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ORIGINAL ARTICLE

Developing a contemporary functional outcome measure for spinal cord injury research

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Study design: This study used qualitative analysis of focus group discussions.
Objective: The primary objective was to select functional activities to include in an item pool, which is the first step in developing a spinal cord injury computer adaptive test (SCI-CAT).
Setting: This multisite study was conducted at six US National Spinal Cord Injury Model Systems Programs.
Methods: Focus group discussions, which included persons with tetraplegia and paraplegia and clinicians, were conducted. Transcripts were analyzed using a grounded theory approach. Functional activities were identified, binned, winnowed, written as functional items, and cognitively tested.
Results: Focus group discussion analysis identified 326 functional activity items that fit into categories outlined in the International Classification of Functioning, Disability and Health (ICF) framework: Mobility (193 items), including assessment of functioning in a manual (44 items) and power wheelchair (19 items); self-care (109 items); and communication (19 items). Items related to sexual function were also identified (5 items).
Conclusion: The SCI-CAT item pool includes items that assess functional activities important to persons with SCI. Items cover a wide range of functional ability and reflect most ICF categories. The SCI-CAT pool is currently being field tested to develop a calibrated item bank. Further development will yield a CAT of functional activities appropriate for SCI research.
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Introduction

Spinal cord injury (SCI) research efforts would benefit from a comprehensive, precise, and sensitive functional measure. Recommendations from the International Campaign for Cures of Spinal Cord Injury Paralysis Clinical Guidelines Panel, an international panel established to review the methodology for clinical trials in SCI, emphasize the urgent need for accurate and sensitive functional measures for use in clinical trials.[1] Clinicians also recognize the need for functional measures that are sensitive to clinically meaningful change and assess functional abilities that are important and relevant to persons with SCI.[2]

Three types of measures are currently used to assess the functioning of persons with SCI: (1) generic measures applied to individuals with SCI such as functional independence measure (FIM—a trademark of Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.); (2) measures developed specifically for individuals with SCI, such as the spinal cord independence measure (SCIM III),[3] and (3) measures developed for specific subsets of the SCI population, such as the quadriplegic index of function (QIF)[4] for individuals with tetraplegia and the walking index for spinal cord injury (WISCI II)[5] for persons with incomplete lesions. Limitations associated with these functional activity measures may include a lack of precision and sensitivity, inadequate range of items, and limited applicability for all persons with SCI.

Traditional approaches to developing a SCI functional outcome measure present a challenge because persons with SCI have a tremendous range of functional ability—from learning to use mouth controls for powered mobility to returning to vigorous sports activities. The ideal functional measure would include activities that are meaningful and

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relevant to persons across all levels of SCI injury and degrees of severity. However, such a measure would include a significant number of items that would be irrelevant because they are too challenging or too easy for different individuals. Moreover, administration of a comprehensive traditional functional assessment would be impractical and burdensome.

Contemporary measurement techniques, such as computer adaptive testing (CAT), provide a promising solution to this problem. CAT applications are based on item banks—a comprehensive set of items for a specific outcome domain that consistently scale along a dimension from a low- to high-level of functioning.[6] CAT applications use a simple form of artificial intelligence to select items from a scaled item bank that match the ability level of each person being assessed. A CAT assessment begins with items in the middle range of the scale and subsequent items are selected from different locations along the scale based on the individual's responses to prior items.[7] Throughout the assessment, functional score estimates and confidence intervals are calculated. One advantage of the CAT approach is that stopping rules can adjust the length of the assessment to reach a desired confidence interval around the estimate.[8] Thus, with the CAT approach, a few well-selected items are administered to obtain a precise estimate of an individual's placement along a continuum of functional ability. The CAT approach is a promising strategy for developing a comprehensive, precise, and practical functional outcome measure for SCI. A recent review notes the significant limitations associated with current SCI functional measures and considers the potential for using a CAT approach.[9]

In this paper, we present the first step in our work to develop a CAT-based functional outcome designed specifically for persons with SCI (SCI-CAT). We describe the process used to identify, evaluate, and organize items for the SCI-CAT functional activity item pool, including the following steps: (1) review items from existing instruments; (2) conduct focus group sessions to identify important functional content; (3) organize items into content bins; (4) reduce the number of items in the pool; and (5) refine item wording through qualitative item review.

Materials and methods

A comprehensive review of current functional outcome literature was completed. Content categories and items from current functional assessments used in SCI were reviewed (see Table 1). We conducted a series of focus group sessions to develop new items to identify functional activities that persons with SCI considered important. One clinician focus group and two focus groups comprised of individuals with SCI (one tetraplegia and one paraplegia group) were held at each of the following six National Model Spinal Cord Injury Systems rehabilitation facilities: Boston Medical Center, Craig Hospital, Kessler Institute for Rehabilitation, Mount Sinai Medical Center, Rehabilitation Institute of Chicago, and University of Michigan Medical Center. Two moderators began by explaining that the purpose of the focus group was to explore functional activities important to persons with SCI. The term 'functional activity' was defined for participants in keeping with the World Health Organization's International Classification of Functioning, Disability and Health (ICF) definition as the 'execution of a task or action by an individual.'[10] After 1 h of open discussion, participants viewed a list of categories and sample items compiled from existing instruments. For the final 30 min, participants discussed about the functional activities and categories that were not included in the list or mentioned during previous discussion. Focus group discussions were audiotaped and transcribed.

All focus group transcripts were independently reviewed by two investigators (PAK, MDS) to identify content related to specific functional activities. Grounded theory analysis of focus group transcripts and constant comparative analysis were used to develop primary, secondary and tertiary nodes, or content categories.[11] These content categories provided the coding structure for transcript analyses. Items from transcripts were coded using NVivo software and placed in the appropriate content category (that is bin) based on the primary, secondary, and tertiary nodes that fit the content. Finally, two other investigators (AMJ, DST) reviewed the coded items to ensure that items were placed in appropriate bins.[12]

Activities were written as functional items designed to assess an individual's capacity to perform an activity. These items were rated by eight reviewers who were Model System Program Directors, co-investigators, or consumers. The goal was to omit items that were inappropriate, redundant, or did not fit the activity construct. Item scores were summarized across raters and grouped into three categories: retain, omit, or undetermined. Items categorized as undetermined were reviewed by two investigators (AMJ and DST) for a final assignment. Retained items were cognitively tested during a review by 12 persons with SCI who identified wording that could diminish instrument performance. Items were rewritten based on cognitive testing feedback.

Results

Individuals with SCI ($N = 71$) who participated in the focus group discussions had an appropriate range of functional abilities—from walking independently to requiring a ventilator. Participant demographics are summarized in Table 2. Clinician focus groups ($N = 34$) included physical therapists (32%), occupational therapists (21%), physicians (21%), nurses (9%), psychologists (6%), social workers (6%), a case manager (2.5%), and a recreational therapist (2.5%).

As the coding structure for the transcript content emerged, similarities between the identified primary, secondary, and tertiary nodes and the ICF first- and second-level categories were noted. Therefore, whenever possible, ICF terminology was adopted for the emergent transcript coding structure. Transcript analysis yielded 743 activities that were initially placed into appropriate content bins based on the following ICF activity categories: general tasks and demands (14 items), communication (55 items), mobility (341 items), self-care (250 items), and domestic life (71 items). Transcript analysis also

Table 1 SCI functional outcome measures reviewed

Instrument	*Domains or subscales (number of items)*	*Rating scale*	*Intended population*
Functional independent measure (FIM)	Motor (13) Cognitive (5)	Burden of care—scores range from 1 (total assistance) to 7 (complete independence)	All persons with functional limitations
Spinal cord independence measure (SCIM III)	Self-care (4) Respiration and sphincter management (4) Mobility in room and toilet (3) Mobility indoors and outdoors (6)	Different scoring criteria for each item to describe activity and/or assistance required. Item scores range from 0–1 (transfers from floor to ground) to 0–15 (sphincter management—bladder)	All persons with SCI
Walking index for spinal cord injury (WISCI II)	Walking—20 items describe walking ability, the amount of assistance required and aids used	Scores range from 0 (unable to walk) to 20 (walks >10 m without walking aids or assistance)	Persons with SCI who are ambulatory
Quadriplegic index of function (QIF)	Feeding (8) Bed activities (5) Grooming (4) Bathing (4) Transfers (8) Dressing (9) Wheelchair mobility (7)	Burden of care—scores range from 0 (dependent) to 4 (independent)	Persons with tetraplegia

Table 2 Focus group participants: persons with SCI

	Tetraplegia (n = 40)	*Paraplegia (n = 31)*
Average age	42 years[a]	47 years
Male	55%	74%
Race and ethnicity		
Caucasian	82%	77%
African American	15%	19%
Other	3%	4%
Time since injury		
Average	13 years[b]	11.6 years
Range	6 months–40 years[b]	10 months–46 years
1 year or less	6%[b]	10%
2–5 years	30%[b]	35%
>5 years	64%[b]	55%
Type of mobility aid[c]		
Manual wheelchair	35%	77%
Power wheelchair	50%	7%
Walker, crutches, cane	7%	17%
Sip and puff control	8%	0

[a]Data missing for three subjects.
[b]Data missing for four subjects.
[c]Some individuals used >1 type of mobility aid.

identified 12 activities related to sexual function, although sexual function is not included as an ICF activity category.

On the basis of the results from the winnowing process, general tasks and demands (for example managing daily routine, planning) and domestic life (for example acquisition of necessities) items were omitted because they were more related to the concept of participation, as defined by ICF. Reviewer ratings of the remaining items were used to winnow the items to the final SCI-CAT item pool, which consists of 326 items: mobility—193 items (60%), self-care—109 items (33%), communication—19 items (6%), and sexual function—5 items (1%). In addition to activity categories, transcript content analysis identified cross-cutting categories, related to how the activity was accomplished, which included the use of manual wheelchair (44 items), power wheelchair (19 items), walking device (10 items), specific equipment (30 items), and personal assistance (10 items). Tables 3–5 present a breakdown of the SCI-CAT item pool content ICF categories and cross-cutting content.

SCI-CAT items covered most ICF categories. For mobility, ICF categories with the highest percentage of items were *moving around using equipment* (14%), *transferring while sitting* (9.3%), *changing body position lying down* (7.8%), *lifting objects* (7.8%), *fine hand use—manipulating* (5.7%), and *hand and arm use—reaching* (5.7%). The ICF categories under self-care with the highest percentage of items were *eating* (19.3%), *dressing—putting on clothes* (18.4%), *caring for body parts—caring for skin* (11%), *toileting–regulating urination* (10.1%), and *toileting—regulating defecation* (9.2%).

Discussion

The SCI-CAT item pool provides valuable insights into the broad range of functional activities that are important to persons with SCI. The SCI-CAT activity items cover most ICF first- and second-categories for mobility, self-care, and communication. Activities included in the item pool highlight three areas that have been identified as important to individuals with an SCI: functional mobility (including transfers and wheelchair use), dressing, and grooming.[13] The distribution of activities across ICF categories presents a profile of the unique concerns of persons with SCI.

As one participant observed, his wheelchair is an extension of his body—a sentiment echoed by many focus group participants. The fact that the ICF category *moving around using equipment*, which includes wheelchair use, has the highest percentage of items demonstrates the wide variety of wheelchair activities that are important to persons with SCI. SCI-CAT items provide an in-depth assessment of wheelchair activities including the time, distance, and terrain involved and the ability to perform wheelies. There are also wheelchair items in the *lifting and carrying objects* category

Table 3 Distribution of SCI-CAT item pool content—mobility

Categories	*Item count (% of category)*	*MWC*	*PWC*	*WD*	*PA*	*Equip*
(d410) Changing basic body position						
(d4100) Lying down	15 (7.8%)				(1)	(1)
(d4103) Sitting	6 (3.1%)	(3)	(1)			
(d4104) Standing	8 (4.1%)			(2)		
(d4105) Bending	7 (3.6%)	(2)	(2)			
(d415) Maintaining a body position						
(d4152) Kneeling position	1 (<1%)					
(d4153) Sitting position	12 (6.2%)	(1)	(3)			(2)
(d4154) Standing position	3 (1.5%)					(1)
(d420) Transferring oneself						
(d4200) While sitting	18 (9.3%)	(5)		(1)		(5)
(d430) Lifting and carrying objects						
(d4300) Lifting	15 (7.8%)	(7)	(4)			
(d4302) Carrying in the arms	2 (1%)					
(d440) Fine hand use						
(d4400) Picking up	4 (2%)					
(d4401) Grasping	5 (2.6%)					
(d4402) Manipulating	11 (5.7%)					
(d445) Hand and arm use						
(d4450) Pulling	1 (<1%)	(1)				
(d4451) Pushing	5 (2.6%)				(1)	
(d4452) Reaching	11 (5.7%)	(2)	(2)			
(d450) Walking						
(d4500) Short distances	1 (<1%)					
(d4501) Long distances	4 (2%)			(1)		
(d4502) On different surfaces	5 (2.6%)			(1)		
(d4503) Around obstacles	5 (2.6%)					
(d455) Moving around						
(d4550) Crawling	1 (<1%)					
(d4551) Climbing	8 (4.1%)			(3)		
(d4552) Running	5 (2.6%)					
(d4553) Jumping	1 (<1%)					
(d4554) Swimming	1 (<1%)					
(d460) Moving around in different locations						
(d4600) Within the home	2 (1%)			(1)		
(d4602) Outside the home and other buildings	4 (2%)			(1)		
(d465) Moving around using equipment	27 (14%)	(20)	(7)			(1)
(d470) Using public transportation	2 (1%)					(1)
(d475) Driving	3 (1.6%)					
Item totals	193	(41)	(19)	(10)	(2)	(11)

Abbreviations: SCI-CAT, spinal cord injury computer adaptive test.
Category items that include cross-cutting content: MWC, manual wheelchair; PWC, power wheelchair; WD, walking device; PA, personal assistance; Equip, specialized equipment.

(for example lifting objects while seated in the wheelchair) and in the *dressing* category (for example dressing in the wheelchair). A recent review of wheelchair measures concluded that there is an urgent need to improve assessment of wheelchair functional abilities.[14] SCI-CAT items provide insight into the types of activities to include in a comprehensive assessment wheelchair function. Another advantage of the SCI-CAT is the use of screening questions, which allows individuals who walk, or use a manual wheelchair or power wheelchair, to receive only items related to the method(s) of locomotion that they actually use.

The SCI-CAT item pool emphasizes other activities that are particularly important to persons with SCI. For example, in the mobility category, 15 items assess *changing basic body position—lying down*, which includes a wide range of bed mobility activities. *Lifting and reaching* activities are also highlighted. Focus group discussion among persons with tetraplegia also emphasized *fine hand use* and the SCI-CAT includes several item that assess the ability to pick up, grasp, and manipulate a variety of objects (for example coins, paper) with different actions (for example turn the knob on a door, use a bottle opener). In the self-care category, several

Table 4 Distribution of SCI-CAT item pool content—self-care

Categories	*Item count/% category*	*MWC*	*PA*	*Equip*
(d510) Washing oneself				
(d5100) Washing body parts	2 (1.8%)			
(d5101) Washing whole body	7 (6.4%)		(2)	(4)
(d5102) Drying oneself	1 (<1%)			
(d520) Caring for body parts	1 (1%)		(1)	
(d5200) Caring for skin	12 (11%)			
(d5201) Caring for teeth	4 (3.7%)			
(d5202) Caring for hair	4 (3.7%)			
(d5203) Caring for fingernails	1 (<1%)			
(d5204) Caring for toenails	1 (<1%)			
(d530) Toileting				
(d5300) Regulating urination	11 (10.1%)		(1)	(2)
(d5301) Regulating defecation	10 (9.2%)			(1)
(d5302) Menstrual care	2 (1.8%)			
(d540) Dressing				
(d5400) Putting on clothes	20 (18.4%)	(2)		(4)
(d5401) Taking off clothes	5 (4.6%)			(2)
(d5402) Putting on footwear	3 (2.7%)	(1)		
(d5403) Taking off footwear	2 (1.8%)			
(d550) Eating	21 (19.3%)		(1)	(2)
(d560) Drinking	2 (1.8%)			
Totals	109	(3)	(5)	(15)

Abbreviations: SCI-CAT, spinal cord injury computer adaptive test.
Category items that include cross-cutting content: MWC, manual wheelchair; PA, personal assistance; Equip, specialized equipment.

Table 5 Distribution of SCI-CAT item pool content—communication

Categories	*Item count/% category*	*PA*	*Equip*
(d 325) Receiving—reading	4 (21%)		(1)
(d349) Producing—speaking	2 (11%)		
(d 345) Producing—writing messages	3 (16%)		(2)
(d360) Use of devices	1 (5%)		
(d3600) Producing—use of telecommunication devices	4 (21%)	(1)	
(d3601) Producing—using writing machines/keyboards	5 (26%)		(1)
Totals	19	(1)	(4)

Abbreviations: SCI-CAT, spinal cord injury computer adaptive test.
Category items that include cross-cutting content: PA, personal assistance; Equip, specialized equipment.

items assess *caring for skin*, which was a particular concern among focus group participants.

Recently published guidelines for evaluating measures used in SCI emphasize the importance of examining the construct being measured and the theory or framework associated with that construct.[15] The ICF provided a useful framework for organizing and evaluating potential items to include in the SCI-CAT item pool. The ICF framework helped define functional activities and provided conceptual clarity during focus group discussions and content analysis. The usefulness of the ICF framework is exemplified by our method for identifying relevant SCI-CAT bowel and bladder items. According to the ICF framework, bowel and bladder function is located under body functions and structures,[16] but other outcome measures used in SCI, such as the FIM and SCIM III, include items that assess continence and residual volume of urine, which are clearly physiological aspects of bowel and bladder function, as part of the functional assessment. Our focus group participants acknowledged the importance of bowel and bladder function and identified functional activities related to bowel and bladder management, including the ability to do self-catheterization, manage a leg bag and perform digital stimulation. These items fit in the ICF categories *regulating urination* and *regulating defecation*. Bowel and bladder function is very important to persons with SCI.[17] SCI-CAT items maintain conceptual clarity by assessing a person's ability to engage in relevant activities related to bowel and bladder function.

The SCI-CAT item pool also includes activities outside of the mobility and self-care categories. Items assess the functional mobility aspects of communication, such as using a computer keyboard or cell phone. Communication assessments typically focus on cognitive aspects, which are less salient for persons with SCI. However, focus group participants identified a functional activity component to communication and emphasized that use of communication technology was critical to their ability to function independently. Sexual function was also frequently mentioned in focus group discussions, but it is not typically included in functional assessments. Although sexual function is included in the body functions component of the ICF framework focus group, participants noted that sexual function also requires physical mobility and the SCI-CAT item pool includes five activity items related to sexual function. The SCI-CAT mobility, self-care, and communication domains also include items that assess the ability to function using personal assistants and specialized equipment, which was frequently mentioned in focus group discussions.

One criticism of current SCI functional measures is that they tend to focus more on the investigator's perspective than on the perspective of persons living with SCI.[9] The SCI-CAT item pool reflects a broad range of functional activities that are important to persons with SCI. We are currently field testing the SCI-CAT item pool in sample of persons who have a diagnosis of traumatic SCI with varying levels of severity and time since injury. Factor analyses will be performed on these data to confirm the unidimensionality of items within each category of function.[18] Items will be scaled using Rasch partial credit modeling. A series of goodness-of-fit statistics will be conducted, and we will examine differential item functioning across SCI diagnoses and levels of severity. Finally, algorithms for CAT will be developed.[19]

The SCI-CAT will provide a conceptually sound and clinically relevant measure of function in SCI that is comprehensive, precise, and easy to administer—characteristics needed to document functional changes in persons with SCI. Furthermore, though not discussed in this manuscript, the SCI-CAT is linked with other new contemporary measurement systems including PROMIS,[20] Neuro-QOL, SCI-QOL, and a Pediatric SCI-CAT; however, the SCI-CAT is

the only new measure being developed specifically for the adult SCI population. The SCI-CAT will be an important step to advance functional measurement in SCI so that we can better determine treatment efficacy, assess the potential impact of new interventions and support efforts to maximize each individual's functional potential through rehabilitation.

Conflict of interest

The authors declare no conflict of interest.

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