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# Development of the Pediatric Quality of Life Inventory™ Spinal Cord Injury (PedsQL™ SCI) module: qualitative methods

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## Abstract

**Study design** It is a qualitative study.

**Objectives** To develop the items and support content validity for the Pediatric Quality of Life Inventory™ (PedsQL™) Spinal Cord Injury Module for youth and emerging adults with spinal cord injury (SCI).

**Setting** Community and children's hospital.

**Methods** A comprehensive literature review was conducted in pediatric and SCI-specific health-related quality-of-life (HRQoL) measures to create an item bank. A multidisciplinary panel of experts convened to discuss the conceptual framework of the module, reviewed the item bank, and generated a core set of items through a process of “binning-and-winnowing”. International clinicians and researchers participated in iterative rounds of a Modified Delphi survey, until 90% agreement was reached on all items of the core set, resulting in the construction of a preliminary module. Cognitive interviews were conducted on individuals with SCI and their parents to determine the relevance of items and age-appropriate wording of the preliminary module. The research team regularly reviewed transcriptions of the interviews, and incorporated participant feedback to modify the modules. This process was repeated until content saturation was achieved.

**Results** A total of 43 participants completed the cognitive interviews. Following five iterations of cognitive interviews and modifications based on participant input, the PedsQL™ SCI Module was generated. It comprised 67 items in the 12 domains of Daily Activities, Mobility, Bladder Function, Bowel Function, Muscle Spasms, Pressure Injury, Pain, Orthostatic Hypotension, Autonomic Dysreflexia, Participation, Worry, and Emotions.

**Conclusions** The PedsQL™ SCI Module was developed using well-established qualitative methods. Internet-based field testing is underway to finalize its development and validation.

## Introduction

Sustaining a spinal cord injury (SCI) greatly impacts the health-related quality of life (HRQoL) of the individual. Impaired mobility and secondary health conditions (SHCs), such as neurogenic bladder and bowel dysfunction,

pressure injury, spasticity, pain, and autonomic dysfunction, can lead to decreased independence, less community participation, and negative psychosocial outcomes [1, 2]. Thus, valid and reliable measures of HRQoL are important in the evaluation of clinical management and research interventions for the individual with SCI [3]. Youth (children and adolescents) who sustain a SCI experience the manifestations of physical impairment and SHCs while simultaneously progressing through the different stages of physical and psychosocial development [4, 5]. Thus, it is crucial to employ measures of HRQoL that are appropriate and relevant to the developmental stage of the youth with SCI, as well as allow longitudinal assessment throughout maturation into adulthood.

While numerous measures are available to assess outcomes in adults with SCI, few measures exist for the pediatric SCI population [6]. To address this deficit, members of the National Institutes of Neurological Disorders and

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Stroke (NINDS) Common Data Elements (CDE) SCI pediatric working group have made recommendations for use of existing measures, and in doing so, also identified the need for further psychometric testing and measurement development [7]. The Pediatric SCI Activity Measure (PEDI-SCI AM), the Pediatric Measure of Participation (PMoP), and the Pediatric Neuromuscular Recovery Scale (PNRS) have been developed and validated for youth with SCI, and the Spinal Cord Independence Measure III self-report for youth (SCIM-III SR-Y) has been adapted for use with children [8–11]. These measures represent major advancement in the assessment of function and participation following pediatric SCI; however, none of them were designed to measure HRQoL.

The Pediatric Quality of Life Inventory™ version 4.0 (PedsQL™ 4.0) Generic Core Scales is a reliable and valid measure of HRQoL that spans childhood and adolescence, with versions for self-report by the Young Child (ages 5–7), Child (ages 8–12), and Teen (ages 13–18), and Parent Proxy versions for the same age groups as well as for the Parent of Toddler (ages 2–4) [12]. In addition, the PedsQL™ Generic Core Scales Young Adult (ages 19–25) version allows for the longitudinal evaluation from adolescence to young adulthood [13]. While this instrument can reliably assess and compare the core domains of physical, emotional, social, and school functioning among different populations, some items may not be applicable to youth with physical disabilities or not be sensitive enough to detect pertinent health issues within a specific health condition. When used in a population of pediatric patients with SCI, the PedsQL™ 4.0 General Core Scales yielded a low internal consistency reliability in various items, suggesting the necessity of a disease-specific measure for youth with SCI [14]. Because of the limitations of generic measures for clinical populations, the PedsQL™ has been expanded to include disease-specific modules for a variety of health conditions, among which include diabetes, cancer, cerebral palsy, neurofibromatosis, and Duchenne muscular dystrophy [15–19]. These modules have been developed and validated for their respective diseases to assess important HRQoL issues in youth.

Qualitative methods have become the standard in developing items and supporting content validity for new patient-reported outcome (PRO) measures [20]. The Food and Drug Administration (FDA) Guidance to Industry recommends a process of comprehensive literature review, expert opinion, and focus group/individual interviews to develop the conceptual model for relevant domains and items, and iterative cognitive interviews to revise the items to achieve content that is appropriate for the consumer [21]. Such methods have been described for the development of previous PedsQL™ Disease-Specific Modules, and used successfully in our work with children with SCI for

development of the PEDI-SCI AM and PMoP [22–26]. Accordingly, we have adopted this methodology to develop a SCI-specific module of the PedsQL™ for youth and emerging adults: the PedsQL™ SCI Module. This paper reports the methods and results of the qualitative research.

## Methods

A multiphase methodology was employed for item bank development, identification of pertinent domains, and obtaining consumer perspective on the relevance and content of the domains and items. The research team comprised three clinicians (pediatrician, physiatrist, and clinical psychologist) with extensive experience in providing care to youth with SCI, and two researchers (occupational therapist and psychologist) with expertise in PRO development and methodology.

### Item bank development

#### Literature review

Over 50 pre-existing outcome measures related to SCI and SCI-related conditions, pediatrics, and pediatric SCI, such as the Spinal Cord Quality of Life measurement system (SCI-QoL), Child Health Questionnaire (CHQ), EuroQoL 5 Dimension Questionnaire—Youth (EQ5DY), SCIM-III SR-Y, and PMoP were reviewed [9, 11, 27–29]. Individual items considered to be relevant to HRQoL in pediatric SCI were collected.

#### Expert opinion

A multidisciplinary panel of seven experts (two pediatric physiatrists specializing in SCI, one research psychologist with extensive experience in rehabilitation outcomes, and four members of the research team) convened to review the item bank and develop the conceptual framework of the module. An iterative process of “binning-and-winnowing” was utilized to construct a core set of domains and items. “Binning” refers to the systematic process of grouping items according to meaning and specific latent content. “Winnowing” is the process of reducing the item pool down to a representative set of items by including or excluding items based on a specific domain definition. This process had been used previously to develop the Patient Reported Outcome Measurement Information System (PROMIS®) [30].

A Modified Delphi survey was subsequently employed to determine the relevance of the domains and items of the core set [31]. Healthcare professionals and researchers specializing in pediatric SCI were identified through

professional organizations (e.g., American Spinal Injury Association, International Spinal Cord Society, and Steel Steel Assembly) and were invited via email to participate in an internet-based survey. The respondents rated each item on a dichotomy scale as either relevant or not relevant to its domain, and provided suggestions regarding age-specific content and appropriate wording. Each domain was also rated as relevant or not relevant, and suggestions were solicited for additional items and domains. Responses from the first round of the survey were reviewed and organized; domains and items achieving 90% agreement were cataloged for incorporation into the preliminary module, and those not achieving 90% agreement were modified according to the recommendations. The modified domains and items with descriptions of the changes and added items were presented in the subsequent round of survey. This iterative process continued until 90% agreement was achieved for each item, and the resulting domains and items were used to construct the preliminary modules.

### Preliminary modules

To stay consistent with the PedsQL™ Generic Core Scales, when possible, items were presented as “*It is hard for me (my child) to ...*” The reading level was set to target children at a third-grade level, and was assessed using the Flesch–Kincaid readability test. Self-report versions were constructed for the following age groups: Young Child (ages 5–7), Child (ages 8–12), Teen (ages 13–18), Young adult (ages 19–25), and parent proxy versions for the same age groups and Toddlers (ages 2–4). The Young Child version was written in interview format, “*Is it hard for you to...?*” as not all children in this age group are fluent readers. The recall period was set as the past 7 days to better capture the most recent HRQoL.

### Cognitive interviews

Youth with SCI 5–18 years of age, emerging adults with pediatric-onset SCI 19–25 years of age, and parents of children (2–25 years of age) with SCI were recruited from the outpatient clinics at Shriners Hospitals for Children—Chicago. Eligibility criteria included time since injury  $\geq 1$  year, and the ability to read and/or communicate in English. Participants were recruited using purposeful sampling to ensure that all age groups and levels of injury were represented.

Cognitive interviews were conducted to obtain participant perspectives of the relevance of the domains and items, as well as to determine age-appropriate content and terminology. Think aloud with verbal probing methodology was used for participants 8 years of age and older [32, 33]. Participants were instructed to read aloud the title of each

domain and each item, and select the response option that “best fit” him/her. If there were words that the participant found difficult to pronounce, the interviewer provided the correct pronunciation and made a note of the word. For children 5–7 years of age, the module was presented as an in-person interview, with the interviewer reading each item and having the child point to one of three facial expression images that best fit their response. This is consistent with the pre-existing PedsQL™ 4.0 Generic Core Scales Young Child (ages 5–7) version [12]. Following completion of each domain, the interviewer reviewed each item with the participant using verbal probes to assess the level of understanding and solicit more appropriate wording. Interviews of the youth with SCI were conducted separately from interviews of the parent. Interviews were audio-recorded and transcribed verbatim for review. Participants were interviewed once and given a \$25 gift card for their participation. The research team met every 2 weeks to review the transcripts of the interviews, and made modifications to the preliminary module based on participant feedback. Subsequent interviews with a new group of participants were conducted using the revised modules. This process was repeated until content saturation was achieved, that is, the point at which no new information or themes were identified [24, 33].

## Results

### Item bank development

A review of literature and existing outcome measures resulted in the collection of 498 relevant items. The subsequent binning-and-winnowing process conducted by the expert panel led to the construction of a core set of 12 domains and 132 related items. Email invitations with a URL link to the Modified Delphi survey on this core set were sent to 88 professionals in pediatric SCI, from which ~36% responded (Table 1). Following two rounds of surveys, all domains and items achieved 90% agreement on relevance, with no further recommendations. Preliminary modules consisting of 12 domains and 62 related items were constructed for each age group described above. For several domains, brief definitions of terminology were provided per suggestions obtained from the Delphi surveys.

### Cognitive interviews

A total 43 cognitive interviews were conducted, with participants comprising 22 individuals with SCI and 21 parents of children with SCI (Table 2). Based on participant input following the first round of interviews, the order of the domains was reorganized to allow for a smoother transition between

**Table 1** Modified Delphi survey participants.

	Round 1	Round 2
Response rate		
Completed surveys from 88 invitees	32 (36.4%)	31 (35.2%)
Discipline		
Physician	10	9
Researcher	4	5
Psychologist	4	6
Nurse	3	3
Physical therapist	10	10
Occupational therapist	1	
Experience		
<5 years	8	4
5–10 years	4	9
10–20 years	14	15
Greater than 20 years	6	5
Location		
United States	22	26
International	10	5

**Table 2** Demographics of cognitive interview participants.

	Individuals with SCI n = 22 (%)	Parents of child with SCI n = 21 (%)
Gender		
Male	9 (40.9)	5 (23.8)
Female	13 (59.1)	16 (76.2)
Race/ethnicity		
White	16	15
Black	2	3
Hispanic	3	3
Mixed/other	1	
Age group, years		
Toddler, 2–4		3 (14.3)
Young child, 5–7	3 (13.6)	3 (14.3)
Child, 8–12	7 (31.8)	7 (33.3)
Teen, 13–18	7 (31.8)	6 (28.6)
Young adult, 19–25	5 (22.7)	2 (9.5)
Level of injury		
Tetraplegia	8 (36.4)	
Paraplegia	14 (63.6)	
Duration of SCI (mean ± SD, years) <sup>a</sup>	5.5 ± 4.5	
Median age of parent (range, years)		42 (30–60)

<sup>a</sup>Includes the three children with SCI in the toddler (2–4 years) age group.

domain concepts: Daily Activities – Mobility – Bladder function – Bowel function – SCI-related SHCs (Muscle spasms – Pressure injury – Pain – Orthostatic hypotension – Autonomic dysreflexia) – Participation – Worry – Emotions. Five iterations of interviews and modifications were conducted until reaching content saturation.

A summary of notable interview comments and revisions is presented in Table 3. The majority of modifications were made to the Parent of Toddler version due to the developmental stage of their child precluding them from performing the items. For example, responses to “*It is hard for my child take a bath or shower*” in the Daily Activities domain included, “My child can’t bathe himself” and “I wash him, so I don’t know how to answer this”. Thus, developmentally inappropriate items were removed from the Parent of Toddler version. Modifications were made to the Young Child version for age-appropriate content and wording due to the children’s limited ability to understand specific concepts and terminology.

Domains pertaining to SCI-specific SHCs (muscle spasms, pressure injury, orthostatic hypotension, and autonomic dysreflexia) were not relevant to some participants as they had never experienced them before or did not experience them within the past 7 days of the time of interview. Following input from the first six interviews, the domain definitions were modified for clarity and included examples to better describe the condition: “*PRESSURE INJURY. Pressure injury/wound is when your skin gets red or soft or breaks in places like your butt or heels because it was pressing against something for a long time*”. In addition, the following instruction was added for these domains: ‘*If you did not have (condition) in the past 7 days, skip this section.*’

Pertinent domain-specific participant feedback is described below.

### Daily activities

This domain contains nine items regarding self-care, and two items related to use of a smartphone/tablet and computers, all of which were considered to be performed universally in all age groups. This domain initially did not have items related to bladder and bowel program, but was added following suggestions from multiple participants. Due to the developmental considerations in toddlers, items pertaining to bathing, bladder and bowel program, and use of computers were removed from the Parent of Toddler version.

### Mobility

Participants mentioned how the presence of stairs or uneven surfaces affects their mobility when reviewing ‘*It is hard for*

**Table 3** Summary of cognitive interview feedback and modifications.

Domain/Original item	Feedback	Modifications
<i>Daily activities</i>		
It is hard for me to take a bath or shower	“Does this include getting into and out of the tub?” Suggestions were made to separate transfers and the actual act of taking a shower or bath.	Added transfer item before shower item, and provided examples: It is hard for me to do transfers (example: move from wheelchair to bathtub, from bed to wheelchair)
It is hard for me to do my bladder program	Younger children (5–7 years) did not know the terminology “bladder program”	It is hard for me to pee
It is hard for me to do my bowel program	Younger children (5–7 years) did not know the terminology “bowel program” “What about play? Play is a daily activity for my 3-year old”	It is hard for me to poop Added “play” to the first item of the Participation domain
<i>Mobility</i>	Younger children (5–7 years) and some children (8–12 years) could not define “mobility”	<i>Moving around</i> for Young Child and Child modules
<i>Bladder function</i>	Younger children (5–7 years) and some children (8–12 years) had difficulty defining “bladder function”	<i>Peeing</i> for Young Child and Child modules
It is hard for me to... because of bladder accidents	Defining “bladder” was difficult for children 9 years and younger “Bladder accident” was difficult for younger children (5–7 years)	Child module: It is hard for me to... because of pee accidents Young Child module: Is it hard for you to... because you pee in your pants
It is hard for me to... because of my bladder program	Defining “bladder program” was difficult for children 9 years and younger	It is hard for me to... because of the way I pee
<i>Bowel function</i>	Younger children (5–7 years) and some children (8–12 years) had difficulty defining “bowel function”	<i>Pooping</i> for Young Child and Child modules
My bowel program takes up too much time	Defining “bowel program” was difficult for children 9 years and younger	The way I poop takes too much time
It is hard for me to... because of bowel accidents	Defining “bowel” was difficult for children 9 years and younger “Bowel accident” was difficult for younger children (5–7 years)	Child module: It is hard for me to... because of poop accidents Young Child module: Is it hard for you to... because you poop in your pants
<i>Muscle spasms</i>	Participants mentioned difficulty with transfers because of muscle spasms	Added: It is hard for me to do transfers because of muscle spasms
<i>Pain</i>	Younger children (5–7) preferred ‘hurt’ over “pain”	Is it hard for you to... because you hurt?
<i>Orthostatic hypotension</i>	Terminology difficult to pronounce by most participants Two parents of toddlers state that their child is not able to clearly communicate their symptoms, making it difficult to detect OH Younger children did not understand this term or the definition provided	Added middle dot [·] after the first syllable in each word <i>Ortho-static hypo-tension</i> Domain deleted from Parent of Toddler and Young Child modules
<i>Autonomic dysreflexia</i>	Terminology difficult to pronounce by most participants Younger children did not understand this term or the definition provided	Added middle dot [·] after the first syllable in each word <i>Auto-nomic dys-reflexia</i> Domain deleted from Young Child module
<i>Participation</i>	Younger children (5–7 years) and some children (8–12 years) had difficulty reading and defining “participation”	<i>Doing things with others</i> for Young Child and Child modules



**Table 3** (continued)

Domain/Original item	Feedback	Modifications
It is hard for me to do things at home	One parent of a 3-year old stated that ‘playing’ was a daily activity when completing the Daily Activities domain	It is hard for me to play or do things at home
It is hard for me to be on social media	“My child is not allowed to be on social media” Most children 12 years and younger were not on social media; however, many of them communicated with others while playing online games	Deleted item for younger children (5–7 years) It is hard for me to be on social media or online games
<i>Worry</i>		
	One parent stated his child’s worries about not being included by peers	Added: I worry about being left out
I worry about my future	Younger children (5–7 years) had difficulty defining ‘future’  Two parents of toddlers stated that many of the worry items are not applicable because it is hard to discern whether the child worries about anything Suggested that getting upset about things is more appropriate	Do you worry about what will happen to you when you are older?  Domain title changed for Parent of Toddler module: <i>Upset</i> Deleted most items, but retained the following: My child gets upset about going to the doctor or hospital My child gets upset about being teased My child gets upset about being left out
<i>Emotions</i>		
	Younger children (5–7 years) had difficulty defining ‘emotions’	<i>Feelings</i> for Young Child module
I feel confident	‘Confident’ was difficult to define for younger children	Do you feel like you can do anything?
I feel hopeful for my future	Younger children (5–7 years) had difficulty defining ‘hopeful’ and ‘future’  “My child gets frustrated more than getting angry” Several parents suggested adding negative emotions that are not in the Generic Core Module	Do you think good things will happen to you when you are older?  Added: I feel frustrated
I feel frustrated	Younger children (5–7 years) had difficulty defining ‘frustrated’	Do you feel upset or frustrated?

me to go wherever I want in my house’ and ‘It is hard for me to go wherever I want out of the house’. After thinking aloud their thought processes, however, participants were able to respond readily to these items, and did not suggest any modifications.

### Bladder function

From the outset, the need to distinguish between the impact of having bladder accidents and performing a bladder program on HRQoL was established by the research team and expert panel, and was confirmed from the Modified Delphi surveys. Participants were able to differentiate between the items pertaining to bladder accidents and bladder program, and responded appropriately. The term ‘*bladder program*’ was unfamiliar to children under the age of 10: “Do you mean cathing?”; “I don’t cath, but need to go every 2–3 h so I don’t leak”. Given the variable methods utilized for bladder program among individuals, this term was modified to ‘*how I pee*’ in the Young Child and Child versions. When

asked about preference between ‘*my bladder program*’ and ‘*how I pee*’ to three children of ages 10–12 years, all recommended the latter because “it would be easier to understand for kids that don’t know what a ‘bladder program’ is.” Similarly, ‘*bladder accidents*’ were modified to ‘*pee accidents*’ in the Child version and ‘*pee in your pants*’ in the Young Child version.

### Bowel function

Similar to the Bladder Function domain, ‘*bowel program*’ was modified to ‘*how I poop*’, and ‘*bowel accidents*’ was modified to ‘*poop accidents*’ for Child version and ‘*poop in your pants*’ for the Young Child version.

### Muscle spasms

During the first round of interviews, two participants with SCI and one parent discussed how muscle spasms impeded the ability to perform transfers. Accordingly, the item ‘*It is*

*hard for me to do transfers because of muscle spasms*’ was added, and subsequent participants reiterated the significance of this item: “I need to get my spasms out before I start to move”; “Yes, sometimes my child has to wait for his spasms to subside before he can transfer”.

### Pressure injury

The definition provided for this domain was considered to be helpful, particularly for children of ages 8–12. Participants in the 5–7-year age group did not know what a pressure injury was, nor did they understand after it was explained to them, so this domain was removed from the Young Child version.

### Orthostatic hypotension (OH) and autonomic dysreflexia (AD)

Pronunciation of ‘orthostatic hypotension’ and ‘autonomic dysreflexia’ was difficult for all age groups and parents. Once the participants heard the correct pronunciation and read it correctly themselves, most of them readily recognized the terminology. To assist in pronunciation, a middle dot ‘•’ was placed between the first and second etymological syllable of each word: ‘Ortho•static Hypo•tension’, ‘Auto•nomic Dys•reflexia’. Following this modification, all participants were able to read these words without difficulty. Parents of toddlers commented that it is not possible to determine if their child experiences symptoms of OH as toddlers cannot clearly communicate their discomfort other than by crying or being irritable. On the other hand, parents did say they are able to detect signs of AD in their child, such as facial flushing and sweating. Children of ages 5–7 did not understand OH or AD. Thus, the OH domain was deleted from the Parent of Toddler version, and both OH and AD domains were removed from the Young Child version.

### Participation

This domain was well accepted, particularly by the parents who voiced appreciation for items assessing community participation for their children. When asked about what ‘... *do things at home*’ of the first item meant to them, most participants responded with activities such as doing chores, walking with the dog, and playing with family. There were, however, several responses pertaining to self-care activities, such as brushing teeth and washing face. In addition, three children 8–9 years of age had difficulty pronouncing and defining ‘Participation’. Thus, to clarify the concept of participation and improve readability, ‘Participation’ was reworded as ‘Doing things with others’ in the Young Child and Child versions.

### Worry

Initially, this domain contained items on all of the SHCs (e.g., ‘*I worry about pressure injuries*’). Over the course of the first six interviews, participants stated that they do not worry about the occurrence of such conditions, reporting, “I just deal with it when it happens”. Accordingly, these items were removed. Items regarding bladder/bowel accidents and smelling bad because of bladder/bowel function, however, were retained as participants considered these to be common occurrences that people with SCI face on daily basis. The other items assessing treatment, peer relationship, and body image were all considered relevant issues that youth with SCI worry about.

### Emotions

The research team focused on four positive emotions to contrast with the negative emotions assessed in the PedsQL™ Generic Core Scales. Following the first round of interviews, participants commented that ‘*I feel good about myself*’ seemed to be the same as ‘*I feel happy*’ or ‘*I feel confident*’, but also stated that the latter two were distinct from each other. Thus, ‘*I feel good about myself*’ was removed. Two parents commented that feeling frustration was a frequent experience in their child, so ‘*I feel frustrated*’ was added.

### Overall

At the conclusion of each cognitive interview session, participants were asked to talk freely about their thoughts on the module. Two children in the 8–12-year age group commented on the length, but said that they were able to complete the module easily. All participants responded positively regarding content and readability. Table 4 lists a few notable comments.

### Discussion

This paper describes the qualitative methods used to develop the PedsQL™ SCI Module. Incorporation of expert opinion by professionals in pediatric SCI and detailed feedback obtained from cognitive interviews of individuals living with an SCI allowed for item development and content validity for this multidimensional HRQoL measurement instrument specific to youth and emerging adults with SCI.

The FDA Guidance strongly recommends in-depth focus group or individual interviews in the early stages of item development to determine concepts most relevant to the consumer [22]. Given the highly heterogeneous

**Table 4** Notable participant comments regarding the PedsQL™ SCI module.

Comment	Participant
“I think it’s really good. This is probably the first questionnaire I’ve seen that’s actually pertaining specifically to a SCI”	Mother of 3-year-old male (T3 paraplegia)
“I like it. Honestly, if it’s something that you guys are going to track for whomever is taking it, it would have been nice for us to see something like this when he first got diagnosed, and now five years into it, to see what areas are getting better and what areas he still needs to work on”	Mother of 9-year-old male (T9 paraplegia)
“This is definitely needed—that way you guys can have a true understanding of what’s going on and also, you can administer what needs to be administered as far as time, dedication, situations, or whatever that applies to that scenario. I believe this is something that is much needed”	Father of 17-year-old male (C7 tetraplegia)
“I wish I would have been asked something like this before, because I feel like this would have helped a lot. This is cool”	21-year-old female (T6 paraplegia)
“They make sense and I think the questions are important to kids like me”	12-year-old male (T12 paraplegia)
“I think it includes all the things that happen daily after the SCI that’s important to keep in mind. I really like it because they helped me to think about things that maybe I don’t realize every day, but is important to know and to do”	16-year-old female (T6 paraplegia)

presentation of SCI depending on the severity and level of injury, however, there was a possibility that focus group or individual interviews would not be able to adequately capture the full spectrum of relevant issues encountered in SCI. Thus, the input obtained from the multidisciplinary expert panel and modified Delphi surveys allowed for a comprehensive collection of relevant concepts affecting HRQoL in youth with SCI, which were then used to develop the preliminary module. The subsequent cognitive interviews conducted using the preliminary modules provided very insightful information on SCI-specific and age-appropriate content and wording. Not surprisingly, the majority of the modifications were made to the Parent of Toddler and Young Child versions due to the developmental stage of the child precluding them from performing activities or understanding the items. The addition of brief definitions and examples for domains pertaining to SHCs was considered to be appropriate and informative, particularly for participants who had not previously experienced the specific condition. All participants responded positively to the PedsQL™ SCI Module, with many commenting how appreciative they were that the instrument measured items that actually impact the daily lives of youth with SCI (Table 4).

This study is limited by the lower proportion of participants with tetraplegia who completed the cognitive interviews, potentially resulting in less information on HRQoL issues related to having higher levels of SCI. In addition, there was a significantly lower number of nonwhite individuals providing their perspectives. As the next step of instrument development, an internet-based field test of the newly developed module is currently underway, and this will be followed by quantitative methods to determine the reliability and validity of the instrument.

In conclusion, we developed the items and established content validity of the PedsQL™ SCI Module for self-report for ages 5–25 years, and parent proxy report for

children with SCI ages 2–25 years. The Parent of Toddler version contains 38 items in 9 domains, the Young Child version contains 56 items in 9 domains, and all other versions contain 67 items in 12 domains. The PedsQL™ SCI Module will be used in conjunction with the PedsQL™ 4.0 Generic Core Scales, and we anticipate that it will provide better understanding of HRQoL in youth and emerging adults with SCI, and allow for longitudinal assessment of health status over time.

### Data availability

Data sharing is not applicable to this paper as no datasets were generated or analyzed during this study.

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**Author contributions** MH substantially contributed to the study design, acquisition, and analysis of cognitive interviews and drafting of the paper. KZ contributed to study conception and design, analysis of interviews, and drafting of the paper. LCV substantially contributed to study conception and design, analysis of interviews, drafting the paper, and acquisition of funding. MJM contributed to the study conception and design, and drafting of the paper. JWV contributed to the study conception and design, analysis of interviews, and review of the paper for critical intellectual content. All authors read and approved the final paper.

### Compliance with ethical standards

**Conflict of interest** JWV holds the copyright and trademark for the PedsQL™ and receives financial compensation from the Mapi Research Trust, which is a nonprofit research institute that charges distribution fees to for-profit companies that use the Pediatric Quality of Life Inventory™.



**Ethics** This study was reviewed and approved by the Western Institutional Review Board (Study Number 1248478). We certify that all applicable institutional regulations concerning the ethical use of human volunteers were followed during the course of this research.

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