Research Article

Development of an ICF Core Set Based Instrument for Individuals with Non-traumatic

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Abstract

Introduction: The International Classification of Functioning, Disability and Health (ICF), describes the functioning and individuals with particular health condition and how context factors can modulate it. The non-traumatic spinal cord injury (NTSCI) has several effects on the functioning. The ICF Core Set for spinal cord injury (CSSCI) can be an innovative assessment of people with NTSCI functioning, but has not been applied in this context and there are no standardization proposals for its implementation.

Objective: To develop a user-friendly instrument based in the International Classification of Functioning, Disability and Health core set for spinal cord injury (CSSCI) to operationalize functioning data of non-traumatic patients.

Method: By studying, the particular uses of CSSCI categories to non-traumatic individuals, the researchers developed specific questions with richly described answer alternatives according with the descriptions of ICF qualifiers. For some categories, validated instruments were adapted, for some others new questions were formulated.

Results: A questionnaire containing 43 sub-items was developed covering aspects of 9 body functions, 4 body structures, 21 activities and participation and 9 environmental factors. Health professional who tested it did not report difficulties to understand or apply the questionnaire, although it may time consuming.

Conclusion: Besides proposing a method to develop ICF based questionnaires, this study developed a functional assessment tool that is very broad in the evaluation of functioning and adds the impact of environmental factors on the overall experience of disability.

Keywords: ICF; ICF core set; Spastic paraparesis; Questionnaires; Spinal cord injury; Non-traumatic spinal cord injury

Introduction

Spastic paraparesis comprises group of non-traumatic spinal health conditions sharing structural and functional impairments in the spinal cord that result in progressive decrease in lower limb muscular strength, spasticity, hyperreflexia, impairments in sphincter control, gait alterations, and decreased functioning [1,2]. Although injuries in the nervous system with varied topographic locations may be associated with this syndrome, in this manuscript spastic paraparesis will related exclusively to spinal conditions, or non-traumatic spinal cord injury (NTSCI), which prevalence is unknown [3]. Disability in this condition varies in severity, but frequently contributes to limitations in the activities of daily living (ADL) and participation.

Assessing and measuring functioning in this group of patients may add relevant data to the traditional clinical examination once it establishes parameters for management and monitoring of the rehabilitation process [4]. Moreover, the systematic and standardized collection of data may be useful for institutional or public health management. The International Classification of Functioning, Disability and Health (ICF) provides updated concepts and a comprehensive and universally accepted framework to describe functioning and disability, and is based on a psychosocial model of human functioning [5].

ICF Core Sets for spinal cord injury (CSSCI) are selections of ICF categories, which describe the living experience of individuals with SCI, either in the post-acute [5] or long-term situations [6]. The Brazilian public health system has very few rehabilitation hospitals for the acute context, so most of the rehabilitation occurs in outpatient settings and it is necessary to adapt those Core Sets to the national clinical practice as well as for peculiarities of NTSCI individuals [7,8]. Brief ICF Core Sets are minimal standards for description of functioning in specific health conditions and were developed with the endorsement of World Health Organization [7].

Description of ICF categories is very broad and pose an obstacle for the standardization of assessment as well as reproducibility of results;

making it difficult for the user to decide which aspects of a task to assess. The developers of ICF core sets noticed such imprecision as they state that these instruments suggest 'what to measure, but not how'. Thus, the aim of this article is to describe the steps to develop a user-friendly ICF CSSCI-based instrument, which contains the specific aspects of functioning of individuals with non-traumatic SCI [9].

Method

This project used as a source document the brief CSSCI for chronic situations that contains 33 second-level ICF categories [10]. According to previous observations of rehabilitation needs of patients in our service, nine categories were added: d360 (Using communication devices and techniques), d450 (Walking), d475 (Driving), d560 (Drinking), d729 (General interpersonal interactions, other specified and unspecified), d760 (Family relationships), d770 (Intimate relationships), d859 (Work and employment, other specified and unspecified), and d920 (Recreation and leisure). The category d530 (Toileting) was further detailed to d5300 (Regulating urination) and d5301 (Regulating defecation). Doing so, the original CSSCI has grown from 33 to 43 categories divided into 9 Body Functions (BF), 4 Body Structures (BS), 21 Activities and Participation (A&P), and 9 Environmental Factors (EF).

When additional categories enrich the brief ICF Core Set for clinical purposes, it is called 'enlarged brief' [10].

Second-level ICF categories are described with broad definitions, which offer many different interpretations for the users, and may, eventually, be further described in lower levels of classification. Although practical for classification purposes, this may be quite burdensome in clinical use. Thus, the next step was to rephrase the categories in such a way that health professionals would always assess the same aspects. The authors studied the reasons for the selection of each category for the Core Set and discussed the most practical and clinically meaningful ways to assess them. The rewriting process followed three basic paths:

First approach: whenever it was possible to trace a direct correlation between the category and an instrument in the literature, the whole instrument or parts of it would be selected. The complete list of instruments and their corresponding categories can be seen in Table 1.

ICF Category	Title	Assessment Instruments
b280	Sensation of pain	Visual Analogue Scale (VAS)
b710	Mobility of joint functions	Goniometry
b730	Muscles power functions	Medical Research Council (MRC)
b735	Muscle tone functions	Modified Ashworth Scale
d410	Changing basic body position	FIM™ (Transfer items)
d520	Caring for body parts	SCIM-III (Toileting items)
d550	Eating	SCIM-III (Feeding items)
d560	Drinking	SCIM-III (Feeding items)

Table 1: Instruments directly correlated to CSSCI categories.

The response alternatives for each of these instruments were then aligned with the five-level answer scheme of ICF qualifiers whenever possible, following the approach used by Dunn et al. [11] (Table 2).

b280 Sensation of pain:
Unpleasant sensation that indicates potential or real injury in some body structure.
Instrument of evaluation: Visual analogue scale (VAS).

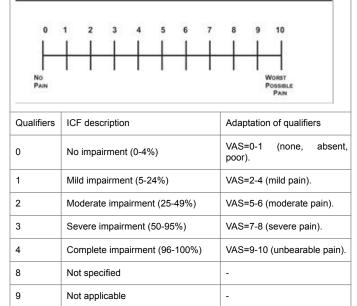| Qualifiers	ICF description	Adaptation of qualifiers
0	No impairment (0-4%)	VAS=0-1 (none, absent, poor).
1	Mild impairment (5-24%)	VAS=2-4 (mild pain).
2	Moderate impairment (25-49%)	VAS=5-6 (moderate pain).
3	Severe impairment (50-95%)	VAS=7-8 (severe pain).
4	Complete impairment (96-100%)	VAS=9-10 (unbearable pain).
8	Not specified	-
9	Not applicable	-

Table 2: Example of the correlation between ICF qualifiers for b280 (Sensation of pain) and response levels in VAS.

When the description of CSSCI categories included more than one aspect, the solution was to isolate each of them in a separate question and offer dichotomous response alternatives (yes/no). Whenever this was the approach, the sum of 'yes' or 'no' would, then, be correlated with ICF qualifiers (Table 3).

d5301 Regulating defecation:
Coordinating and managing defecation such as by indicating need, getting into the proper position, choosing and getting to an appropriate place for defecation, manipulating clothing before and after defecation, and cleaning oneself after defecation.

Question (The subjects ...)	Yes	No
Feels the urge to evacuate?	0	1
Controls the time of the evacuation?	0	1
Goes alone to the bathroom to evacuate in the toilet?	0	1
Takes off and puts clothes, diapers or equivalent on by himself?	0	1
Cleans up after evacuation	0	1
Total qualifier is defined by the sum of the above (0 to 5)		

Qualifiers	ICF description	Adapted qualifiers
0	No impairment (0-4%)	No disability, 0.

1	Mild impairment (5-24%)	Mild disability, 1.
2	Moderate impairment (25-49%)	Moderate disability, 2 or 3.
3	Severe impairment (50-95%)	Severe disability, 4.
4	Complete impairment (96-100%)	Complete disability, 5.
8	Not specified	-
9	Not applicable	-

Table 3: Example of ICF category with too many aspects which requested detailed questioning and adaptation to ICF qualifiers.

The categories for EF include multiple factors that can modulate functioning. Thus, for some EF categories, parts of the definitions can act as facilitators while others, as barriers; this can limit the proper evaluation of the role of the category, especially if both characteristics occur simultaneously.

Therefore, one cannot determine the effect of these categories on functioning based on one single question. Hence the solution was to formulate questions that broach each of the aspects or sub-items of these categories on functioning, keeping the particularities of NTSCI subjects in mind. The following responses were adapted from each of these questions: 0-if the Environmental Factor was neither a facilitator nor a barrier, +1 if a facilitator, and -1 if a barrier. The total score from these sub-items yielded a response to the ICF qualifier, which indicated the overall magnitude of this Environmental Factor in interfering with functioning (Table 4).

Our recommendation for using the ICF Core Sets is that only one qualifier is associated with each category, showing its degree of problem. Consequently, Body Structures categories will not use qualifiers for topography or for the nature of the impairment. Similarly, only the qualifier for performance, and not for capacity, should be used in the Activities and Participations. In accordance with these recommendations, the first qualifier was used as a generic code for each of these categories to prepare the responses to this questionnaire.

e310 Immediate family:

Individuals related by birth, marriage or other relationship recognized by the culture as immediate family, such as spouses, partners, parents, siblings, children, foster parents, adoptive parents and grandparents.

What is the role of the family in relation to:	Helps	Disrupts	Indifferent
Communication	+1	-1	0
Performing their activities of daily living	+1	-1	0
Money	+1	-1	0
Emotional support	+1	-1	0
Transport or mobility	+1	-1	0
Total qualifier is defined by the sum of the above (0 to +5 or 0 to -5)			
ICF Qualifiers	**ICF description**	**Adapted qualifiers**	

0	No barrier /facilitator (0-4%)	No barrier no facilitator; Indifferent, 0.
+1	Mild Facilitator (5-24%)	Mild Facilitator, +1.
.1	Mild Barrier (5-24%)	Mild Barrier, -1.
+2	Moderate Facilitator (25-49%)	Moderate Facilitator, +2.
.2	Moderate Barrier (25-49%)	Moderate Barrier, -2.
+3	Considerable Facilitator (50-95%)	Considerable Facilitator, +3 or +4.
.3	Considerable Barrier (50-95%)	Considerable Barrier, -3 or -4.
+4	Complete/full Facilitator (96-100%)	Complete/full Facilitator, +5.
.4	Complete/full Barrier (96-100%)	Complete/full Barrier, -5.

Table 4: Elaboration of an issue of environmental factors based of brief and expanded ICF core set for chronic spinal cord injury.

Results

The research team succeeded in developing a questionnaire containing 43 questions with sub-items based on the enlarged brief CSSCI injury. It took 45 minutes to be applied and was considered practical and easy to use by the evaluators. After an initial test phase, 9 ICF categories were added, given their relevance to the clinical evaluation of individuals with NTSCI.

For the elaboration of questions and answers, tree strategies were used. Whenever other existing instruments for the assessment of functioning could be linked to the ICF categories, their descriptions would be transferred to the new instrument, as long as the translated Brazilian version was properly validated. In these situations, answer alternatives of the original instruments were calibrated to respect the percentages of problems described for ICF qualifiers (Table 1).

For other categories when the definition included multiple items, each of them was dichotomized to fit "yes/no" responses. Thus the definitions of ICF qualifiers depended on the number of 'yes' answers, indication the sum of problems in that particular category.

Categories of EF usually cover a long list of aspects. The research team selected those more significant aspects for people with NTSCI according to their clinical experience and the literature specific to this condition. However, EF poses another challenge, which is the fact that the same EF category may include facilitators and barriers simultaneously. By using the same approach described in the last paragraph it was possible to sum these positive and negative aspects and translate them in a final composite effect on functioning.

Discussion

The ICF Core Sets indicate 'what' to evaluate, but not 'how to measure' the aspects of functioning that are relevant to a person with a specific health condition. This transfers the problems related to the usability and psychometric properties of the ICF instruments to the hands of the users. The complexity of ICF category descriptions makes them difficult to understand and allows diverse interpretations, according to the background of the professional who uses them. This is why attempts to use the ICF Core Sets based on the original descriptions of categories invariably results in low reproducibility. This study aimed to use a direct, simple and clear terminology in order to prevent the multiple interpretations in some categories. To the best of the knowledge of the authors, any previous text has systematically described the process to develop ICF-based questionnaires, so this study had no equivalents for comparison.

For some categories, parts of previously established instruments served as reference because they referred to the desired aspect of functioning in individuals with NTSCI, this was the preferred alternative in the development of the new ICF based instrument because clinicians would feel more comfortable to use wordings and constructs they are familiarized with. As for alternative responses, the percentages or amounts of problems described in ICF qualifiers were adapted according to the levels of impairment or limitations described in the selected instrument of reference (Table 2). This strategy was used for eight categories described in Table 1. The greatest advantage of this strategy is that it saves time in elaboration of new questions and their answer alternatives. Also, if appropriate computer based logic is developed, the experienced clinician may use the instrument and measurements he is used to deal with and the system can automatically convert these data in ICF codes.

The second strategy for the development of questions involved the division of the multiple aspects of the category description into discrete questions (Table 3). This approach allowed the evaluator to separately assess each item in the category and decide the amount of problem by summing them in a final score. Although we have not tested reproducibility, we believe this strategy may improve this psychometric characteristic because the 'yes/no' answer alternatives are much more objective and the final score based in the sum of answers prevents subjectivity of the evaluator in deciding which aspect of the description of the category is more relevant. However, the weight attributed to all the aspects of the category was always the same, which may not be true, according to its impact on global functioning, so future studies should address this issue.

The descriptions of EF categories allow a wide variety of items to be included and are a source of criticism. To deal with this problem, the Annex 1 of the ICF recommends the linkage of an Environmental Factor category separately to more than one category of Body Functions, Body Structures, and Activities and Participation. For example, a non-steroidal anti-inflammatory (e1101-Drugs) can completely reduce the sensation of pain (b280) (facilitator: e1101+4), but can also cause severe dyspepsia (b535) (barrier: e1101.3) and prevent proper feeding (d550) (barrier: e1101.2). In other situations, the Environmental Factor can present both natures simultaneously in the same category; for example, the stairs at home represent a complete barrier (e1551.4) for an individual with NTSCI to climb (d4551 – Climbing), however, it may also refer to an elevator and be a facilitator (e1551+4). Therefore, the method we used to develop this CSSCI based instrument overcomes these limitations and reduce number of qualifiers to only final score by summing the positive and negative effects on the most relevant aspects of each EF category in this health condition.

Both categories 'protective functions of the skin' (b810) and 'structure of areas of skin' (s810) are associated to pressure sores in NTSCI subjects, which is a frequent major health problem [12]. The removal of one of these categories made the final instrument simpler and easier to understand.

The CSSCI contains the category d455 (moving around), but not the category d450 (walking), which is hardly achieved with complete spinal cord injuries above lumbar levels, which may explain its absence in the ICF core set selection. Over the years, individuals with spastic paraparesis progressively present with modified gait patterns and a loss of functional independence [13]. Because walking can be performed even long after the onset of this health condition and represents such an important functional achievement, it was necessary to include this category in the instrument.

Not only are qualifiers useful as direct measurements of functioning, reflecting accessible relevant information from clinical exams, medical history, and technical evaluation [14,15], but also they can indicate long-term changes in patients' functional profiles [16]. Once health professionals are properly trained, qualifiers help to quantify the extent of the problems, as well as influence of barriers and facilitators, even in areas where they are not specialized [17].

The use of the ICF qualifiers is not yet completely implemented, although there have been many attempts to validate operational scales based on them [18]. The limitations of the qualifiers lie in the difficulty of standardization and the absence of studies of their psychometric features [19]. Nevertheless, such difficulties and obstacles can only be resolved by a routine practical use of this instrument, which may lead to improved adherence by health professionals [18]. There is a urge to implement the ICF Core Sets, but it is hampered by the overly broad definitions of the categories as well as by modifications made to the qualifier system [20]. ICF qualifiers are defined either on a qualitative scale (no problem-complete problem) or by the amount of problem the subject may have in the category (0%-100%, see middle column of Table 2), however there is no description of the definition and magnitude of the five levels of disability in ICF. This poses a problem to the adaptation of answer alternatives of other instruments to ICF, as described in strategy one, because of non-linearity of the correlation between the scales. This might be addressed by advanced statistical models or Rasch analysis, but this was not the scope of this study.

The result of the gathering parts of different instruments and questions created with strategies two and three implies in a patchwork of components from various sources, leaving the final instrument subject to criticism, once it would not be easy to understand which is the dimension being measured (independence, gait speed, strength, and dexterity, etc). The pertinence and validity of an item taken out of its original context also comes to question. This is why it is mandatory to test construct validity and other psychometric characteristics.

Conclusion

This study described the development of a CSSCI based questionnaire to be used by a single health professional to assess functioning in an individual with NTSCI. Although psychometric properties were not characterized, field tests showed that the final instrument is easy to use and apply in clinical practice, and that may be associated to better reproducibility.

Conflict of Interest

The authors report no conflict of interest.

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