Change** Indicate the effect of the treatment on your global wellbeing using one of the following descriptors:
Very much improved (1) – Much improved (2) – Minimally improved (3) – No change (4) – Minimally worse (5) – Much worse (6) – Very much worse (7)