

ARTICLE



Development of the International Spinal Cord Injury Basic Data Set for informal caregivers

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STUDY DESIGN: Mixed-methods, including expert consensus for initial development and a multi-center repeated measures design for field testing.

OBJECTIVES: To develop an International Spinal Cord Injury Basic Data Set for caregivers of individuals with spinal cord injury/disorder (SCI/D) for use in research and clinical care settings.

SETTING: International, multi-disciplinary working group with field testing in five North American pediatric rehabilitation hospitals.

METHODS: The data set was developed iteratively through meetings and online surveys with a working group of experts in pediatric and adult SCI/D rehabilitation and caregivers of individuals with SCI/D. Initial reliability was examined through repeat administration of a beta form with a sample of caregivers recruited by convenience. The sample was characterized with descriptive statistics. Intra-rater reliability of variables was assessed using Intra-Class Correlations.

RESULTS: The beta test form included 27 items, covering 3 domains: (1) demographic information for persons providing care; (2) caregiver's allocation of time and satisfaction; and (3) perceived burden of caregiving. Thirty-nine caregivers completed both administrations. Mean time for completion was 10 min. There was moderate to excellent reliability for the majority of variables, but results indicated necessary revisions to improve reliability and decrease respondent burden. The final version of the data form contains 7 items and is intended for self-administration among informal caregivers of individuals with SCI/D across the lifespan.

CONCLUSIONS: The International SCI Basic Data Set for Informal Caregivers can be used to standardize data collection and reporting about informal caregivers for individuals with SCI/D to advance our understanding of this population and the data form has additional utility to screen for caregiver needs in clinical settings.

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INTRODUCTION

Caregivers of individuals with spinal cord injury or disorder (SCI/D) aid with many aspects of medical care, functional activities, and psychosocial wellbeing, especially in areas where individuals with SCI/D have not reached total independence. Activities commonly performed by caregivers for individuals with SCI/D may include activities of daily living (ADLs; e.g., toileting, dressing, bathing), instrumental activities of daily living (IADLs; e.g., financial management, coordination of care, communication management), play or leisure, and social participation [1]. The scope and intensity of caregiving responsibilities have raised serious concerns about impacts on health and well-being of caregivers [2, 3], especially “informal” caregivers, who do not have professional training or an affiliation with a care agency. Informal caregivers make up the largest proportion of care providers [1], yet there has been limited effort to systematically capture information about this population to understand and address their health and related needs. Therefore, the purpose of this research was to develop a data set focused on informal caregivers for individuals with SCI/D, which

can be used to harmonize international research on caregiving and as a clinical tool to screen for caregiver needs.

Caregivers can experience increased stress and burden when they have difficulty meeting demands of caregiving [4], and rates of mortality have been shown to be significantly higher for caregivers who feel strained [5]. Negative effects of caregiving can lead to depression, psychological distress, impaired self-care, and poorer self-reported health of the caregiver [3]. Caregivers of adults with SCI/D have also been found to have higher rates of cardiac disease, physical distress, obesity, and sleep dysfunction when compared to informal caregivers of adults with other neurological conditions [6]. To minimize increased morbidity and mortality, it is imperative to support individuals in caregiving roles.

Caregiving responsibilities constrain social, vocational, and recreational opportunities for caregivers [3, 7] and can significantly impact all areas of participation. Caregivers of children with disabilities, including SCI/D, require special consideration in clinical and research settings [8, 9]. Usual parenting roles expand

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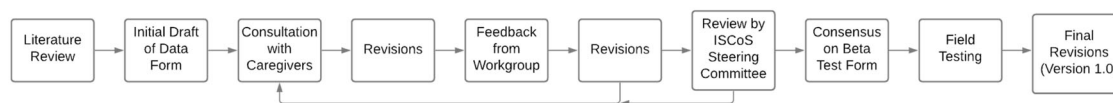


Fig. 1 Process for Development of Data Set. Description: Iterative process of developing form for Caregiver Data Set with international workgroup and ISCoS Steering committee.

to manage sequelae from SCI while simultaneously supporting the child to experience childhood and grow with a chronic disability. For example, parent caregivers orchestrate their child's participation in recreation and leisure activities. Informal caregivers of children with SCI/D, often mothers [10–12], are also responsible for their children's health and integration into family, school, and community life [8], including activities, such as attending a place of worship or doing errands. The toll of informal caregiving on parent caregivers for children with chronic conditions, including SCI/D, is alarming. Family support can be a buffer to stress, but caregivers for children with SCI/D still experience depression and feel burdened by caregiving responsibilities, even when satisfied with life [13]. Negative effects of caregiving include emotional stress, anxiety, depression, poor mental health, and barriers to social, vocation, and personal pursuits [14–16].

Perceived stress or burdens of care can also have adverse effects on individuals receiving care. Previous studies have identified links between health-related quality of life of caregivers and individuals for whom they provide care [14, 17]. For example, coping strategies of caregivers have been associated with coping of youth with SCI/D, and functional and mental health outcomes of children are shown to be poorer when caregivers experience high levels of stress and anxiety [11, 18, 19]. Increasing support for caregivers is necessary to improve health and quality of life of caregivers and the individuals whom they assist.

Support for caregivers is an issue of public interest. Increased attention must be given to the experiences and needs of informal caregivers of individuals with SCI/D to: (1) minimize risks to the caregivers' health and ability to effectively remain in caregiving roles, and (2) improve quality of life for individuals with SCI/D. However, few tools exist to understand and address the needs of informal caregivers for this population. A tool to standardize the collection of data related to caregiver experiences and needs could have significant utility in research and clinical care to plan and deliver necessary support.

The International SCI Data Sets initiative grew from widespread interest to standardize the capture of information pertinent to an individual's medical status and experience living with SCI/D – regardless of where they receive care. As part of this work, a collection of basic data sets have been developed to focus on the minimum amount of data necessary to guide research and clinical care. The International SCI Core Data Set [20] was created first, followed by more than 20 other data sets that capture highly relevant information about individuals with SCI/D, such as Bowel Function, Urinary Tract Imaging, and Quality of Life. The data sets originally focused on adults with SCI/D and included consideration for pediatric use. However, more recent efforts, stimulated by expert consensus on pediatric practice [21], have directly addressed children with SCI/D for systematic monitoring and clinical care guidance across the lifespan. Leaders of these initiatives endorsed need for a new basic data set specific to caregivers, who impact the lives of individuals with SCI/D of all ages and who have relevant needs of their own. The objective of this paper is to describe the development of a data set for informal caregivers of individuals with SCI/D, including results of field testing, which informed revision to the data set.

METHODS

Development of the International SCI Basic Data Set for Caregivers

To develop the data set for informal caregivers of individuals with SCI/D, an international, multi-disciplinary working group of experts in pediatric and adult SCI/D convened with caregivers of persons with SCI/D to identify areas of greatest interest relating to caregiver wellbeing in research and clinical care. The process to develop the basic data set was iterative (See Fig. 1). First, a core group of clinicians and researchers reviewed existing literature and measures on caregivers for individuals with chronic conditions to generate an initial draft of the data form, which was distributed to a larger working group for review and feedback. After several rounds of revisions, a final draft of the beta test form was reviewed by the project steering committee and representatives from the International Spinal Cord Society (ISCoS). With approval from the steering committee, the beta form was exposed to field testing to examine initial reliability and elicit feedback for revisions. Results of field testing informed a final round of review and revisions to the data form, which is presented in Appendix 1.

The beta test form contained 27 items, organized into 3 domains: (1) basic demographic information of persons providing care for the individual with SCI/D (8 items); (2) description of the primary caregiver's allocation of time and satisfaction with how their time is spent (18 items); and (3) the caregiver's perceived burden associated with caregiving responsibilities (1 item). If more than one caregiver was said to provide some assistance for the person with SCI/D, the caregiver completing the form was asked to answer questions in the first domain about the other caregivers' involvement. At the end of the beta test form, participants were also asked four open-ended questions to elicit feedback on the form:

1. Were these questions easy to answer?
2. Were you able to understand all of these questions?
3. Were there any questions you found difficult to answer?
4. Are there any issues around caregiving we neglected to ask in these questions?

Field testing

Design. A multi-center repeated measures design was used to field test the beta form and obtain initial data on test-retest reliability of the Caregiver Data Set.

Participants. Caregivers were recruited at five North American pediatric hospitals. Caregivers were included if they were the legal guardian and self-identified primary caregiver of a child between 0–21 years of age with a non-progressive, acquired SCI/D. Participation was also limited to caregivers who spoke English since the data set has not yet been translated for use in other languages. In addition, the child with SCI/D had to be at least three months post-discharge from initial SCI/D rehabilitation and speak English. Caregivers of children with congenital spine dysfunction, such as spina bifida, or with a suspected conversion syndrome, were excluded from participating in this study.

Data collection tools and instruments. Demographic data on the caregivers were collected via the International Spinal Cord Injury Socio-demographic Data Set [22], and case report forms created specifically for the study that recorded additional information on the caregiver and child with SCI/D. Participants' characteristics were collected once, at study entry, by recording variables, including age, gender, years of education, household composition, and employment status.

Neurological data: The child's neurological level of injury (NL) and severity of injury, as defined by the American Spinal Injury Association Impairment Scale (AIS) [23] were obtained from the medical records. There

Table 1. Demographics of the caregivers and their children with SCI/D.

	Trial 1 (N = 41)	Trial 2 (N = 39)
CAREGIVERS		
Gender N (%)		
Male	7 (17)	7 (18)
Female	34 (83)	32 (82)
Race N (%)		
Caucasian	30 (73)	29 (74)
African American	9 (22)	8 (21)
Not reported	2 (5)	2 (5)
Ethnicity N (%)		
Hispanic	1 (2)	1 (3)
Non-hispanic	39 (95)	37 (95)
Not reported	1 (2)	1 (3)
Marital status N (%)		
Never married	9 (22)	8 (21)
Married	26 (63)	26 (67)
Divorced	5 (12)	5 (13)
Widowed	1 (2)	0
Years of formal education M (SD)	15.6 (2.6)	15.6 (2.6)
Primary occupation N (%)		
Paid work	26 (63)	24 (62)
Homemaker	12 (29)	12 (31)
Student	1 (2)	1 (3)
Unemployed	2 (5)	2 (5)
Children with SCI/D	(N = 41)	(N = 39)
Age group in years N (%)		
1–5	12 (29)	12 (31)
6–12	17 (42)	16 (41)
13–15	5 (12)	4 (10)
16–17	3 (7)	3 (8)
18–21	4 (10)	4 (10)
Gender N (%)		
Male	20 (49)	18 (46)
Female	21 (51)	21 (54)
Race N (%)		
Caucasian	30 (73)	29 (74)
African American	9 (22)	8 (21)
Other	1 (2)	1 (3)
Not reported	1 (2)	1 (3)
Ethnicity N (%)		
Non-Hispanic	40 (98)	38 (97)
Not reported	1 (2)	1 (3)
Neurologic level grouping N (%)		
C1–C4	3 (7)	3 (8)
C5–T1	8 (20)	8 (21)
T2–T12	16 (39)	15 (39)
L1–S4/S5	4 (10)	3 (8)
Unknown	10 (24)	10 (26)
AIS Classification N (%)		
A	13 (32)	12 (31)
B	1 (2)	1 (3)
C	5 (12)	4 (10)

Table 1. continued

	Trial 1 (N = 41)	Trial 2 (N = 39)
CAREGIVERS		
D	5 (12)	5 (13)
Unknown	17 (42)	17 (44)

were cases where there was no NL and AIS recorded, particularly in children younger than six years old [24]. These data were obtained at study entry.

The International SCI Basic Data Set for Caregivers—beta test form: The beta test form of the International SCI Basic Data Set for Caregivers was completed by the caregiver at the point of care by way of self-report, twice separated by a minimum of 15 min. The minimum time between administrations of the data form was determined primarily by considerations for feasibility to complete both administrations within a usual care encounter to standardize the responder and minimize undue burden for participants. Time to complete the data form was recorded for each participant.

Data management. Using site and participant-specific unique identification numbers, data were de-identified prior to transmission to the lead site. Once received by the lead site, the study coordinator reviewed data for completeness and quality. If there were any omissions or questions about the data, they were sent back to the respective site for confirmation and clarification. Following quality review, data were entered into a secure study-specific database. All study data were exported to SPSS for analysis (version 24.0, IBM Corp, Armonk, NY).

Data analysis. Items on the beta form were organized as 34 variables for analysis. Descriptive statistics were used to characterize the study sample. The number of caregiving responsibilities was calculated from responses in Section 1 to create a caregiver responsibility composite score (highest Number = 8 and lowest Number = 0), which was used to examine the association between the number of caregiving responsibilities, perceived burden of care, and time spent caregiving, using Spearman's Correlation. Strength of association was considered poor ($r < 0.10$), weak ($r = 0.10–0.39$), moderate ($r = 0.40–0.69$), strong ($r = 0.70–0.89$) or very strong ($r = 0.90 >$) [25]. Test-retest reliability of each variable was assessed using Intra-Class Correlations (ICC [2,k] with 95% CI. Correlation coefficients < 0.5 were considered poor, between 0.5 and 0.75 were considered moderate, between 0.76 and 0.9 were considered good, and > 0.90 indicated excellent reliability [26].

Responses to the four open-ended questions for feedback on the form were summarized for content analysis to inform final revisions to the caregiver data set. Free-text comments were coded thematically and analyzed for qualitative description.

RESULTS

Reliability study results

A total of 41 caregivers participated after screening and enrollment. As shown in Table 1, the majority of caregivers were female (83%), Caucasian (73%), and non-Hispanic (95%). The mean age of the caregivers was 39 years (range = 28–54 years). Caregivers had an average of 16 years of education (range = 9–20 years), and the majority had paid employment (63%) outside of the home. Demographics for the children with SCI/D associated with caregivers in the trial are also shown in Table 1. Mean age of the children was 9.2 years (range = 1–20 years), and on average, they sustained their injuries 4.85 years prior to enrollment (range = 7 months–14.5 years). Fourteen children (34%) were classified as having motor complete injuries (AIS A or B), whereas only 10 (24%) were classified as having motor incomplete injuries (AIS C or D). Forty-two percent of children did not have AIS designation due to their young age.

Of the 41 caregivers, 39 (93%) completed both administrations of the beta test form. Average time between trials was 1 h and 14 min. The mean time to complete the form was 10 min (range 4–30 min),

Table 2. Intra class correlation coefficients for caregiver beta test form variables.

Variable	Primary Caregiver (n = 39)	Secondary Caregiver as reported by Primary (n = 19)
	ICC (95% CI)	ICC (95% CI)
Relationship to Child with SCI	1.00	1.00
Age	1.00	1.00
Gender	0.95 (0.91–0.98)	1.00
Date when assumed care	0.83 (0.67–0.91)	1.00
Lives in home with person with SCI/D (full-time, part-time, or no)	1.00	0.66 (0.14–0.87)
Average hours spent caring for person with SCI/D per week	0.74 (0.28–0.90)	0.94 (0.82–0.98)
Caregiving Responsibilities:		
Activities of Daily Living	1.00	1.00
Instrumental Activities of Daily Living	0.55(0.14–0.77)	0.38 (–0.61–0.75)
Rest and Sleep	0.76 (0.54–0.87)	0.76 (0.42–0.90)
Education	0.75 (0.51–0.87)	0.81 (0.53–0.92)
Work	0.77 (0.57–0.88)	0.64 (0.15–0.85)
Play	0.93 (0.87–0.97)	0.91 (0.78–0.96)
Leisure	0.86 (0.73–0.93)	0.40 (–0.45–0.75)
Social Participation	0.75 (0.53–0.87)	0.04 (–1.36–0.61)
Payment for Caregiving	0.88 (0.78–0.94)	1.00
Time spent in various domains and satisfaction with time spent in each domain:		
Time spent caregiving for person with SCI/D	0.98 (0.95–0.99)	
Satisfaction on time caregiving for the person with SCI/D	0.98 (0.96–0.99)	
Time spent caregiving for persons other than person with SCI/D	0.96 (0.96–0.99)	
Satisfaction on time caregiving for persons other than the person with SCI/D	0.81 (0.63–0.90)	
Time spent on ADLs	0.83 (0.68–0.91)	
Satisfaction on time on ADLs	0.65 (0.34–0.81)	
Time spent on IADLs	0.79 (0.60–0.89)	
Satisfaction on time on IADLs	–0.02 (–0.96–0.47)	
Time on sleep	0.73(0.48–0.86)	
Satisfaction on time on sleep	0.94 (0.89–0.97)	
Time on employment	0.95 (0.90–0.97)	
Satisfaction on time on employment	0.07 (–0.85–0.51)	
Time on volunteer/unpaid employment	0.98 (0.96–0.99)	
Satisfaction on time on volunteer	0.30 (–0.33–0.64)	
Time on leisure activities	0.67 (0.37–0.83)	
Satisfaction on time on leisure activities	0.14 (–0.61–0.55)	
Time on social participation	0.85 (0.72–0.92)	
Satisfaction on time on social participation	0.11 (–0.63–0.52)	
Caregiving burden	1.00	

Test-retest reliability of each variable was assessed using Intra-Class Correlations (ICC) with 95% CI.

Poor reliability = <0.5.

Moderate reliability = 0.5–0.75.

Good reliability = 0.76–0.9.

Excellent reliability = >0.90.

and there was not a statistically significant difference between durations to complete the first and second administration of the form.

Using Spearman's Correlation, the strength of association between caregiving burden and time spent caregiving ($r = 0.43$) and the number of caregiving responsibilities and time spent caregiving ($r = 0.43$) was moderate. The association between caregiving burden and number of caregiving responsibilities was weak ($r = 0.18$).

As shown in Table 2, 22 (64.7%) of the 34 caregiving variables had good to excellent reliability ($ICC = > 0.75$), 7 (20.6%) had good to moderate reliability ($ICC = 0.5–0.75$), and 5 (14.7%) had poor reliability ($ICC = < 0.5$), all of which evaluated satisfaction with their own life domains. Variables with poor reliability were specific to caregiver demographics, how time was spent, and satisfaction with time spent. In cases where more than one caregiver was listed on the form, the reliability of the demographics for the first caregiver listed was stronger than the reliability of the information on the second

Table 3. Summary of responses to evaluative questions for caregivers.

	Yes n (%)	No n (%)	Other (i.e., “somewhat,” “most”) n (%)
Q1: Were these questions easy to answer?	29 (70%)	9 (21%)	4 (9%)
Q2: Were you able to understand all of these questions?	32 (76%)	3 (7%)	7 (17%)
Q3: Were there any questions you found difficult to answer?	22 (52%)	20 (48%)	0
Q4: Are there any issues around caregiving we neglected to ask in these questions?	12 (29%)	30 (71%)	0

Table 4. Thematic coding of free-text responses to evaluative questions 1–3.

		# of Comments	Examples from Data
1	Activities to assist child with SCI/D are enmeshed in parenting; difficult to differentiate some aspects of care specific to disability.	6	“Toddler needs vs SCI needs is difficult to separate - needs go hand in hand” “Time frame is difficult because I am with him all day as a parent”
2	Difficult to specify hours spent caregiving (section 3)	12	“Hard to figure out time”
3	Didn't understand different occupational domains and how to rate satisfaction (section 3)	6	“Questions about time for activities and how to rate satisfaction [were difficult to answer]” “Confusing if domain should be answered for self or child with SCI”
4	Burdensome to complete data form	2	“Lots of thought (burden) to answer questions”
5	Difficult to answer question about burden (section 4)	2	“Last question [burden] [was not] easy to answer; ‘burden’ is rude”
6	Confusing overall; needed more detailed instructions	4	“[Need to] explain with instructions, descriptives” “[Questions] not clearly defined”
7	Data set is missing key information	2	“Not specific enough”
8	Hard to determine when caregiving really began post-SCI (in hospital?)	1	“Confusing about when time started to care for child with SCI; in hospital doctors [were] caring for child, but we were present”

and third caregivers listed (ICC Range: 0.55–1.00 versus 0.04–1.00 and –2.00–1.00, respectively). Although the correlation coefficient was good for number of other caregivers listed (ICC = 0.79, 95% CI: 0.59–0.89), there were 11 cases (28%) where the number of additional caregivers was different between trials. The *Time Spent* items had higher reliability coefficients than their corresponding *Satisfaction with Time Spent* items for all but one domain (*sleep*).

Analysis of responses to the four evaluative questions yielded important considerations for final revisions to the caregiver data set. Dichotomous answers are summarized in Table 3. Eight themes emerged from analysis of free-text comments for questions 1–3 (Table 4). In response to question 4, caregivers identified several issues related to caregiving that were missing from the data set, including: how caregiving responsibilities impact ability to work; the availability of resources or other trusted care providers at school or in other settings; responsibilities for care management (e.g., dealing with insurance, medical appointments); the child's level of functional independence and safety, including during sleep; mental health of caregivers; and impact on family life and other leisure.

DISCUSSION

Based on results of field testing, the working group identified necessary revisions to the Caregiver Basic Data Set. The majority of variables in the original data set had moderate to excellent reliability, but several items required clarification and simplification for more feasible and reliable widespread use. Therefore, the working group focused on revising or removing items with the poorest reliability and used data from the four evaluative questions to guide further revisions. The overarching goals of the revision were to improve reliability of the data and decrease respondent burden for completion of the data form. Items in the final data form focus primarily on the caregiver's experience or perception of

burden since there was a weak association between specific responsibilities and perceived burden. This aligns with prior research showing that caregiver experience has greater impact on health and well-being than particular types or intensities of responsibilities for caregiving. A description of changes from the beta test form to the final form (the International SCI Basic Data Set for Informal Caregivers, Version 1.0) is provided in Table 5.

Respondent burden, time for completion

The first of the changes was aimed at simplifying and shortening the overall length of the data form. Mean time for completion was 10 minutes, with a range up to 30 min, which could negatively impact implementation of routine data collection in clinical and research settings. Additionally, results indicated the area of greatest burden to respondents was Section 2: description of primary caregiver's allocation of time and satisfaction with how their time was spent. The revised version simplified this construct to ask whether caregiving interferes with doing other activities of importance to the caregiver.

Despite the strong reliability for items assessing multiple caregivers in Section 1, the reliability of repeated administrations was always weaker when a caregiver reported on behalf of secondary and tertiary caregivers. Only 28 of the 39 participants (72%) who completed the second administration reported the same number of caregivers for both administrations. Because of this, one cannot assume that the beta test form reliably captures the number of persons providing care for the person with SCI/D. The final version (Version 1.0) focuses specifically on demographics and experiences of the caregiver completing the form. In place of detailed questions about additional caregivers, a single item was added to probe whether any individuals – other than the caregiver completing the form – have been actively involved in providing care during the previous week. We anticipate this

Table 5. Description of changes from beta test form to final (Version 1.0).

Section	# of items		Domain	Description of change(s)	Reason(s) for change(s)
	Original	Final			
1	8	4	Basic Caregiver Information	- Focus on caregiver completing data form - Describes caregiver's age, gender, primary relationship to person with SCI/D - 1 item for whether anyone else provides care for person with SCI/D	- Poor reliability of data collection on additional caregivers - Ease response burden
2	18	2	Allocation of Time, Satisfaction	- Focus on whether caregiving responsibilities interfere with other important activities	- Address confusion and increase reliability - Ease response burden
3	1	1	Caregiver Burden	- No changes to rating scale, but modified prompt to focus on "strain" instead of "burden"	- Increase sensitivity to caregiver concerns about framing care as "burdensome"

change will improve accuracy of reporting since caregivers are only asked to recall other support within the previous week, and respondents will only need to consider whether or not anyone else has provided assistance.

Self-report

Most of the International SCI Basic Data Sets were intended to be administered by health care professionals by way of interview and with supplemental data in the medical record. However, for this field testing, caregivers were given the forms to complete by self-report. To further facilitate use of the Caregiver Data Set across clinical and research settings, the final version of the form was edited for clarity to be completed by self-report. A brief introduction to the data set was added to the top of the data form for caregiver respondents to review before completion, and the language of individual items was simplified to support comprehension. In addition, the Lexile analyzer (available online at www.lexile.com) was used to calculate a score for readability [27, 28] that is sensitive to anticipated variations in health literacy [29]. The Lexile score of Version 1.0 is 800L–900L, which converts to the approximate equivalent of a fifth-grade reading level in the United States.

Clinical uptake and harmonization of the data

In addition to the overall length and readability of the new data set, we also considered feasibility of widespread use and harmonization of data. Although the original intent was to focus on "primary" caregivers, the working group concluded that it would be exceedingly difficult to limit respondents to caregivers in a "primary" role since there is no standardized or internationally-accepted way to define this population and control access with inclusion or exclusion criteria. Therefore, we predicted that the caregiver data set would be unreliable for describing primary caregivers. The final version focuses more broadly on informal caregivers, who are vulnerable to negative health effects of providing care, and who go largely unrecognized and unsupported within health care systems.

Limitations and outstanding domains of interest

While the International SCI Basic Data Set for Informal Caregivers is recommended for use with informal caregivers of persons with SCI/D across the life course, the development team and field testing only involved caregivers of youth with SCI/D—all of whom identified as parents of the children with SCI/D. Reliability testing of the revised data set is required with a more heterogeneous group of caregivers, including individuals who assist adults with SCI/D.

The basic data set captures caregivers and their experiences at a discrete moment in time. People with SCI/D often have multiple informal caregivers, and their caregivers, along with their needs and associated experiences, change over time. Thus, the basic data set must be interpreted as a snapshot in time. Furthermore, by nature, the basic data set could not accommodate for data collection on all domains of interest to caregiving. For a reliable basic data set, we

prioritized simple and focused questions. We anticipate development of extended data set(s) in the future, which can more thoroughly and effectively evaluate caregiving responsibilities and caregiver needs. Participant responses to question 4 of the evaluative supplement for caregivers should be addressed in extended data set(s). Other recommendations from existing literature and content experts for more extensive data collection include capturing intrinsic factors of caregivers, such as race, ethnicity, cultural practices, religion or spirituality, physical pain, depression, anxiety, knowledge of SCI/D, and problem-solving skills, as well as extrinsic factors, including descriptions of family functioning and support, features of physical environment(s) where individuals live and function, and responsibilities for coordinating healthcare.

CONCLUSION

There has perhaps never been a more critical time for informal caregiving to be recognized. The SARS-CoV-2 pandemic has widely exposed the critical value of informal caregiving for health and economies across the world—and how little support this population receives [30]. Gathering data on informal caregivers can inform a necessary extension of public health initiatives to support this essential population.

The form for the International SCI Basic Data Set for Informal Caregivers, Version 1.0, is considered ready for use, but work on the data sets is an ongoing, iterative process. We encourage anyone interested in using this form to contact members of the working group or ISCoS International Data Set Committee through the corresponding author for this article. As data are collected across settings, we will continue to examine the reliability and utility of the data set. We anticipate the data set will generate a foundation for understanding who informal caregivers for individuals with SCI/D are and how they experience caregiving responsibilities. With this knowledge, clinical care can be tailored to the needs of caregivers, alongside those with SCI/D, and research can more accurately identify associations for effective, targeted interventions to improve the health and well-being of caregivers.

DATA AVAILABILITY

Data Archiving: Reasonable requests can be made to senior author (Mulcahey).

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AUTHOR CONTRIBUTIONS

CH: Co-chair for the Caregiver Data Set Working Group. Contributed to review of background literature, coordination of workgroup meetings, data form development, review of protocol for field testing, interpretation of results, and manuscript writing. RM: Chair for the Caregiver Data Set Working Group. Contributed to review of background literature, coordination of workgroup meetings, development of data forms, review of protocol for field testing, screening study participants, analysis of results, and manuscript writing. KD: Study Coordinator. Contributed to coordination of workgroup and meetings, data input and organization, data analysis, and manuscript writing. MJM: Principal Investigator. Contributed to the conceptualization of the project, securing research funding, monitoring the scientific, financial, and regulatory aspects of the study, assisting with data analysis and interpretation, and manuscript writing.

ETHICS APPROVAL

The study was approved by IRB at each of the participating sites as well as Jefferson.

COMPETING INTERESTS

The authors declare no competing interests.

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