

## INTERNATIONAL SPINAL CORD INJURY PHYSICAL THERAPY – OCCUPATIONAL THERAPY BASIC DATA SET (Version 1.1)

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**Changes from Version 1.0 to Version 1.1** include minor adjustments to text to enhance clarity in the description of variables. The variable “Total intervention time” has been changed to “Total activity- and impairment-directed intervention time”.

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.

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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.

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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.

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

DESCRIPTION: This variable captures any intervention related to sitting balance, 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 include rolling from supine to side-lying and side-lying to sitting.

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

DESCRIPTION: This variable captures any intervention related to standing, balance, standing transfers, or weight bearing on lower extremities. Included are 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. Balance is a prerequisite to participating in activities of daily living, as captured by FIM Instrument/SCIM III (Wirz and Van Hedel, 2018).

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

DESCRIPTION: This variable captures any intervention involving more than one active sequential step, that is unrelated to balance or standing training. 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 ISNCSCI lower extremity motor score (Alcobendas-Maestro et al., 2012; Hornby et al., 2005; Buehner et al., 2012). In one RCT that included multiple interventions, wherein locomotor training was a large component of the training, improvements in ISNCSCI lower extremity motor score were associated with training (Jones et al 2014). Walking and stair climbing both are encompassed within the FIM Instrument/SCIM III, thus these interventions directed at these activities may influence FIM Instrument/SCIM III scores in the mobility subscales.

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

DESCRIPTION: This variable captures 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 include activities performed with 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, and interventions that incorporate unilateral and bilateral functional reach.

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

DESCRIPTION: This variable captures any interventions intended to facilitate routine daily activities that require active movement to accomplish a fine motor task. These interventions include unilateral, bilateral, and bimanual movements incorporating 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). This category also includes office and communication activities such as writing, managing electronic devices (phone, laptop, tablet), as well as leisure / hobby activities (crafts, games), when included in the rehabilitation PT-IT activities. Physical assistance and adaptive equipment may be used as needed.

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

DESCRIPTION: This variable captures strength training with or without electrical stimulation, which may increase voluntary strength (Aravind et al., 2019; Harvey et al., 2016).

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

COMMENTS: Therefore, it may affect the ISNCSCI motor scores, which, in turn, could determine the ISNCSCI motor levels and American Spinal Injury Association (ASIA) Impairment Scale (AIS) grades, and FIM Instrument/SCIM III subscores (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, electrical stimulation used to decrease spasticity, etc).

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

DESCRIPTION: This variable captures endurance training with or without electrical stimulation provided with the aim of increasing 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 ISNCSCI motor scores which, in turn, could determine the motor levels, the single neurological level, and AIS grades, and potentially FIM/SCIM III subscores. This variable does not capture electrical stimulation used for purposes other than to increase endurance (e.g. 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, electrical stimulation used to decrease spasticity, etc).

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VARIABLE NAME: Total activity- and impairment-directed intervention time

DESCRIPTION: The variable indicates the total time spent in the specified session on the activity- and impairment-directed interventions excluding time spent on other activities such as passive transfers, time donning and doffing assistive devices, instruction time, etc.

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

COMMENTS: The total time spent is recorded by selecting the corresponding time interval.

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**International Spinal Cord Injury (ISCI) Physical Therapy-Occupational Therapy (PT-OT) Basic Data Set (BDS)  
Form (Version 1.1)**

**Center name:** \_\_\_\_\_ **Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_  
**Therapist name:** \_\_\_\_\_  
**Patient identification:** \_\_\_\_\_

**Setting:**  inpatient  outpatient

**Introduction (Intent)**  
The ISCI PT-OT BDS represents categories of interventions that commonly are used in PT and OT 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 category during a single therapy session (individual or group) under direct supervision.

**Instructions**  
The ISCI PT-OT BDS has categories intervention grouped as activity-directed interventions and impairment-directed interventions; use this form if any of the interventions in these categories were part of the session. 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 category, 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 categories and time spent on each (ie therapy time may be divided over multiple categories but each should be scored one time only).

Time: Indicate active time spent in an intervention category 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 motor scores, family training, patient instruction, etc). This form is not intended to be used for billing purposes.

INTERVENTION CATEGORY		TIME (in minutes)				
<b>ACTIVITY-DIRECTED INTERVENTIONS</b>						
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 upper extremity: dressing, washing, manual wheelchair mobility	<15	15-29	30-44	45-60	>60
E	Fine motor upper extremity: grooming, self-feeding, buttoning, zipping, adjustment of clothing	<15	15-29	30-44	45-60	>60
<b>IMPAIRMENT-DIRECTED INTERVENTIONS</b>						
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
<b>TOTAL ACTIVITY- AND IMPAIRMENT-DIRECTED INTERVENTION TIME</b>						
Total time spent on interventions in categories A-G excluding time spent on other activities such as passive transfers, time donning and doffing assistive devices, instruction time, etc.		<15	15-29	30-44	45-60	>60