Care CDE Structure

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
Participant Medical History	Participant History	Medical History	Prior to SCI	Care	International SCI Clinical Record (attached: International SCI Clinical Record_Relevant Questions)	Charlson Comorbidity Index	NIH Medical History CDE Plus standard questions: (attached: F0013_Medical_History_v5.0_20130716)	NIH Medical History CDE and include the following Int SCI Data Set questions from Int SCI Clinical Record (questions 2.1 to 2.6): (1) Cardiovascular function before SCI (2) Pulmonary conditions diagnosed before SCI (3) Endocrine and metabolic diagnosed before SCI (4) Neuro-musculoskeletal history before SCI (5) Urinary tract impairment before SCI (6) Gastrointestinal or anal sphincter dysfunction unrelated to SCI	S - NIH CDE option E - Int SCI Data Set related questions
		Prior Medications	Prior to SCI	Care	NA	NA	NIH Prior and Concomittant Medications CDE (attached: Prior_and_Concomitant_Medications_SCI)	NIH Prior and Concomittant Medications CDE	S - NIH CD E - Int SCI Data Set related questions for a specific study
		Smoking	Care		International SCI Clinical Record (attached: International SCI Clinical Record_Relevant Questions)	NA	NIH CDE RFQ-U Smoking and Tobacco	Int SCI Clinical Record (question 13.1): (1) smoking history	S
		Drug Use	Care		NA	NA	NIH Drug Abuse CDE_NEW (attached: F0378_Substance_Abuse_Questions_from_the_TBI_Model_Systems_Database)	NIH Drug Abuse CDE_NEW question (1) drug use (292a1)	S
		Diet	Care		NA	Diet Questionnaire	WHO - ASSIST 3.0 Questionnaire (attached: F0787_Food_Frequency_Question	NIH CDE Food Frequency Questionnaire	E
			Care		International SCI Clinical Record (attached: International SCI Clinical Record_Relevant Questions)	CAGE Questionnaire	The Alcohol Use Disorders Identification Test (AUDIT) or WHO - ASSIST V3.0	International SCI Clinical Record (questions 13.2, 13.3): (1) how often do you have a drink containing alcohol (2) How often do you have five or more drinks on one occasion	S
		Behavioral History	Alcohol	Care	International SCI Clinical Record (attached: International SCI Clinical Record_Relevant Questions)	CAGE Questionnaire	The Alcohol Use Disorders Identification Test (AUDIT) or WHO - ASSIST V3.0	The Alcohol Use Disorders Identification Test (AUDIT)	E
	Family History	Family History	NA	Care	NA	NA	NIH Family History CDE (attached: F0011_Family History)	NIH Family History CDE	E

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
Injury and Pre-Hospital Care	History of Injury	Non-Traumatic Etiology	NA	Care	**(1) International SCI Core Data Set** (attached: Current International SCI Data Sets_Links) **(2) International SCI Non-Traumatic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Non-Traumatic Extended Data Set	E
		Timeframe of onsent (Non-traumatic SCI)	NA	Care	**International SCI Non-Traumatic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Non-Traumatic Data Set question (1) Timeframe of Onset (response options: acute; sub-acute; prolonged; lengthy)	S
		Date of injury (Traumatic SCI)	Date	Care	**International SCI Core Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	Date of injury	C
		Time of onsent (Traumatic SCI)	Time	Care	**International SCI Core Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	Add new data element (1) Time of injury	S
	Pre-Hospital Care		Other Associated Injuries	Care	**International SCI Core Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	Int SCI Core Data Set question (1) Associated injuries	S
		Pre-Hospital Assessment	Other Associated Injuries	Care	**International SCI Core Data Set** (attached: Current International SCI Data Sets_Links)	(AIS-90) (http://www.aaam.org/about-ais.html) (attached: Injury_severity_scoring_Critical CareSummary) **(2) Injury Severity Scale (ISS)** (attached:	**NIH Pre-Hospital Emergency Medical Service** (attached: F1158_Pre-Hospital_Emergency_Medical_Service_EMS_Course_v2.0_20130723)	NIH Pre-Hospital Assessment (modified form F1158 - remove question #9 and delete GCS and LAMS) Suggest 3 measures: (1) AIS - report to 9 levels (2) ISS (3) GCS	S (all)
		Physical Exam	NA	Care	NA	NA	**NIH Physical Exam_Stroke or TBI**	Link to relevant International SCI Data Sets included in the Clinical Assessment Questionnaire (cardiovascular, respiratory, gastrointestinal, genitourinary, musculskeletal, skin, endocrine)	S
		Spinal Column Diagnosis	NA	Care	**International SCI Spinal Column Injury Basic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Spinal Column Injury Basic Data Set all questions.	S
			Current use of ventilatory assistance	Care	**International SCI Pulmonary Function Basic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Pulmonary Function Basic Data Set question (1) Ventilatory assistance	S

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
		Pulmonary Assessment	Sleep Apnea	Care	NA	Berlin questionnaire (attached: see Berlowitz questionnaire)	NA	Berlin questionnaire	E
		Swallowing Assessment	Dysphagia	Care	NA	NA	NA	Consider adding: ASHA NOMS Swallowing Scale (clinical assessment) - this was removed by WG Swallowing Disturbance questionnaire (patient-reported) - this was selected by WG	E
		Cardiovascular Assessment	Cardiovascular physical assessment	Care	International SCI Cardiovascular Function Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	International Cardiovascular Function Basic Data Set questions: (1) Events related to CV function after SCI (2) CV after SCI within last 3 months	S
			Urinary tract assessment	Care	International SCI Lower Urinary Tract Function Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	International Lower Urinary Tract Basic Data Set questions: (1) Awareness of the need to empty the bladder (2) Bladder emptying (3) Avg voluntary bladder emptying (4) Any involuntary leakage (5) Collecting appliances for urinary incontinence (6) Any change in urinary symptoms in past year	S
			Urinary tract infections	Care	International SCI Urinary Tract Infection Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Urinary Tract Infection Basic Data Set all questions	S
		Bladder Assessment	Urodynamic assessment	Care	International SCI Urodynamic Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	International Urodynamic Basic Data Set all questions	S
			Basic assessment	Care	International SCI Bowel Function Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	Int SCI Bowel Basic Data Set questions (1) Awareness of need to defecate (2) Defecation method (3) Avg time required for defecation (4) Frequency of defecation (5) Freq of incontinence (6) Need to wear a pad or plug (7) Medication affecting bowel function (8) Perianal problems	S
		Bowel Assessment	Expanded assessment	Care	International Bowel Function Extended Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	Int SCI Bowel Function Extended Data Set -all questions	E

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
Assessments and Examinations	Clinical Assessment		Skin - pressure ulcer screening	Care	NA	(1) Norton Measure (2) Braden Scale (http://www.in.gov/isdh/files/Braden_Scale.pdf) (3) Abruzzese Scale (4) Gosnell Measure (5) Waterlow Scale (6) SCI Pressure Ulcer Scale - Acute (SCIPUS-A) (7) SCI Pressure Ulcer Scale (SCIPUS) (http://www.rehabmeasures.org/Lists/RehabMeasures/DispF	NA	Suggest: (1) SCIPUS (2) Braden Scale	E
		Skin and Thermoregulation Assessment	Skin - assessment	Care	International SCI Skin and Thermoregulation Basic Data Set (attached: Current International SCI Data Sets_Links)	(1) Stirling's Pressure Ulcer Severity Scale (2) Skin Management Needs Assessment Checklist	NA	International SCI Skin and Thermoregulation Function Basic Data Set questions (1) Any pressure ulcer present (2) Date of appearance of the ulcer (3) Any other pressure ulcer in the last 12 months	S
			Thermoregulation	Care	International SCI Skin and Thermoregulation Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Skin and Thermoregulation Function Basic Data Set qustions (1) Thermoregulation history after SCI	S
		Musculoskeletal Assessment	NA	Care / Neurological (will include spasticity assessments)	International SCI Musculoskeletal Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Musculoskeletal Basic Data Set questions (1) Fractures since SCI (2) Heterotopic ossification (3) Contracture (4) Degenerative changes (5) SCI related neuromuscular scoliosis (6) Method of assessment when scoliosis present (7) Other musculoskeletal problems (8) Does any of the musculoskeletal challenges interfere with ADL (9) Presence of spasticity/spasms	S
		Endocrine and Metabolic Assessment	NA	Care	International SCI Endocrine and Metabolic Basic Data Set (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Endocrine and Metabolic Basic Data Set questions (1) Endocrine and metabolic conditions diagnosed after SCI (2) Gonadal status	S

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
			Male	Care	**International SCI Male Sexual Function Basic Data Set** (attached: Current International SCI Data Sets_Links)	**(1) Sexual Attitude and Information Questionnaire (SAIQ)**	NA	International SCI Male Sexual Function Basic Data Set questions (1) Interest in discussing sexual issues (2) Sexual issues unrelated to SCI (3) Sexual issues related to SCI (4) Psychogenic erection (5) Reflex erection (6) Ejaculation (7) Orgasmic function	S
		Sexual Function Assessment	Female	Care	**International SCI Female Sexual and Reproductive Function Basic Data Set** (attached: Current International SCI Data Sets_Links)	**(2) Knowledge, Comfort, Approach and Attitude towards Sexuality Scale (KCAASS) (3) Sexual Behaviour Scale (SBS) (4) Sexual Interest and Satisfaction Scale (SIS)**	NA	International SCI Female Sexual and Reproductive Function Basic Data Set questions (1) Interest in discussing any sexual issues (2) Sexual issues unrelated to SCI (3) Sexual dysfunction related to SCI (4) Psychogenic arousal (5) Reflex genital arousal (6) Orgasmic function (7) Menstruation	S
		Sleep Assessment	NA	Care	NA	**Sleep Medicine Criteria (2) Athens Insomnia Scale (3) Berlin Questionnaire (4) Epworth Sleepiness Score (5) Functional Outcomes of Sleep Questionnaire (6) Pittsburgh Sleep Quality**	NA	(1) American Academy of Sleep Medicine Criteria (2) Berlin Questionnaire (3) Epworth Sleepiness Score (4) Functional Outcomes of Sleep Questionnaire (5) Pittsburgh Sleep Quality Index	(1) American Academy of Sleep Medicine Criteria - S (2) Berlin Questionnaire - E (3) Epworth Sleepiness Score - E (4) Functional Outcomes of Sleep Questionnaire - E (5) Pittsburgh Sleep Quality Index - E
		Other Diagnoses	NA	Care	NA	NA	NIH CDE	Use NIH CDE question	S
		Height and Weight	NA	Care	**(1) International SCI Endocrine and Metabolic Basic Data Set** (attached: Current International SCI Data Sets_Links) **(2) International SCI Clinical Record** (attached: International SCI Clinical Record_Relevant Questions)	NA	NA	International SCI Endocrine and Metabolic Basic Data Set questions (1) Height and weight (see also Int SCI Clinical Record question A.1 and A.2)	S

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
	Vital Signs and Body Measures	Pulse and Blood Pressure	NA	Care	**(1) International SCI Cardiovascular Function Basic Data Set** (attached: Current International SCI Data Sets_Links) **(2) International SCI Clinical Record** (attached: International SCI Clinical Record_Relevant Questions)	NA	NA	International Cardiovascular Function Basic Data Set questions: (1) Time performed (2) Position during testing (3) Devices during testing (4) Pulse (5) Blood pressure (see also Int SCI Clinical Record question B.1, B.2, B.3, B.4, B.5 and B.6). Also added mean arterial pressure as recommnded by Brian Kwon.	S
		Temperature	NA	Care	(1) **International SCI Skin and Thermoregulation Basic Data Set** (attached: Current International SCI Data Sets_Links) **(2) International SCI Clinical Record** (attached: International SCI Clinical Record_Relevant Questions)	NA	NA	International SCI Skin and Thermoregulation Function Basic Data Set qustions (1) Time performed (2) Temperature (see also Int SCI Clinical Record question C.1, C.2, C.3, and C.4)	S
		Pulmonary Function Tests	NA	Care	Set (attached: Current International SCI Data Sets_Links) **(2) International SCI Clinical Record**	NA	NA	(1) Pulmonary function tests (see also Int SCI Clinical Record question D.1 and D.2). Also added 02 saturation as recommnded by Brian Kwon.	S
		Urodynamic assessment	NA	Care	**International SCI Urodynamic Basic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International Urodynamic Basic Data Set all questions	S
	Lab Tests	Serum Lipid Profile	NA	Care	(1) **International SCI Endocrine and Metabolic Basic Data Set** (attached: Current International SCI Data Sets_Links) **(2) International SCI Clinical Record** (attached: International SCI Clinical Record_Relevant Questions)	NA	NA	International SCI Endocrine and Metabolic Basic Data Set questions (1) Fasting serum lipid profile performed in the last year (see also Int SCI Clinical Record question E.1 and E.2)	S
		Other Standard Tests	NA	Care	NA	NA	NIH CDE Laboratory Tests Stroke (attached: Laboratory Tests_Stroke)	Use NIH CDE Laboratory Tests Stroke	E
	Imaging	Urinary Tract	NA	Care	**International SCI Urinary Tract Imaging Basic Data Set** (attached: International SCI Clinical Record_Relevant Questions)	NA	NA	Include as part of Care and Comorbidity WG since it will not be included by Imaging WG.	S
		Concomittant Medications	Following SCI	Care	**International Cardiovascular Function Basic Data Set** **International Lower Urinary Tract Function Basic Data Set** **International Bowel Function Basic Data Set** (attached: International SCI Clinical Record_Relevant Questions)	**Treatment Satisfaction Questionnaire for Medication**	**NIH Prior and Concomittant Medications CDE** (attached: Prior_and_Concomittant_Medications_SCI)	NIH Prior and Concomittant Medications CDE. Added the medication questions from the International SCI Data Sets (International SCI Clinical Record questions 14.1, 14.2, 14.3, 14.4). Also added question on vasopressor use as recommnded by Brian Kwon. Added question on administration of steroids from the Rick Hansen SCI Registry based on review of SCI registry forms.	S

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
Treatments and Interventions	Treatments and Interventions	Surgical and Procedural Interventions	Spinal Column Interventions	Care	**International SCI Spinal Interventions and Surgical Procedures Basic Data Set** (attached: 20131012_Int_SCI_Spinal_Interventions Basic Data Set Version 1.0)	NA	NA	International SCI Spinal Interventions and Surgical Procedures Basic Data Set all questions	S
			Urinary Tract	Care	**International SCI Lower Urinary Tract Function Basic Data Set; International SCI Urinary Tract Infection Basic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International Lower Urinary Tract Function Basic Data Set questions (1) Surgical procedures on urinary tract	S
			Bowel	Care	**International SCI Bowel Function Basic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Bowel Function Basic Data Set question (1) Surgical procedures on the gastrointestinal tract	S
			Skin	Care	**International SCI Skin and Thermoregulation Basic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Skin and Thermoregulation Basic Data Set questions (1) Surgical treatment (2) Surgical treatment of any other pressure ulcer in the past 12 months	S
			Musculoskeletal	Care / Neurological	**International SCI Musculoskeletal Basic Data Set** (attached: Current International SCI Data Sets_Links)	NA	NA	International SCI Musculoskeletal Basic Data Set questions (1) Surgical treatment of the scoliosis (2) Treatment for spasticity within the past 4 weeks	S
			Upper Extremity	Care	**SCI Upper Extremity Basic Data Set**	NA	NA	International SCI Upper Extremity Basic Data Set questions (1) upper extremity / hand reconstructive surgery (2) Performed Upper Extremity / Hand Reconstructive Surgery	S
			Open Text	Care	NA	NA	**NIH CDE TBI Surgeries and Other Procedures** (not directly related to SCI or spinal column) (attached: F1180_Surgical_and_Procedural_Interventions_v2.0_20130723)	Include the first page from the form (F1180)	S
	Other Investigational Clinical Treatments	TBD	TBD	No working group at this time	NA	NA	**NIH General CDE Supplemental Therapies Data Elements** (http://www.commondataelements.ninds.nih.gov/General.aspx#tab=Data_Standards)	Add RHSCIR question regarding other clinical trials	S

Care CDE Structure

SCI Main Categories	Domains	Sub-domains	Sub-domains areas	Relevant SCI Working Group in charge of sub-domain	Relevant Int. SCI Data Sets	Relevant Other Instruments (from SCIRE and others)	Relevant CDES (e.g. other health conditions)	Recommendation	Recommendations (Core; Supplementary; Exploratory)
	Rehabilitation or Other Therapies	TBD	TBD	Care	NA	SCIRehab taxonomies	NIH CDE TBI Therapies - (1) Post Discharge/Outpatient (2) Therapy Intensity Level	Added all the taxonomies from SCIRehab, including: nursing, PT, OT, recreation, social work/case management, speech language, psychology (note respiratory and physiatry did not have published taxonomies).	E
	In-Patient Hospital Management	Acute Admission/Discharge	NA	Care	International SCI Core Data Set (attached: Current International SCI Data Sets_Links)	Post Acute Care Admission Continuity Assessment Record and Evaluation Tool	NIH CDE TBI ER Destination	Draft form based on NIH forms, Int SCI Core Data Set and Rick Hansen SCI Registry.	S
		Rehab Admissin/Discharge	NA	Care	International SCI Core Data Set (attached: Current International SCI Data Sets_Links)	Post Acute Care Admission Continuity Assessment Record and Evaluation Tool	NIH CDE TBI Discharge Status	Draft form based on NIH forms, Int SCI Core Data Set and Rick Hansen SCI Registry.	S
	Out-Patient Hospital Management	Out-Patient Hospital Treatment	NA	TBD	NA	NA	NIH Post Discharge Out-Patient Treatment (attached: F0336_Post_Discharge_Outpatient_Treatment_v3.0_20130725)	TBD	TBD
	Adverse Events	During Initial Hospitalization	Adverse Events	Care	NA	Spine Adverse Events Scale (SAVES) (attached: Street_2013)	NIH General CDE Adverse Events (attached: Adverse Events)	NIH Adverse Events - Adverse Events	S