INTERNATIONAL SPINAL CORD INJURY PHYSICAL THERAPY – OCCUPATIONAL THERAPY BASIC DATA SET (Version 1.0)

The working group consists of:

Kim Anderson-Erisman, Co-chair
Edelle Field-Fote, Co-chair
Fin Biering-Sørensen
Anne Bryden
Lisa Harvey
Linda Jones
MJ Mulcahey
Sara Mulroy
Vanessa Noonan
Marcel Post
Ruediger Rupp
Mary Schmidt-Read

The purpose of the International Spinal Cord Injury (ISCI) Physical Therapy – Occupational Therapy (PT-OT) Basic Data Set (BDS) is to standardize the collection and reporting of the content of PT-OT sessions that are conducted as part of or in conjunction with interventional clinical trials in accordance with the purpose and vision of the International Spinal Cord Injury Data Sets (Biering-Sørensen et al., 2006).

The ISCI PT-OT BDS represents components of interventions that commonly are used in physical and occupational therapy sessions during SCI rehabilitation. It is important to note that therapy provided in the clinical rehabilitation setting is not uniform. Rather, it is tailored to the individual's needs and, thus, variable across persons (Franz et al., 2018). When research interventions are being tested in the setting of clinical rehabilitation, this variability may influence outcomes being assessed. The intent of the ISCI PT-OT BDS is to track (not prescribe) PT and OT rehabilitation interventions that possibly could influence outcomes commonly assessed in clinical trials. Only therapies with a potential impact on the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI), Functional Independence Measure (FIM), and Spinal Cord Independence Measure (SCIM) were included in the BDS, because in nearly all clinical trials these are used as primary or secondary endpoints. Clinical trial investigators need to be able to analyze the relationships, if any, between ongoing PT and OT rehabilitation therapies ("Treatment as usual") and the experimental interventions under investigation, which may or may not include PT and/or OT components. For example, in a study of a drug/biological agent with a primary outcome of neurological improvement as measured by ISNCSCI motor scores, or improved function as measured by FIM or SCIM, rehabilitation could be considered a moderator, in that it could increase the efficacy of the intervention. Thus, it is important to measure rehabilitation to determine if differences in effect size may be related to differences in rehabilitation vs. the primary intervention. In order to measure rehabilitation, there is a growing need for a routinely applicable taxonomy for documentation of the PT and OT rehabilitation therapies being delivered.

The ISCI PT-OT BDS represents a standardized reporting tool to capture time and type of therapy administered in an inpatient or outpatient setting. The therapist uses the form during each therapy session to indicate the amount of time expended in each activity during a supervised single therapy session (individual or group). It is not designed to capture unsupervised home or community-based therapies.

The ISCI PT-OT BDS should be used in conjunction with the ISCI Core Data Set version 2.0 (Biering-Sørensen et al., 2017).

To reduce therapist reporting burden and the need for equipment, the data set purposefully was kept brief, and time is denoted as a range of minutes. Users of the dataset have the option to add sensitivity by recording the actual number of minutes, record/count repetitions, or use activity monitors. Intensity of training is not recorded in the current version, but may be included in future versions (eg, accelerometry-based measures).

VARIABLE NAME: Date of data collection

DESCRIPTION: This variable documents the date of data collection.

CODES: YYYYMMDD

COMMENTS: This collection of data on PT and OT rehabilitation interventions may be carried out at any time after the spinal cord injury. Therefore, the date of data collection is imperative to be able to identify the data collected in relation to other data collected on the same individual at various time points.

VARIABLE NAME: Time of data collection

DESCRIPTION: This variable documents the time of data collection.

CODES: HHMM (24 hour format)

COMMENTS: This collection form is for a single session of PT or OT. More than one session can be provided on the same date. Therefore, the time of data collection is imperative to be able to identify the data collected in relation to other data collected on the same day in the same individual.

VARIABLE NAME: Setting

DESCRIPTION: This variable documents whether the patient is an inpatient or outpatient.

CODES: Inpatient
Outpatient

COMMENTS: Delivery of rehabilitation interventions may have a different focus based on the setting. Therefore, identification of the inpatient or outpatient setting is included.

VARIABLE NAME: Activity-directed interventions - Bed/seated activities: balance, seated transfers, bed mobility

DESCRIPTION: This variable includes any interventions related to sitting balance and seated transfers and bed mobility. Sitting balance and seated transfers include interventions delivered while the patient is in an upright seated position, with or without assistive devices, such as a transfer board, and with any amount of physical assistance. Bed mobility includes interventions delivered while the patient is in a lying position and/or sitting position, with or without use of assistance, and with any amount of physical assistance.

CODES: Time in minutes

<15
15-29
30-44
45-60
>60

COMMENTS: Examples include sitting balance training on even or uneven surfaces as well as seated transfers from bed to wheelchair, wheelchair to toilet or shower and wheelchair to floor. Bed mobility examples would include rolling from supine to side-lying and side-lying to sitting.

VARIABLE NAME: Activity-directed interventions - Standing activities: standing, balance, standing transfers weight bearing

DESCRIPTION: This variable includes any interventions related to standing, balance, standing transfers, and/or weight bearing on lower extremities. Any interventions performed in an upright position, with or without assistive devices or lower extremity bracing, with or without physical assistance (ranging from supervision to maximal assistance), and any number of personnel. This encompasses any intervention that is not considered walking, but is performed in a lower extremity weight bearing position.

CODES: Time in minutes
<15
15-29
30-44
45-60
>60

COMMENTS: Examples include weight shifting, balance perturbations, stepping up and down (therapeutically, not as stair climbing), sit to and from stand, standing unsupported or supported, standing transfers, single or double leg stance. Sitting and standing balance are pre-requisites to participating in activities of daily living, as captured by FIM and SCIM III (Wirz and Van Hedel, 2018). Interventions, including task specific stand training, can improve standing balance (Tse, et al., 2018).

VARIABLE NAME: Activity-directed interventions - Walking, stairs (inside, outside)

DESCRIPTION: Includes any interventions that are not related to balance or standing training, and involves more than one sequential step. These interventions would be performed in an upright, lower extremity weight bearing position, with any amount of physical assistance, assistive device(s), or lower extremity bracing.

CODES: Time in minutes
<15
15-29

30-44
45-60
>60

COMMENTS: Examples include over ground walking, walking over uneven terrain, treadmill gait training, walking inside or outside, and stair climbing with or without use of railings. Interventions may occur in a variety of gait patterns (such as reciprocal, step to, swing through, etc). Locomotor training is associated with improvements in the lower extremity motor score component of the ISNCSCI (Field-Fote & Roach, 2011; Jones et al 2014), Walking and stair climbing both are encompassed within FIM and SCIM III, thus these interventions directed at these activities may influence FIM and SCIM III scores in the mobility sub-scales (Kapadia et al 2014; Jones et al 2014). The use of lower extremity orthotics is associated with improvement in FIM scores (Hada et al, 2018).

VARIABLE NAME: Activity-directed interventions - Gross motor UE: dressing, washing, bathing, manual wheelchair propulsion

DESCRIPTION: Includes any interventions that incorporate broad movements of the upper extremity at the shoulder and elbow. These interventions involve active movement such as reaching in multiple planes and upper extremity weight-bearing, and include physical assistance or adaptive equipment as needed. Activity-directed interventions involving gross motor UE movements have been associated with improvements in functional activity performance (Yarkony et al, 1987; Schonherr et al, 1999; Spooren et al, 2008).

CODES: Time in minutes
<15
15-29
30-44
45-60
>60

COMMENTS: Examples include upper body dressing and bathing, wheelchair propulsion, upper extremity weight-bearing, and interventions that incorporate unilateral and bilateral functional reach.

VARIABLE NAME: Activity-directed interventions - Fine motor UE: grooming, self-feeding, buttoning, zipping, adjustment of clothing

DESCRIPTION: Includes any interventions to facilitate routine daily activities that require active movement to accomplish a fine motor task. These interventions would include unilateral and bilateral motions incorporating movements at the elbow, forearm, wrist, and hand. Activities may be performed with or without adaptive equipment or adaptations. Activity-directed interventions involving fine motor UE

movements have been associated with improvements in functional activity performance (Yarkony et al, 1987; Schonherr et al, 1999; Spooren et al, 2008).

CODES: Time in minutes
<15
15-29
30-44
45-60
>60

COMMENTS: Examples include personal self-care such as grooming, feeding, and clothing management (buttoning, zipping, adjustments). Also may include office and communication tasks such as writing, managing electronic devices (phone, laptop, tablet) as well as leisure / hobby activities (crafts, games). Physical assistance and adaptive equipment may be included as needed.

VARIABLE NAME: Impairment-directed interventions - strength training and/or electrical stimulation administered to increase strength.

DESCRIPTION: This variable captures any type of strength training with or without electrical stimulation provided with the aim of increasing voluntary strength.

CODES: Time in minutes
<15
15-29
30-44
45-60
>60

COMMENTS: Strength training (with or without electrical stimulation) may increase voluntary strength (Aravind et al., 2019; Harvey et al., 2016). Therefore, it may affect the motor scores of the ISNCSCI which, in turn, could determine the motor levels and AIS grades, and SCIM/ FIM scores (Stone et al, 2019). This variable does not capture electrical stimulation used for purposes other than to increase voluntary strength (eg. it does not capture electrical stimulation when used as a neuroprosthesis, electrical stimulation used to induce hypertrophy in fully paralyzed muscles, electrical stimulation used to improve cough, electrical stimulation used to increase cardiovascular fitness, etc).

VARIABLE NAME: Impairment-directed interventions - Endurance training and/or electrical stimulation administered to increase endurance

DESCRIPTION: This variable captures any type of endurance training with or without electrical stimulation provided with the aim of increasing either cardiovascular fitness and/or neuromuscular fatigue resistance.

CODES: Time in minutes
<15
15-29
30-44
45-60
>60

COMMENTS: Endurance training (with or without electrical stimulation) may increase voluntary strength. Therefore, it may affect the motor scores of the ISNCSCI which, in turn, could determine the motor levels and AIS grades, and potentially SCIM and FIM scores. This variable does not capture electrical stimulation used for purposes other than to increase endurance (eg. it does not capture electrical stimulation when used as a neuroprosthesis, electrical stimulation used to induce hypertrophy in fully paralyzed muscles, electrical stimulation used to improve cough, electrical stimulation used to increase voluntary strength, etc).

VARIABLE NAME: Total intervention time

DESCRIPTION: The variable describes the total time of rehabilitation interventions above, i.e. the five 'activity-related' and the two 'impairment-directed' categories included in one session.

CODES: Time minutes
<15
15-29
30-44
45-60
>60

COMMENTS: Add up the total time of all intervention categories performed during one session, then circle the corresponding time interval.

References

Biering-Sørensen F, Charlifue S, DeVivo M, Noonan V, Post M, Stripling T, Wing P**.** International Spinal Cord Injury Data Sets. *Spinal Cord.* 2006; 44:530-534.

Aravind N, Harvey LA, Glinsky JV. Physiotherapy interventions for increasing muscle strength in people with spinal cord injuries: a systematic review. *Spinal Cord*. 2019 Feb 5. doi: 10.1038/s41393-019-0242-z. [Epub ahead of print]

Biering-Sørensen F, DeVivo MJ, Charlifue S, Chen Y, New PW, Noonan V, Post MWM, Vogel L International Spinal Cord Injury Core Data Set (version 2.0)—including standardization of reporting. *Spinal Cord.* 2017;55:759–764.

Field-Fote EC, Roach KE. Influence of a locomotor training approach on walking speed and distance in people with chronic spinal cord injury: a randomized clinical trial. *Phys Ther*. 2011;91(1):48-60.

Franz M, Richner L, Wirz M, von Reumont A, Bergner U, Herzog T, Popp W, Bach K, Weidner N, Curt A. Physical therapy is targeted and adjusted over time for the rehabilitation of locomotor function in acute spinal cord injury interventions in physical and sports therapy. *Spinal Cord.* 2018;56:158-167.

Granger CV, Albrecht GL, Hamilton BB. Outcome of comprehensive medical rehabilitation: measurement by pulses profile and the barthel index. *Arch Phys Med Rehabil*.1979;60(4):145–54.

Kapadia N, Masani K, Catharine Craven B, Giangregorio LM, Hitzig SL, Richards K, Popovic MR. A randomized trial of functional electrical stimulation for walking in incomplete spinal cord injury: Effects on walking competency. *J Spinal Cord Med.* 2014;37(5):511-24.

Harvey LA, Glinsky JV, Bowden JL. The effectiveness of 22 commonly administered physiotherapy interventions for people with spinal cord injury: a systematic review. *Spinal Cord* 2016; 54: 914-923.

Hada T, Momosaki R, Abo M. Impact of orthotic therapy for improving activities of daily living in individuals with spinal cord injury: a retrospective cohort study. *Spinal Cord.* 2018;56(8):790-795

Schönherr MC, Groothoff JW, Mulder GA, Eisma WH. Functional outcome of patients with spinal cord injury: Rehabilitation outcome study. *Clinical Rehabilitation* 1999.13(6):457–63.

Spooren AIF, Janssen-potten YJM, Snoek GJ, Ijzerman MJ, Kerckhofs E, and Seelen HAM. Rehabilitation outcome of upper extremity skilled performance in persons with cervical spinal cord injuries. *J Rehabil Med.* 2008; 40:637–44.

Stone WJ, Stevens SL, Fuller DK, Caputo JL. Ambulation and physical function after eccentric resistance training in adults with incomplete spinal cord injury: A feasibility study. *J Spinal Cord Med*. 2019;42(4):526-533.

Tse CM, Chisholm AE, Lam T, Eng JJ. A systematic review of the effectiveness of task-specific rehabilitation interventions for improving independent sitting and standing function in spinal cord injury. *J Spinal Cord Med.* 2018;41(3):254-266.

Wirz M, van Hedel HJA. Balance, gait, and falls in spinal cord injury. Handb Clin Neurol. 2018;159:367-384.

Yarkony GM 1987. Benefits of rehabilitation for traumatic spinal cord injury: multivariate analysis in 711 patients. *Archives of Neurology*. 1987;44(1):93.

International Spinal Cord Injury (ISCI) Physical Therapy-Occupational Therapy (PT-OT) Basic Data Set (BDS) Form (Version 1.0)

Center name: **Date:** **Time:**

Therapist name:

Patient identification:

Setting: ☐ inpatient ☐ outpatient

Introduction (Intent)

The ISCI PT-OT BDS represents sets of interventions that commonly are used in physical and occupational therapy sessions during SCI rehabilitation. The goal is to track (not prescribe) rehabilitation interventions that potentially could influence outcomes. Therefore, the data set purposefully was kept short. The therapist uses the form after each therapy session to indicate the amount of time in each activity during a single therapy session (individual or group) under direct supervision.

Instructions

The ISCI PT-OT BDS has two broad intervention categories: activity-directed interventions and impairment-directed interventions; use this form if any of the items in these categories were part of the intervention. The interventions assume active participation on the part of the patient, including when the movement is driven by electrical stimulation. The intent is to track the intervention, and not the goal of the intervention.

Selecting a category: Categories are intentionally broad. For interventions that are both activity-directed and impairment-directed, score the item in the activity-directed category only. If there are multiple interventions during one session, circle the items and time spent on each intervention (ie therapy time may be divided over multiple items but each time increment should be scored one time only).

Time: Indicate active time spent in an intervention by circling the most appropriate time range. Active therapy time typically will be less than the scheduled therapy session, as scheduled time includes items that are important but which are not tracked as part of this form (ie, interventions that are unlikely to influence sensory/motor scores, family training, patient instruction, etc). This form is not intended to be used for billing purposes.

	ITEM	TIME (in minutes)				
	ACTIVITY-DIRECTED INTERVENTIONS					
A	Bed/seated control activities: balance, seated transfers, bed mobility	<15	15-29	30-44	45-60	>60
B	Standing control activities: standing, balance, standing transfers weight bearing	<15	15-29	30-44	45-60	>60
C	Walking, stairs (inside, outside)	<15	15-29	30-44	45-60	>60
D	Gross motor UE: dressing, washing, manual wheelchair mobility	<15	15-29	30-44	45-60	>60
E	Fine motor UE: grooming, self-feeding, buttoning, zipping, adjustment of clothing	<15	15-29	30-44	45-60	>60
	IMPAIRMENT-DIRECTED INTERVENTIONS					
F	Strength training (including electrical stimulation for strength)	<15	15-29	30-44	45-60	>60
G	Endurance training (including electrical stimulation for endurance)	<15	15-29	30-44	45-60	>60
	TOTAL INTERVENTION TIME					
	Sum of time spent on individual items	<15	15-29	30-44	45-60	>60