Developing a Contemporary Patient Reported Outcomes Measure for Spinal Cord Injury

David S. Tulsky[a], **Pamela A. Kisala**[a], **David Victorson**[b], **Denise Tate**[a], **Allen W. Heinemann**[c], **Dagmar Amtmann**[d], and **David Cella**[b]

[a]Department of Physical Medicine and Rehabilitation, University of Michigan, Ann Arbor, MI

[b]Department of Medical Social Sciences, Northwestern University, Chicago, IL

[c]Department of Physical Medicine and Rehabilitation, Northwestern University, and Rehabilitation Institute of Chicago, Chicago, IL

[d]Department of Rehabilitation Medicine, University of Washington, Seattle, WA

Abstract

Objective—To develop a spinal cord injury (SCI)-specific patient reported outcome (PRO) measure of health related quality of life covering multiple domains of functioning, including physical, emotional, and social health.

Design—Focus groups

Setting—Four SCI Model Systems rehabilitation hospitals

Participants—62 individuals with SCI and 42 clinicians

Interventions—Not applicable

Main Outcome Measure—SCI-QOL measurement system

Results—Qualitative analysis yielded three domains of primary importance, physical-medical health, emotional health, and social participation. Results were used to guide domain and item decisions in the development of the Spinal Cord Injury Quality of Life (SCI-QOL) PRO measurement system. The qualitative data were used to develop item pools with item content specific to individuals with SCI across a wide spectrum of functioning. When possible, items from other major measurement initiatives were included verbatim in the item pools to link the measurement systems and facilitate cross-study and cross-population comparisons.

Conclusions—Issues that impact individuals' quality of life following SCI are varied and several issues are unique to individuals who have had a traumatic injury. From these qualitative

Address reprint requests to: David Tulsky, Ph.D. Department of Physical Medicine and Rehabilitation North Campus Research Complex 2800 Plymouth Road Building NCRC B520, Office 3210 Ann Arbor, MI 48109-2800 Phone: (734) 763 - 4096 dtulsky@med.umich.edu.

data, three major domains and 18 subdomains of functioning were identified. Item pools were developed in each of these 18 areas to measure functioning related to physical-medical issues, emotional status, and social participation.

Keywords

Spinal Cord Injuries; Quality of Life; Outcome Assessment (Health Care)

According to the National Spinal Cord Injury Statistical Center, about 12,000 Spinal Cord Injuries (SCIs) are reported annually in the United States, with around 250,000 Americans living with SCI.[1] A recent study by the Christopher and Dana Reeve Foundation estimates as many as 1.2 million Americans are living with SCI.[2] This reflects the differing methodology used in the two studies, where the former samples individuals with SCI who were admitted to Model Systems centers, while the latter reflects a population-based sampling approach. Either way, it is clear that SCI is a widespread problem for people living in the United States. More relevant to the topic, SCI and associated disorders encompass a broad constellation of physiological changes, secondary complications, and impaired functioning. These factors combine with environmental barriers[3] and lead to altered social roles, all of which significantly impact health-related QOL.[4]

The Need for New Measures of Health Outcomes

Despite rapid growth in the number of clinical trials designed to restore functioning and treat secondary complications following SCI, there is a paucity of appropriate tools to assess QOL in an SCI population[5]. Patient-reported outcomes (PRO) measures used in SCI clinical trials [e.g., Medical Outcomes Study 36-item Short Form (SF-36)[6], Satisfaction with Life Scale (SWLS)[7]] have often been developed for general medical populations[8] or the general population[7], and after the fact have been applied to SCI research[5,9-11]. and _ENREF_8_ENREF_7These measures contain irrelevant material, such as items in the SF-36[6] that ask about running or climbing several flights of stairs or an item in the SWLS[7] that asks participants if they are so content with life that they would not change anything, that could be considered offensive by an individual who has experienced a traumatic injury resulting in physical disability.[12,13] At the very least, irrelevant items lack face validity and as a result, the sensitivity and utility of these generic measures are questionable. Moreover, these measures do not include items related to relevant areas of health and functioning for an individual with an SCI. This lack of content coverage raises additional questions about the sensitivity and specificity of each of these measures for the SCI population. For these reasons, it is unclear if these measures are useful in clinical trials that must detect small changes in functioning or overall health.

When targeted SCI outcomes measures (i.e., measures designed specifically for an SCI population) have been developed, the measures are generally narrow in scope, focusing on a single, limited domain (e.g., neurological functioning or functional independence) rather than assessing global PROs such as multidimensional QOL. PRO instruments covering a single domain of health or functioning include the CHART[14] (e.g. social participation)_ENREF_15. SCI specific measures have been developed utilizing classical

test theory and are generally administered as static measures. These targeted SCI measures contain a preselected set of items that measure functioning within a narrow range. For this reason, the scales are only appropriate for a subset of the SCI population and not appropriate for the entire spectrum of neurological injuries (e.g., complete and incomplete tetraplegia and paraplegia). An example is the Quadriplegia Index of Function (QIF)[15] which is a measure designed for individuals with tetraplegia. In studies that include individuals with tetraplegia and paraplegia, the SCI researcher could not use the QIF to assess all participants, because the QIF is not applicable across all levels of functioning. This makes it difficult to use some of the established SCI measures to evaluate new treatment approaches across a spectrum of individuals with varying degrees of neurological functioning. Finally, researchers have no "gold standard" that can be utilized across studies, making it difficult to compare results across studies and research teams. In their recent systematic review of QOL outcomes measures used in the SCI literature, Wilson, Hashimoto, Dettori, and Fehlings[5], have underscored the need for QOL measures which have been developed with individuals with SCI. This manuscript describes efforts to develop a comprehensive, sensitive, and specific PRO measure for SCI that maintains relevance across a wide range of neurological function. The new measure will utilize advanced psychometric techniques (e.g., item response theory, computerized adaptive testing, and item banking) which will contain items representing the full range of potential responses within one subdomain, thereby enabling the estimation of level of functioning with a small number of relevant items and less error than a static measure[16,17]. This paper outlines the qualitative methods and results of the current study and provides a description of the domains, item pools, and item counts that were used in field testing.

An Efficient Individualized Approach to Measurement

The measure will be developed using Item Response Theory (IRT) and will include calibrated item banks containing items across the entire range of functioning in each quality of life (QOL) domain. These features ensure that the instrument will have domain relevance and appropriate content coverage for individuals with SCI. The new measure is predicated on the hypothesis that calibrated item banks spanning the entire hierarchy of functioning will save time and effort for participants and administrators. Although participants complete only a small subset of the items, their score are extrapolated as if they completed the entire set of items. These subsets of items can be administered using a computerized adaptive test (CAT) approach or a tailored short form, as described in detail by Lai and colleagues (in this issue)[16] and Fries and colleagues[18]. Thus, calibrated item banks can be administered as brief measures that are time efficient, specific and precise to subgroups, and flexible with regard to item selection, yet total scores are comparable across a wide range of health and functioning.[17,19].

Quality of Life Outcomes: Background History

Health-related quality of life (HRQOL or simply QOL) is a subjectively evaluated multidimensional construct that "refers to the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatment" (p. 73)[20]. QOL is an increasingly important PRO across general and specific

health populations,[21,22] as seen in the increasing number of federal initiatives focused on developing QOL measures for use in clinical trials. The National Institutes of Health (NIH) established the development of PROs as part of their "roadmap" for medical research in the 21st century, a goal of which "is to catalyze changes that are necessary for transforming new scientific knowledge into tangible benefits for people."[23,24] A description of the resulting measure, the Patient Reported Outcomes Measurement Information System (PROMIS), is provided elsewhere (including Amtmann et al. in this issue).[19,25]

The National Institute of Neurological Disorders and Stroke (NINDS) prioritized the development of PROs as part of their efforts to develop common data elements to be used in their research studies. The Neuro-QOL measurement system is a set of PRO item banks for individuals with neurological disorders. The Neuro-QOL incorporates many PROMIS items to facilitate linkages between the two measurement systems. The Neuro-QOL is described in detail elsewhere.[26]. The Neuro-QOL measurement system does not include specific measurement of SCI and, as such, may have limited relevance to individuals with SCI. The SCI-QOL builds on PROMIS and Neuro-QOL by 1) utilizing participatory action research[27,28] and qualitative analysis to determine critical aspects of QOL in the SCI population, and 2) developing meaningful, relevant, and psychometrically-sound, SCI-specific item banks that are linked with Neuro-QOL and PROMIS. The qualitative phase consisted of focus groups with individuals with SCI and clinicians at 4 National Institute on Disability and Rehabilitation Research (NIDRR) funded Model SCI System sites. In addition to the focus group feedback, the overall project benefitted from a series of interactive discussions with a regional SCI consumer advisory board who provided input on study methodology and results. Individuals with SCI were also included in the item writing process through a series of cognitive debriefing interviews (n=28). Through qualitative analysis of focus group feedback, primary stakeholders (individuals with SCI and SCI clinicians) informed the structure of this SCI-specific measurement system. They assessed and revised the Neuro-QOL domain framework of Physical, Emotional, and Social Health for use in this population, and created SCI-specific subdomains and items in relevant content areas not addressed by the Neuro-QOL system.

Identification of Measurement Domains and Subdomains

Methods

Participants—Twelve consumer focus groups included 65 individuals with SCI recruited through the local SCI Model System site and 4 clinician/provider focus groups included 42 providers. Institutional review boards at each institution reviewed and approved this research. Participants, including individuals with SCI and clinicians, were recruited through their local SCI model systems site. Consumers were included in this study if they had sustained a traumatic SCI and had the ability to read and understand English. However, each site was instructed to recruit individuals with SCI across all levels of injury, and to ensure representation from various racial, ethnic, gender, and socioeconomic groups. This helped ensure groups of a heterogeneous makeup. Clinicians were recruited based on their level of experience with spinal cord injury. The clinician/provider groups included physiatrists,

physical therapists, psychologists, and nurses who work primarily (i.e. 50% of the time for a minimum of 3 years) with persons with SCI.

Procedure—Focus groups were used to identify topics relevant to individuals with SCI and their treating clinicians. Focus group moderators were the study PI and a Ph.D.-level co-investigator. The lead moderator had extensive experience (i.e. >20 groups) conducting focus groups related to HRQOL and measurement development. The co-moderators debriefed following each focus group session to help ensure adherence to the focus group guide and method. Moderators facilitated discussions in a semi-structured manner by providing basic rules and providing general topics for discussion, yet allowed participants to discuss their own stories and perspectives. Participants were encouraged to discuss experiences and issues that affect their QOL. The focus group moderators prompted participants to focus on both positive and negative aspects of life with SCI to ensure a range of feedback.

After discussing experiences with their own QOL or, for the clinicians, that of their patients, group members defined QOL and outlined what they perceived to be the most important aspects of QOL for an individual with SCI. Following this general discussion, different groups were asked to focus on one specific Neuro-QOL domain area, e.g. Physical Health, Emotional Health, or Social Participation. A parallel set of focus groups covered physical functioning and activity limitations. Results from these focus groups are reported elsewhere. [29] The provider/clinician groups covered all of the above domains of functioning, e.g. Physical Health, Emotional Health, and Social Participation. Focus groups reviewed the Neuro-QOL structure and item content for relevance and importance to SCI. Saturation in focus groups is a method to ensure that all themes are identified[30,31]. As seen in our qualitative analysis of the data, we reached saturation for new issues for the primary themes in each domain during group 2. The remaining groups in each domain were used to confirm these themes. Group discussions were audio-recorded and transcribed verbatim to facilitate data analysis.

Qualitative Analysis—A minimum of two investigators reviewed each transcript independently, iteratively developing an initial list of themes. Then, investigators conducted a series of teleconferences, completed further reviews, developed a coding system for these themes (e.g. a hierarchical codebook), and maintained a log of transcript quotes that could form the basis of new items. Finally, codebooks were expanded to include definitions, rules for inclusion and exclusion, and, where applicable, verbatim transcript text for semantic clarification. The qualitative data analysis procedure is described elsewhere.[32]

Next, researchers assessed inter-rater reliability of domain codes and selectively coded transcripts to validate codes. For each domain, two raters applied a code to each segment of transcript text according to the hierarchical codebook. To maximize rater synchronization, two raters coded the first transcript together. Then, the raters coded transcripts independently, iteratively logging and reconciling disagreements in order to achieve 100% agreement. This final code for each chunk of text was used to calculate the relative frequency of mention of focus group topics.

Results

The demographic characteristics of the SCI focus group participants are presented in Table 1. All SCI-QOL investigators and members of the study team reviewed the qualitative analysis results of focus group data and clarified the methodology for determining which domains and subdomains would be included. The World Health Organization (WHO) concept of health consisting of physical, mental, and social components[33] served as the basis for the domain framework for PROMIS[34] and Neuro-QOL[35]. With this framework and the qualitative analysis results in mind, the investigators verified the assumption that physical health, emotional health, and social participation were all important domains.

Physical-Medical Domain—Physical health in SCI encompasses two primary components, physical function and secondary medical complications. Because the physical function domain has been examined in the SCI-CAT[29] project, the SCI-QOL physical domain is focused on secondary medical issues that influence QOL. Results are presented in Table 2. Percentages in this section represent only the Physical-Medical and provider groups.

Pain was the most frequently mentioned secondary complication with 16% of comments. Participants discussed specific types of pain such as neuropathic ("I can't even begin to tell you the type of pain I have. It's not stabbing, it's not a burn, it changes, it evolves constantly…") and musculoskeletal ("I've had a lot of muscle pain though…chronic pain in the shoulder"), as well as the overall effects of pain on living one's life ("Pain could have a limiting effect in terms of how much they are going to do for themselves").

Issues related to bowel and bladder management were also mentioned quite frequently (12% of comments). This topic area included issues related to both bowel ("I would like to be able to use the bathroom again like a normal person. I can't have a regular bowel movement") and bladder ("I had a kidney stone that developed into three centimeters and that screwed my life up for the next three year(s)") functioning and management. Participants also discussed musculoskeletal (10%) issues including muscle tone ("My biggest problem is just overriding stiffness and tightness and I guess they call it tone") and spasticity ("The muscle maintenance is the thing about spasticity. It's not always recognized that there's a benefit"), as well as issues related to skin breakdown (9%, "I had a pressure ulcer…for four years and it's still a pressure ulcer").

Other medical issues were discussed less often, including temperature regulation (5%, "Even in the summertime, I have footies on and a scarf and socks on my hand. And it could be 90 outside. I have to have a blanket on me"), fatigue (4%, "I used to work 10, 12 hours a day seven days a week as a bricklayer. Now, I work three hours, and I have to go home and take a nap. I'm tired."), cardiovascular (4%, "I had blood clots break free…and I ended up getting a pulmonary embolism and had a heart attack from it") and issues related to bone and connective tissue (4%, "[Heterotopic ossification] is mostly calcium deposits usually on the hip. Mine was on the right hip"). Three percent of comments were related to respiratory complications ("I had pneumonia twice and that was from lying down [so often]"), and 2% of comments related to sexuality ("Haven't had sex since my injury, really don't have the urge because I have a complete injury, I don't have any feeling…"). Overall, participants

reported that the occurrence and severity of secondary medical complications have noticeable effects on QOL. Participants discussed two additional concepts: health promotion (15%) and impact of medications (12%) but these areas were outside of the scope of the construct of secondary medical complications and are not typically used as outcomes in SCI clinical trials.

Emotional Health Domain—As defined by the PROMIS cooperative group,[36] emotional health refers to pleasant or unpleasant feelings or emotions that are experienced subjectively and, therefore, are best assessed through self-report as a patient-reported outcome. PROMIS and Neuro-QOL contain item banks (i.e., unidimensional groups of items of varying "difficulty" which have been calibrated using item response theory [IRT]) measuring anxiety, depression, anger, positive psychological function, and stigma. Focus group feedback highlights the importance of additional aspects of emotional health that are salient in the SCI population (see Table 2). Focus group participants highlighted the significance of grief and the loss of abilities and lifestyle, resilience to bounce back after injury and begin a new life, and self-esteem or self-awareness that results from one's injury. Issues related to grief/loss and resilience were mentioned more frequently than depression and anxiety, and self-esteem/awareness issues were mentioned as often as depression. Percentages in this section represent only the Emotional and provider groups.

Participants discussed feelings of sadness and depression (11% of emotional focus group comments, "I felt very depressed the first couple of years, with the huge change of lifestyle and a lot of depression"). Some participants discussed fleeting feelings of sadness ("I can remember this underlying sadness"), while some individuals reported feelings of wanting to end their own life as a result of their SCI ("You get to a state of why do I even want to be here anymore? [Depression] was the most insidious thing of my injury…"). Clinicians also emphasized the significance of depression ("We see a lot of depression"; "I think it's an issue when depression gets in the way and you can't do anything"). Overall, some level of sadness or depression was a common theme among individuals with SCI.

Themes related to grief and loss were prominent[37] (14% of comments, "I was unable to do any of the things that I was used to doing and I felt like it just took everything away from me"; "I had a job that I loved and I…couldn't go back), and the negative feelings resulting from significant losses ("…the depressing parts you know, everything that I can't run and go play with [my son] in a park like he wants to do you know…"). Though many studies[38,39] have shown a clear distinction between grief and depression, the construct of grief is not usually measured in multifaceted PRO measures and is not included in Neuro-QOL or PROMIS.

Aspects of general positive psychological functioning (9% of comments) including hope ("I just feel better days are coming…I really do"), happiness ("As the years go by I'm feeling better… I'm happy"), gratitude ("I am 100% grateful to the God that I worship"), and joy ("You find new joys, you know, and move forward") were mentioned across both consumer and clinician groups. Individuals with SCI emphasized the concept of resilience. Resilience is defined as positive behavioral adaptation in the face of adversity such as trauma.[40] Tugade, Fredrickson, and Barrett[41] suggest that resilience likely has a positive impact on

health outcomes, and recent research has demonstrated the importance of this construct among individuals with SCI.[42] Resilience was mentioned in 15% of focus group comments ("Being in this wheelchair honestly has made me a stronger person because…I never thought that I could overcome this much") and reflects an individual's ability to live with an SCI and thrive in the face of ongoing challenges and limitations.

Self-esteem/self-awareness was another common theme; 11% of the consumer comments and 16% of clinician comments pertained to this topic. King[43] lists several definitions of self-esteem including Coopersmith's[44] definition as self-evaluation and Atherley's[45] explanation of self-esteem in relation to the discrepancy between one's actual and ideal self, with a large difference between the actual and ideal resulting in a negative self-perception and lower self-esteem. Individuals in the focus groups discussed negative self-perceptions and self-esteem ("I never thought that…somebody would just wanna be with me" and "I feel like I'm not good for anything…"). These negative self-evaluation and appraisals were common. Moreover, this appears to be related to, but distinct from, the construct of stigma, a domain of Neuro-QOL.[46] Stigma, prejudice or negative stereotyping which leads to discrimination[47], was mentioned in all groups (e.g., "People…think that someone in a chair is mentally retarded") though at a lower percentage than self-esteem/self-awareness (3%). It is not clear whether judgments by others and self fall on the same continuum, or whether they are distinct constructs.

Finally, issues related to anxiety/fear were discussed often by individuals with SCI (7%) and clinicians (6%). Participants cited specific worries, "I am scared of getting in a car a lot, just because whenever we get on the highway and go fast, it's like, okay, this is going to happen again," as well as an overall feeling of general anxiety, "Sometimes you get anxiety, fear, you know."). Participants and clinicians infrequently discussed anxiety resulting from the sudden (e.g., "It's not like you were sick and gradually got worse. This is one second you're walking, the next you're not"), traumatic nature of the injury (e.g., "sometimes you see post-traumatic stress of nightmares") which may be relevant to individuals who were injured during an incident of violence or members of the military who have sustained deployment-related injuries. While trauma only constituted 1% of all focus group comments, it comprised 7% of all anxiety comments and may be a separate construct.

Anger was mentioned in 7% of focus group comments, warranting an additional emotional subdomain. Participants discussed general ("I just get mad and it carries on to other people or, you know, makes you do stuff that you don't want to do…"; "It's not anger like at people in general, just like anger at life) and specific instances of anger ("I get angry because I don't really have anybody to vent to…"; "I'm really pissed that I can't go nowhere [due to lack of accessible transportation]").

The study team expected that the Neuro-QOL emotional subdomains would be appropriate for the SCI population. Qualitative analysis of focus group results supported the expectation that depression, anxiety, positive psychological functioning are important and, to a lesser extent, stigma. The qualitative data indicate that other emotional subdomains are more salient to the SCI population, including grief/loss, resilience, and self-esteem/self-awareness.

Social Participation Domain—Participants in all focus groups reported that SCI and associated environmental barriers and supports had an impact on social relationships and social participation. The most frequently discussed subtopic was Family and Friends (40%), which was comprised of general ("I'm lucky enough that I have some good friends") and specific ("You get invited and you don't go because you just don't feel like dealing with… friends that are drinking") interpersonal interactions, relationships ("My social network has changed"), and roles ("It was a problem after a couple years because we didn't really seem to have a husband and wife relationship anymore, it was more like caregiver and patient"). Percentages in this section represent only the Social participation and provider groups.

Leisure activities (29%) were discussed as a key aspect of social health. Leisure includes community life ("I'd like to know I did a little amount of work towards helping people with disabilities, helping at the hospital as a peer counselor is really rewarding for me"), home life ("I do all the laundry, I do the shopping and so forth and she shovels and mows the lawn…definitely the roles have changed in our house"), recreation ("I've played wheelchair sports since I've been using a chair"), and communication ("I've been told by so many people I should have a computer, so I can get on the internet and do this and do that. And I'm seeing that that's true for socialization"). Participants also discussed work and employment (12%) which includes employment ("I've been fortunate enough to have a tremendous amount of success at work"), financial independence ("Do you have enough money so that if you get a job, you can afford to get off Medicaid or whatever and still be able to get medical insurance"), education ("It was a difficult transition for me to go back to school and just be a college student again, but I'm in a chair"), and the need for vocational training ("I think these vocational schools are a great thing for them to try to get in and get a little training of some kind").

Additionally, environmental factors, including both barriers and supports, were a major theme arising from the Social Participation focus group. This is important because environmental factors have a direct impact on social participation. According to the World Health Organization's International Classification of Functioning, Disability, and Health[48](ICF), environmental factors make up the physical, social, and attitudinal world in which people live. These factors may serve as barriers or facilitators to participation based on individuals' perspectives. Barriers and facilitators include products, services, design and construction of buildings, and natural and human-made changes to the environment. Among individuals with SCI, frequently mentioned environmental factors included accessibility of buildings and activities ("you don't even know how many times you go to a hotel or a major establishment and they just have no idea of how to deal with a wheelchair"; "Some members of my family had ramps [put in] and didn't think anything of it and some never did it, never got around to it"), community services, systems, and policies ("people…are needing a lot of help, or medical supplies, equipment…and you can't get it through Medicaid or an agency"), and societal attitudes ("You know, you get some looks from people, almost like you've done something wrong"; "There's that group of people that I feel like snub us, too").

In addition to environmental factors and the common QOL issues shared with individuals with other neurological conditions, 5% of the comments in the social focus groups (and 7% of comments in the emotional focus groups) were related to issues of independence

("Quality of life would be so much better if that family sat back and allowed that person to be independent…many people can be so much more independent than their families allow them to be"), dependence ("Some people's goal is to become as independent as possible at the wheelchair level which is a very big change from independent person, and some people may never get to that level. They will stay dependent"), interdependence ("If I expect people to treat me a certain way, I have to educate them so that they can"), and autonomy ("I can take care of myself, going to the bathroom, you know") that are unique to SCI. Because participants discussed issues of interdependence in the context of relationships to other people, we have included this topic within our Social domain.

Sexual Functioning—Sexuality and sexual functioning were mentioned by all focus groups despite instructions to focus on a specific topic area (e.g., physical, emotional, or social content). However, sexual functioning was mentioned at a low rate as focus group participants reported physical (2% of physical group comments, "You lose a lot of your ability to perform"), emotional (2% of emotional group comments, "all the spontaneity is gone"), and social concerns (2% of social group comments, "My wife she's done a 180 degree on me…she don't even wanna touch me in no kinda way"). Additionally, some participants commented on the way that their sexuality has been affected by SCI ("My sex life – I didn't care for it anymore because I wasn't feeling anything. I didn't think it makes sense for me to get involved"). Providers echoed the importance of this area emphasizing that sexuality is especially relevant since many are young males at a time of their lives when their sexuality is very important to them. Other providers stressed that sexuality is important to so many individuals and it is significantly impacted by SCI.

Discussion

Qualitative analyses of the focus group data identified issues that should be included in a PRO measurement tool for individuals with traumatic SCI. In the domain of emotional health, the issues that matter the most are resilience and being able to "start a new life" following the loss of functioning, grief due to the loss of one's "former life," and self-esteem including concern about one's ability to do important activities. These themes parallel the pioneering work of Beatrice Wright[49] and Tamara Dembo[50] in their discussion of value changes accompanying acceptance of loss. These issues were discussed more frequently than depression and anxiety. Other aspects of emotional health in Neuro-QOL, positive psychological function and stigma, are relevant for individuals with SCI. The Neuro-QOL emotional domain and subdomains are relevant in an SCI population but do not capture the full spectrum of emotional factors that someone who has sustained a traumatic injury experiences. New content areas of grief and loss may reflect a new and unique subdomain of emotional functioning which should be assessed in a new item bank or they may expand the depression subdomain for an SCI population. Similarly, resilience may be a specialized subdomain or simply an extension of positive psychological functioning. Data support developing new item banks to capture these new ideas.

From a physical-medical health standpoint, there are several secondary medical conditions with the capacity to disrupt functioning and impact QOL. Neuropathic and musculoskeletal pain, bowel and bladder functioning and management, and skin breakdown/pressure ulcers

were experienced by a majority of participants. This is consistent with findings that physical-medical issues such as neuropathic pain and neurogenic bladder and bowel are associated with decreased QOL[51]. Other, well-documented secondary complications and comorbid conditions such as cardiovascular disease, respiratory functioning, blood pressure regulation and autonomic dysreflexia were also discussed, but at a lower frequency given that not everyone with SCI will experience these complications. At the same time, respiratory complications have been associated with a reduction in HRQOL[52], are a leading cause of death in individuals with SCI and warrant further consideration despite the lower prevalence of mention in the qualitative data.

In terms of social health and participation, the SCI-QOL focus group results closely mirror the results of the Neuro-QOL focus groups[53]. Participants discussed changes in social roles and relationships, the ability to participate in leisure and recreational activities, and the importance of education and employment. The Neuro-QOL social health banks of social role performance and social role satisfaction are appropriate for use with individuals with SCI, though they should be supplemented with additional items addressing independence and autonomy and their impact on social relationships and the ability to participate.

A final cross-cutting topic, sexual functioning, was discussed consistently though not frequently across all focus groups. Satisfaction with sexual life is decreased in individuals with SCI relative to the general population[54], and sexual functioning impacts an individual's physical, emotional, and social quality of life. Therefore, consideration of sexual functioning is important when measuring QOL in individuals with SCI.

As shown in Table 2, both individuals with SCI and clinicians who work with people with SCI focused on similar issues during the focus group discussions, which confirms the importance of the emerging domains and subdomains. The one area where clinicians focused on additional medical problems and secondary conditions was in the area of physical-medical health, where clinicians discussed other health issues (e.g. metabolic issues, obstetric/gynecological issues, immunological concerns), though these were mentioned with relatively low frequency.

It is important to acknowledge that qualitative data collection and analysis methodology is limited for several reasons. When using a focus group methodology, some groups may focus on certain areas while other groups will focus on different content areas, often dictated by the composition of the group. This study utilized a thorough methodology to quantify qualitative feedback[32], but the generalizability of this information is limited by the representativeness of the sample, the dynamics within the group setting, and some degree of subjectivity in the evaluation and coding of responses. Nevertheless, this is an established method of obtaining feedback, information, and guidance directly from individual members of the population in question.

The next step was to integrate the focus group findings with the literature searches conducted by the Neuro-QOL[26] and SCI-QOL teams and finalize decisions about domains and subdomains. A detailed overview of this decision process, as well as the methodology for developing, categorizing, and reducing item pools may be found in Kisala and Tulsky

(2010). Specifically, for this project all items went through cognitive testing with a minimum of 5 individuals with SCI, reading level was reviewed to ensure all items were at or below a 6th grade reading level, and a translatability review was conducted to facilitate future translation of final SCI-QOL items. Finally, the team worked to ensure linkages with PROMIS and Neuro-QOL scales and prepare for large-scale calibration field testing. Based on the feedback provided in the focus groups and item development process, twenty two item banks have been developed. _ENREF_32 _ENREF_58

Acknowledgement

List of Abbreviations

CAT	Computerized Adaptive Test
CHART	Craig Handicap Assessment and Reporting Technique
HRQOL	Health-related Quality of Life
ICF	International Classification of functioning, disability, and health
IRT	Item Response Theory
Neuro-QOL	Quality of Life for Neurological Disorders [measurement system]
NIDRR	National Institute on Disability and Rehabilitation Research
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
PRO	Patient Reported Outcomes
PROMIS	Patient Reported Outcomes Measurement Information System
QIF	Quadriplegia Index of Function
QOL	Quality of Life
SCI	Spinal Cord Injury
SCI-CAT	Computerized adaptive measure of Functional Activities / Activity Limitation in SCI

SCIM-III	Spinal Cord Independence Measure version 3
SCI-QOL	Spinal Cord Injury Quality of Life Measurement System
SF-36	Medical Outcomes Study 36-Item Short Form
SWLS	Satisfaction with Life Scale
WHO	World Health Organization

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Table 1

Focus Group Participants: Persons with SCI N=65 [% or Mean (SD)]

	Total	New Jersey	Ann Arbor	Chicago	Seattle
	N=65	N=20	N=16	N=14	N=15
Demographic characteristics					
Age in years [Mean (SD)] [d]	45.6 (14.2)	42.5 (12.5)	43.8 (13.5)	40.9 (14.9)	56.3 (11.8)
Gender (%)					
Male	72.3	80.0	75.0	50.0	80.0
Female	27.7	20.0	25.0	50.0	20.0
Race/ethnicity (%) [c]					
Non-Hispanic White	69.2	65.0	75.0	50.0	86.7
African American	20.0	25.0	18.8	35.6	0.0
Hispanic	6.2	10.0	6.2	7.2	0.0
Native American / Alaskan Native	3.1	0.0	0.0	0.0	13.3
Asian/Pacific Islander	1.5	0.0	0.0	7.2	0.0
Injury characteristics					
Injury level (%)					
Paraplegia	52.3	50.0	62.5	50.0	46.7
Tetraplegia	47.7	50.0	37.5	50.0	53.3
Years since injury [Mean (SD)] [d]	12.6 (11.5)	10.4 (9.3) [a]	11.7 (7.1) [b]	5.0 (5.9) [c]	22.2 (13.4) [abc]
Assistive technology use (%) [d]					
Wheelchair	84.6	95.0	80.0	80.0	71.4
Walker, cane or crutches	14.3	0.0	—	20.0	28.6
None	2.0	5.0	—	0.0	0.0

Note. Significance tests are based on F test of means. Dashes indicate values that were not obtained or not reported.

[a] Bonferroni post-hoc tests: Values with identical superscripts differ at the 0.01 level.

[b] Bonferroni post-hoc tests: Values with identical superscripts differ at the 0.01 level.

[c] Bonferroni post-hoc tests: Values with identical superscripts differ at the 0.01 level.

[d] N varies due to reporting differences across sites

Table 2

SCI-QOL Qualitative Analysis Results by Domain.

PHYSICAL-MEDICAL HEALTH: Secondary Complications		
	% CONSUMER Comments	*% CLINICIAN* Comments
Pain	16%	14%
Toileting (bowel / bladder)	11%	16%
Muscular	11%	7%
Skin	9%	10%
Temperature regulation	7%	2%
Fatigue	4%	5%
Cardiovascular	4%	5%
Bone & connective tissue	4%	3%
Autonomic dysreflexia	4%	1%
OTHER	7%	23%
EMOTIONAL HEALTH		
	% CONSUMER Comments	*% CLINICIAN* Comments
Resilience	15%	18%
Loss/grief	16%	9%
Self esteem	11%	16%
Sadness, depression	11%	12%
Positive emotions	9%	8%
Other emotions	9%	6%
Independence autonomy	7%	6%
Emotional roadblocks	5%	9%
Anxiety/fear	7%	6%
OTHER	4%	7%
SOCIAL HEALTH and PARTICIPATION		
	% CONSUMER Comments	*% CLINICIAN* Comments
Interpersonal relationships	41%	39%
Significant other role	9%	7%
Leisure	29%	29%
Work and employment	12%	18%
Stigma	10%	6%
Independence/autonomy[a]	5%	6%

Note: Percentages do not add to 100% due to rounding and omission of infrequently (<3%) mentioned topic