SPECIAL REPORT

SETTING UP A COHORT STUDY OF FUNCTIONING: FROM CLASSIFICATION TO MEASUREMENT

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Objective: **Cohort studies are an appropriate method for the collection of population-based longitudinal data to track people's health and functioning over time. However, describing and understanding functioning in its complexity with all its determinants is one of the biggest challenges faced by clinicians and researchers.**

Design: **This paper focuses on the development of a cohort study on functioning, outlining the relevant steps and related methods, and illustrating these with reference to the Swiss Spinal Cord Injury Cohort Study (SwiSCI).**

Methods and results: **In setting up a cohort study the initial step is to specify which variables are to be included, i.e. what to assess. The International Classification of Functioning, Disability and Health (ICF) is valuable in this process. The second step is to identify how to assess the specified ICF categories. Existing instruments and assessments can then be linked to the ICF.**

Conclusion: **The methods outlined here enable the development of a cohort study to be based on a comprehensive perspective of health, operationalized through functioning as conceptualized and classified in the ICF, yet to remain efficient and feasible to administer.**

Key words: International Classification of Functioning, Disability and Health; standardized reporting; cohort study; epidemiology.

INTRODUCTION

Gaining an understanding of health, in all its complexity with all of its components and determinants, is one of the biggest challenges faced by clinicians, health researchers and policy-makers. Such understanding requires consideration of the interaction of a health condition with its related impairments and the person's environment, which together yield the person's experience of living with a given health condition. Describing the occurrence and distribution of relevant outcomes related to health, informing the generation of specific hypotheses, and providing the foundation for the planning and evaluation of health and related policies and programmes is at the core of descriptive epidemiology (1). Within epidemiology, cohort studies constitute an observational study design suitable for the collection of population-based longitudinal data (2). Common outcomes of cohort studies are morbidity, including the incidence and prevalence of a health condition, and mortality (3). Functioning, which according to the World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF) is the operationalization of health from a comprehensive perspective (4, 5), is also a relevant outcome (6), but this has not, as yet, received as much attention.

Functioning is an umbrella term for the interaction of a health condition, including impairments of body functions and structures of a person, activities and participation of a person with personal and environmental factors (4). The ICF, which offers an internationally agreed standard for describing and monitoring functioning, has been endorsed by all WHO member states (4). As shown in Fig. 1, the ICF is structured into 2 parts, each of which is further specified into 2 components, which together classify more than 1,450 ICF categories. ICF categories are the units of the classification and are presented in the ICF with alphanumeric codes that reflect: (*i*) the part to which the category belongs, e.g. codes starting with a *d* belong to the component Activity and Participation, and (*ii*) their location in the hierarchy, e.g. codes on the second level have 3 digits (e.g. *d440 Fine hand use*) and codes on the third level 4 digits (e.g. *d4402 Manipulating*). The specificity of an ICF category increases with each level. The ICF provides a promising conceptual framework and, at the same time, an exhaustive classification for setting up a cohort study of functioning. However, ICF categories have not been developed as operational variables, but rather mutually exclusive and cumulatively exhaustive units of a classification to describe a universal human experience. Hence, the ICF neither specifies which ICF categories of a component are the most relevant
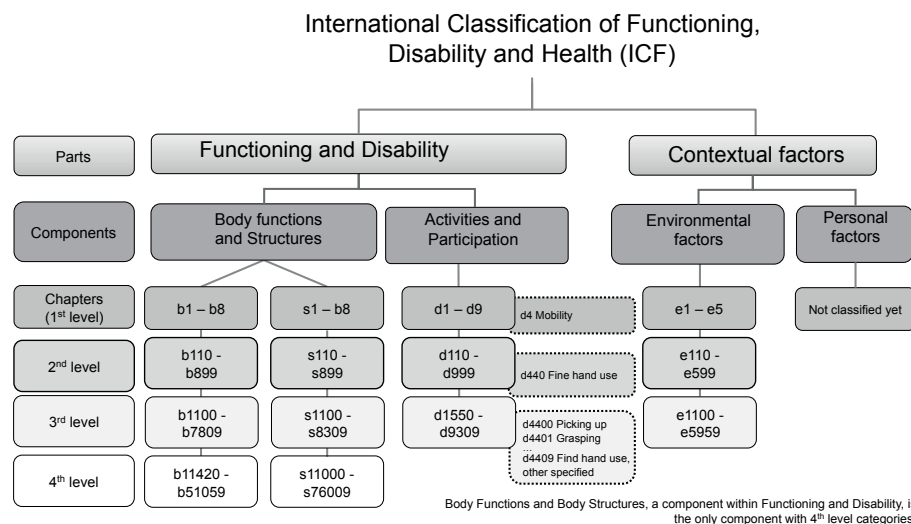
Fig. 1. Components and classification trees of the International Classification of Functioning, Disability and Health (ICF). The hierarchical structure is exemplified in detail by the ICF category *d440 Find hand use*.

to describe, nor in which context, and it certainly does not determine how to measure those categories that are relevant. Nevertheless, once relevant ICF categories have been specified, data on these aspects of functioning can be derived by conducting clinical tests, interviews or surveys, as well as through existing registries or hospital and health statistics. Regardless of which source the information is derived from, a commonly agreed framework is needed that provides the conceptual foundation to facilitate the development of a new cohort study on functioning, in particular to facilitate the systematic selection of which variables to include, while at the same time enabling the comparability of existing data sets. The question remains, therefore, how to proceed from the complex phenomenon of functioning to operational variables for a cohort study designed to describe and understand functioning over time.

This paper tackles this challenge by outlining the steps and related methods in the development of a cohort study on functioning, and illustrating these steps and methods by drawing on the example of the Swiss Spinal Cord Injury Cohort Study (SwiSCI). SwiSCI, we believe, can serve as a model for this purpose, as it is one of the few cohort studies that has as its main objective describing the functioning of people living with a health condition over their life-span (7).

METHODS

There are 2 main steps involved in setting up a cohort study on functioning. The first is to specify the relevant aspects of functioning to be considered in the cohort study. Secondly, suitable instruments for the assessment of these aspects must be identified. Fig. 2 outlines these 2 steps and summarizes the relevant considerations in each.

Step 1: Specification of relevant aspects of functioning to be considered in a cohort study on functioning

The first step in setting up a cohort study on functioning is to determine the relevant domains for assessing the components and determinants

of functioning for a given clinical population. This process serves the specification of the variables to be included in the study and responds to the question *what to assess*. The strength of the ICF is its comprehensiveness, although this also makes it impractical for use in routine practice or research. A systematic approach is needed to determine the ICF categories that are most relevant in a given setting or context. In response to this challenge, ICF Core Sets have been developed. These are sets of ICF categories that have been identified by means of a multi-phase and multi-method, international consensus process for certain health conditions (8). A comprehensive and brief version of the Core Sets exists for each health condition for which an ICF Core Set is available. Comprehensive ICF Core Sets contain a number of ICF categories necessary to be sufficiently comprehensive in describing the typical spectrum of functioning of a person with a given health condition. Brief ICF Core Sets are a selection of ICF categories from the corresponding Comprehensive ICF Core Set and are recommended for use in clinical studies (9). Each ICF Core Set can be complemented with any category of the ICF, as deemed relevant in a given context.

There are 2 points worth mentioning regarding ICF Core Sets. First, their development aimed to identify the most relevant ICF categories to be consistently described and reported in a given health condition based on what we know from the literature and from experts, including patients themselves, across the world (8). While these ICF categories are definitely significant for a comprehensive description of functioning, we also need to ensure that the ICF Core Sets contain those ICF categories that make it possible to best describe variations in functioning within and between individuals and populations. In response to this challenge, additional statistical sets have been developed that build upon, and are complementary to, the existing ICF Core Sets. Statistical sets are compiled based on regression models using self-reported and clinician-reported health as dependent variable and the ICF categories from the comprehensive ICF Core Sets as independent variables (10). The ICF categories found to have most explanatory power of self-reported health in a given health condition can then be added to the ICF categories that were selected from the literature and expert opinion during the multi-stage consensus process in the development of ICF Core Sets.

Secondly, the health condition-specific focus of ICF Core Sets has limited value for ensuring comparability with the general population, as well as with other clinical populations. To address this problem, ICF Generic and Rehabilitation Sets have been developed psychometrically. The ICF Generic Set contains 7 ICF categories that have shown statisti-
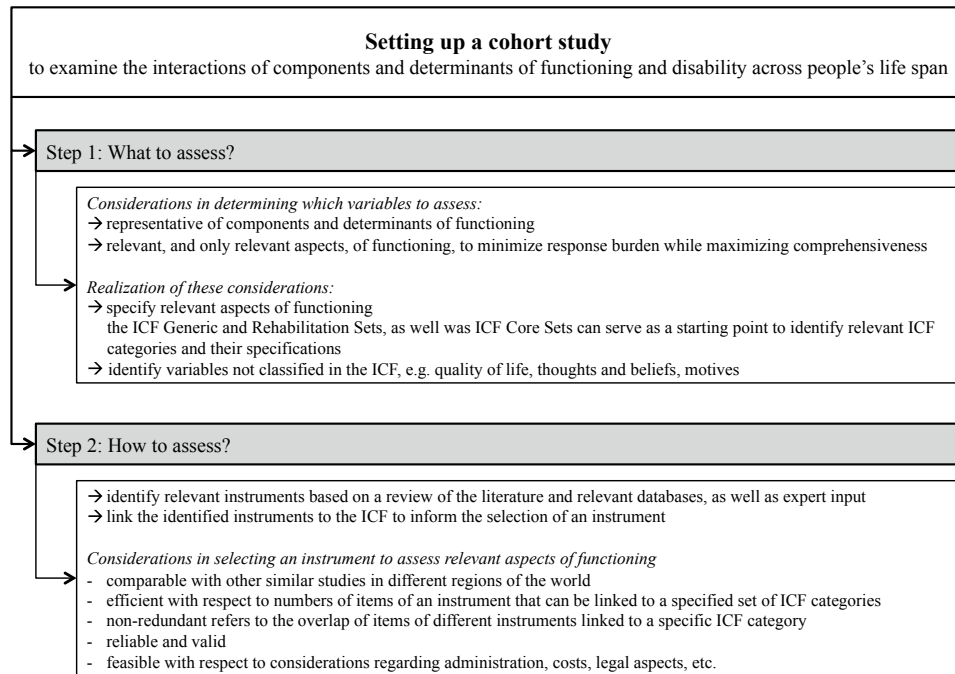

Setting up a cohort study

to examine the interactions of components and determinants of functioning and disability across people's life span

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Step 1: What to assess?

Considerations in determining which variables to assess:
→ representative of components and determinants of functioning
→ relevant, and only relevant aspects, of functioning, to minimize response burden while maximizing comprehensiveness

Realization of these considerations:
→ specify relevant aspects of functioning
    the ICF Generic and Rehabilitation Sets, as well was ICF Core Sets can serve as a starting point to identify relevant ICF categories and their specifications
→ identify variables not classified in the ICF, e.g. quality of life, thoughts and beliefs, motives

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Step 2: How to assess?

→ identify relevant instruments based on a review of the literature and relevant databases, as well as expert input
→ link the identified instruments to the ICF to inform the selection of an instrument

Considerations in selecting an instrument to assess relevant aspects of functioning
- comparable with other similar studies in different regions of the world
- efficient with respect to numbers of items of an instrument that can be linked to a specified set of ICF categories
- non-redundant refers to the overlap of items of different instruments linked to a specific ICF category
- reliable and valid
- feasible with respect to considerations regarding administration, costs, legal aspects, etc.

Fig. 2. Overview of the process toward setting up a cohort study of functioning.

cally to best describe functioning in people across health conditions and the general population (11). When the focus is specifically on clinical populations, these ICF categories can be complemented with 23 ICF categories into a more extended ICF set of 30 ICF categories, referred to as the ICF Rehabilitation Set (12). These additional 30 ICF categories best describe functioning across various clinical populations and across the continuum of rehabilitation care from acute, to early post-acute and long-term care. To summarize, the ICF Generic and Rehabilitation Sets contain the ICF categories most relevant to compare information across the general and clinical populations. ICF Core Sets for a specific health condition complement the ICF Generic and Rehabilitation Set with ICF categories that are most relevant to be described in a specified clinical population. Furthermore, a statistical set adds additional relevant ICF categories by specifying those ICF categories needed to best describe variations in functioning within a given health condition. Any additional ICF category that is relevant in a given context or for a particular patient can subsequently be added from the entirety of the ICF.

A further consideration is that ICF categories are ordered hierarchically, with increasing levels of specificity, as illustrated in Fig. 1 by a detailed illustration for the ICF category *d440 Fine hand use*. The majority of ICF categories contained in the ICF Core Sets are on the second level. Regardless of the level in the hierarchy, in order to be transparent concerning the operational variables that need to be considered in a cohort study some further specification of identified categories may be required. Category specification therefore refers to the identification of the aspect of an ICF category that is particularly relevant to assess in a given population As highlighted by Cieza et al. (23), category specifications need to relate to the same component of functioning as the category itself (e.g. only body functions can be specifications of Body Functions) and may or may not correspond to a more detailed level of ICF category. For instance, the category specification for *b152 Emotional functions* may include anxiety in its specification, which is covered by neither of the third-level ICF categories. On the other hand, the category specification for *b134 Sleep functions* may refer to sustaining sleep throughout the night, which corresponds to *b1342 Maintenance of sleep*. The proposed methods

therefore require a further systematic literature review of completed and ongoing studies and international recommendations, in order to determine the most relevant constructs in a given field and population related to an ICF category to be accounted for as variables in clinical research and practice specific to the area of study (13).

Step 2: Identification of how to assess relevant aspects of functioning

Once it has been specified *what* to assess, the second step is to identify *how* to assess the specified ICF categories. Given the number of instruments and assessment tools that have been developed over the decades there is no need to develop new instruments, but rather to link existing instruments and assessments to the ICF. To identify relevant instruments, various sources of information can be used, including a review of the literature, existing databases on outcome measures commonly used in the field (e.g. 14), and expert feedback on what is used in practice. Relevant instruments can then be linked to the ICF based on established rules (15, 16).

Once relevant items, sub-scales, or full instruments have been specified, the researchers need to reflect on the properties of an instrument, which include comparability, efficiency and non-redundancy, reliability and validity, as well as feasibility to finally decide which to select (17). Comparability with other studies or routine clinical practice is important, as it influences whether the study findings can be later pooled or compared with data and knowledge in the field of practice. In this context "efficiency" refers to the number of items of an instrument that can be linked to a specified ICF category, based on the selected ICF Core Sets and the total number of items in an instrument. The instrument is most efficient if most of its items link to an ICF category that has been selected as relevant for consideration in a cohort study on functioning. Redundancy points to the number of items derived from various identified instruments and linked to the same ICF category in relation to the overall number of ICF categories identified in the linking process. The instrument is most redundant if the items of both instruments are linked to the same ICF categories. There are no predefined cut-off points for when an instrument is inefficient or redundant. Examining these properties is meant to provide relevant information on the content coverage of relevant ICF categories in

the process of deciding which one of several instruments to use. To ensure that the data gathered are eventually reliable and valid, the psychometric properties of instruments must be examined. Existing standards, such as the Consensus-based Standards for the Selection of Health Measurement Instruments (18), may serve to guide the critical appraisal of instruments. Feasibility refers to practical considerations, such as the administration mode (e.g. patient-administered vs expert-administered), costs and legal aspects associated with administering a certain instrument, as well as the acceptability of certain questions in a given (sub-)population and length of an instrument. To make the final determinations of which items, sub-scales or instruments to use, researchers need to ensure that, as far as possible, the respondents' burden is minimized, while comprehensiveness and comparability are maximized (17). Additional variables on aspects not classified in the ICF, e.g. quality of life, thoughts and beliefs, and personal motives can be added when meaningful for a given study.

Development of SwiSCI as a case in point

The process outlined in Fig. 2 has been followed in the case of SwiSCI. We present here examples from the development of SwiSCI. The full materials can be requested from the authors.

Step 1: What to assess in SwiSCI. The aim of SwiSCI is to examine the components and determinants of functioning in people living with spinal cord injury (SCI) in Switzerland. Using the ICF Generic and Rehabilitation Sets as the starting point for specifying variables ensured that most relevant aspects of functioning for people with SCI were considered, in addition to aspects of functioning relevant for comparison across different health conditions. Subsequently, SCI-specific Brief ICF Core Sets were identified; one for the early post-acute (19) and another for the long-term (20) context. In addition, a statistical set has been developed for SCI (10). It is worth mentioning that the latter set was developed only after SwiSCI was launched, so that the categories in the statistical set were not considered in the first survey wave. Table I outlines the list of ICF categories contained in SwiSCI and lists the ICF set from which they are derived. Fig. 3 outlines the linking of these items to the components of the ICF.

To move from ICF categories to operational variables, the ICF categories were further specified based on a literature review of PubMed, recommendations for data sets by the International Spinal Cord Society (ISCoS, 21), and a platform focusing on rehabilitation evidence in SCI (22). Through this process the category specifications for, e.g. *b152 Emotional functions*, became anxiety and depression, and for *b280 Sensation of pain*, shoulder pain and pain in general (Table II, columns 1 and 2). Details of the literature search and analysis have been published previously (23).

Additional variables relevant from a psychological personal perspective, such as life satisfaction, self-efficacy, and coping, have also been identified through systematic literature reviews (24).

Step 2: How to assess relevant aspects of functioning in SwiSCI. Based on the category specification for each ICF category, (sub-)scales or (items of) instruments were identified that are commonly used to assess the respective aspects of functioning. Systematic literature searches were conducted (24–27), as well as reviews of SCI-specific databases (14, 21, 22). To exemplify this process, the second part of Table II (columns 3 and 4) lists all the resulting scales and instruments for *b152 Emotional functions* and *b280 Sensation of pain*. The same process was conducted for all of the identified ICF categories.

Once the ICF categories to be translated into operational variables were specified and the linking tables of each instrument developed, issues of comparability, efficiency, non-redundancy, reliability and validity, and feasibility were considered. Table III shows the linkings of instruments identified to assess Activities and Participation. All of these instruments have shown to be reliable and valid, while accounting for the fact that some instruments have been in use for longer (e.g. Functional Independence Measure (FIM)) than others Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P). The figures at the end of the Table show that all instruments contain items linked to ICF categories identified as relevant for SwiSCI. The instruments vary, however, in terms of the number of items beyond those in the SwiSCI category set. For instance the SCIM-SR includes only 1 item outside relevant ICF categories, whereas the ICF Measure of Participation and ACTivities – Screener (IMPACT-S) contains 17 items. On the other hand, Spinal Cord Independence Measure – Self-Report (SCIM-SR) lacks items relevant to 9 ICF categories in the SwiSCI set, whereas IMPACT-S lacks only 1 item. Thus, there is no single instrument that captures all aspects of the Activities and Participation component well while not including too many additional aspects. Thus, a combination of instruments was considered for SwiSCI. As SCIM is an SCI-specific instrument widely used in clinical practice, it was considered as a very important instrument by the SwiSCI study team. However, from the point of view of feasibility, SCIM is an expert-administered instrument. To make it feasible for reliable and valid use in the SwiSCI study required the development of a self-report version (28, 29). When combining items from SCIM-SR and USER-P, all except 3 ICF categories of the SwiSCI category set, and only 5 additional ICF categories not in the category set, are covered. The 3 ICF categories not covered are: *d240 Handling stress and other psychological demands, d445 Hand and arm use,* and *d710 Basic personal interactions.* The 5 additional categories are: *d360 Using communication devices and techniques, d650 Caring for household*

Health condition
Spinal Cord Injury (SCI)

Body Functions & Structures
- Injury level and completeness
- SCI-SCS
- SCQ
- Fatigue rating scale
- SF-36 Mental Health Sub-scale
- International SCI Basic Pain Data Set[a]

Activities & Participation
- IMPACT-S[a]
- SCIM-SR
- USER-P

Environmental Factors
- NEFI-SF
- Swiss Health Survey 2007[a]

Personal Factors
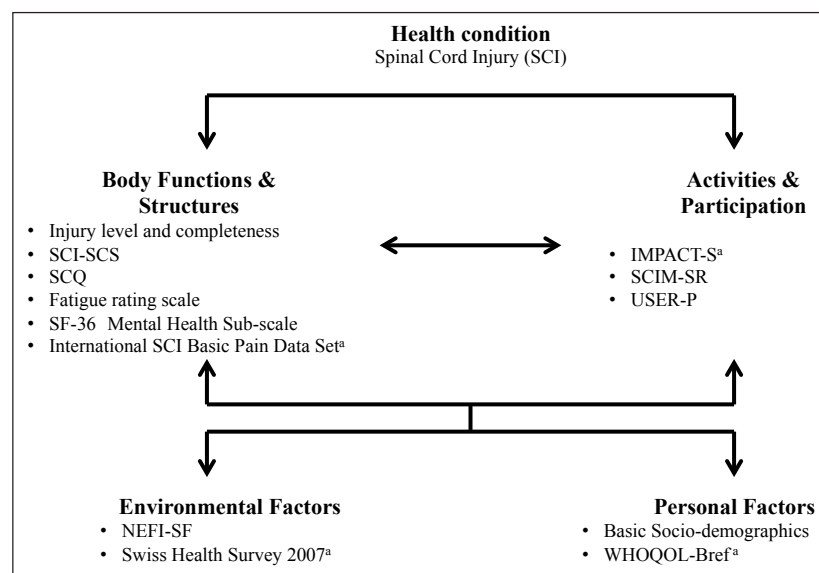- Basic Socio-demographics
- WHOQOL-Bref[a]

Fig. 3. Overview of components of the International Classification of Functioning, Disability and Health (ICF) and the corresponding instruments included in the Swiss Spinal Cord Injury Cohort Study (SwiSCI) community survey. SCI-SCS: SCI Secondary Conditions Scale; SCQ: Self-Administered Comorbidity Questionnaire; SF-36: 36-item Short Form; IMPACT-S: ICF Measure of Participation and Activities Questionnaire-Screener; SCIM-SR: SCI Independence Measure Self-Report; USER-P: Utrecht Scale for Evaluation Rehabilitation-Participation; NEFI-SF: Nottwil Environmental Factor Inventory Short-Form; WHOQOL-BREF: 5-item World Health Organization Quality of Life Assessment. [a]Selected items of the instrument are included.

Table I. *International Classification of Functioning, Disability and Health (ICF) categories contained in the Swiss Spinal Cord Injury Cohort Study (SwiSCI), and the ICF set from which they were derived*

ICF Code	Title	ICF Generic Set	ICF Rehabilitation Set	Brief EPA	90%[a] EPA	Pat EPA Ranking[b]	HP EPA Ranking[b]	Brief LT	90%[a] LT	Pat LT	Pat LT Ranking[b]	HP LT Ranking[b]
b126	Temperament and personality functions					17	12			1	6	27
b130	Energy and drive functions	1	1			6				1	7	7
b134	Sleep functions		1							1	5	22
b152	Emotional functions	1	1	1		11		1		1	4	6
b270	Sensory functions related to temperature and other stimuli						19					
b280	Sensation of pain	1	1	1				1				
b415	Blood vessel functions					28	7					
b420	Blood pressure functions											29
b430	Haematological system functions					27	11					
b440	Respiration functions				1							
b445	Respiratory muscle functions						15					
b455	Exercise tolerance functions		1									35
b525	Defecation functions				1			1				
b530	Weight maintenance functions											26
b550	Thermoregulatory functions						16					
b610	Urinary excretory functions											33
b620	Urination functions			1	1		6	1				34
b640	Sexual functions		1					1				19
b670	Sensations associated with genital and reproductive functions					20						
b710	Mobility of joint functions		1			14		1				
b715	Stability of joint functions						18					
b730	Muscle power functions		1	1	1			1	1			
b735	Muscle tone functions			1				1	1			
b740	Muscle endurance functions				1				1			
b750	Motor reflex functions								1			
b755	Involuntary movement reaction functions					13						
b760	Control of voluntary movement functions					24						
b780	Sensations related to muscles and movement functions						17					
b810	Protective functions of the skin			1		15		1				37
b840	Sensation related to the skin									1	13	15
s120	Spinal cord and related structures			1	1			1	1			
s430	Structure of respiratory system			1			13	1				
s610	Structure of urinary system			1		8		1				
s720	Structure of shoulder region					29						
s810	Structure of areas of skin						22	1				
d155	Acquiring skills											12
d230	Carrying out daily routine	1	1					1				
d240	Handling stress and other psychological demands		1				9	1		1	9	
d360	Using communication devices and techniques											4
d410	Changing basic body position		1	1				1				
d415	Maintaining a body position		1									
d420	Transferring oneself		1	1				1				
d435	Moving objects with lower extremities				1							
d445	Hand and arm use		1					1		1	16	16
d450	Walking	1	1	1								
d455	Moving around	1	1		1			1	1			
d460	Moving around in different locations				1							
d465	Moving around using equipment		1			4	3	1				
d470	Using transportation		1					1				
d475	Driving											10
d510	Washing oneself		1	1								
d520	Caring for body parts		1					1				2
d530	Toileting		1	1		7		1				
d540	Dressing		1	1								

Table I. *Contd.*

ICF Code	Title	ICF Generic Set	ICF Rehabilitation Set	Brief EPA	90%ª EPA	Pat EPA Rankingᵇ	HP EPA Rankingᵇ	Brief LT	90%ª LT	Pat LT	Pat LT Rankingᵇ	HP LT Rankingᵇ
d550	Eating		1	1				1				
d560	Drinking			1								
d570	Looking after one's health		1			1				1	3	
d620	Acquisition of goods and services									1	1	
d630	Preparing meals					2	2					
d640	Doing housework		1									
d660	Assisting others		1							1	11	3
d710	Basic interpersonal interactions		1									
d770	Intimate relationships		1			3	4			1	8	11
d820	School education									1	18	
d840	Apprenticeship (work preparation)											17
d845	Acquiring, keeping and terminating a job											5
d850	Remunerative employment	1	1									
d870	Economic self-sufficiency						1			1	2	
d910	Community life											1
d920	Recreation and leisure		1									
d930	Religion and spirituality					18	10					
e110	Products or substances for personal consumption		1					1				
e115	Products and technology for personal use in daily living		1	1				1				
e120	Products and technology for personal indoor and outdoor mobility and transportation		1	1		9	20	1				
e125	Products and technology for communication					26						
e135	Products and technology for employment		1			25	14					31
e140	Products and technology for culture, recreation and sport					23				1	15	9
e150	Design, construction and building products and technology of buildings for public use		1			19		1		1	12	
e155	Design, construction and building products and technology of buildings for private use		1					1				20
e165	Assets						21					39
e225	Climate		1									
e310	Immediate family		1	1	1			1				
e320	Friends		1									
e325	Acquaintances, peers colleagues, neighbours and community members					10				1	17	
e340	Personal care providers and personal assistants			1			8	1				14
e355	Health professionals		1	1	1			1				
e360	Health-related professionals					30						30
e415	Individual attitudes of extended family members									1	14	8
e420	Individual attitudes of friends											36
e440	Individual attitudes of personal care providers and personal assistants									1	19	
e450	Individual attitudes of health professionals		1		1					1	20	
e455	Individual attitudes of health-related professionals											25
e460	Societal attitudes											28
e510	Services, systems and policies for the production of consumer goods											21
e515	Architecture and construction services, systems and policies											13

Table I. *Contd.*

ICF Code	Title	ICF Generic Set	ICF Rehabilitation Set	Brief EPA	90%[a] EPA	Pat EPA Ranking[b]	HP EPA Ranking[b]	Brief LT	90%[a] LT	Pat LT	Pat LT Ranking[b]	HP LT Ranking[b]
e525	Housing services, systems and policies											32
e530	Utilities services, systems and policies											23
e540	Transportation services, systems and policies									1	21	
e555	Associations and organizational services, systems and policies					5	5					18
e575	General social support services, systems and policies					12						38
e580	Health services, systems and policies			1				1				
e585	Education and training services, systems and policies									1	10	24

[a]90% refers to ICF categories, in the description of functioning of persons with SCI, for which more than 90% of people in the empirical study indicated problems. These categories were, however, not included in the Regression model for developing the statistical set due to their lack of variance.

[b]Ranking refers to the explanatory value of the ICF category; it was ranked according to the size of the regression coefficients that resulted from the Lasso regression analysis in the development of the statistical sets; the smaller the number, the higher the rank.

Brief: Brief ICF Core Set; EPA: early post-acute; Pat: patients; HP: health professionals; LT: long-term.

objects, d740 Formal, d750 Informal social relationships, and *d810-d830 Education*. The items of the 2 instruments appeared to be non-redundant. Thus, for assessing relevant aspects of functioning in people with SCI with respect to the Activity and Participation component, the SCIM-SR and USER-P were selected. To assess the ICF categories not captured by these instruments, an additional item from the IMPACT-S was chosen for *d240 Handling stress and other psychological demands*. With regard to *d445 Hand and arm use* and *d710 Basic interpersonal interactions*, the balance between completeness of relevant aspects to be covered and the length of the survey were considered, and it was agreed by the research team that these aspects are addressed indirectly through other items. For instance, items in SCIM-SR imply a certain ability to reach for things or to rotate the hands. This example illustrates the value of having a linking table to inform the selection of instruments and items. In addition, the

Table II. *International Classification of Functioning, Disability and Health (ICF) Category Specification and the pool of candidate measurement instruments found in the literature exemplified for b152 Emotional functions and b280 Sensation of pain*

ICF category	Specification	Measurement instrument	Type of measurement	Number of items/questions[a]
b152 Emotional functions	Anxiety Depression	Hospital Anxiety and Depression Scale	SR, OBS	14
		Centre for Epidemiological Studies Depression Scale	SR, SSI	20
		Patient Health Questionnaire-9	SR, SSI	9
		Zung Self-Rating Depression Scale	SR, SSI	20
		Montgomery-Asberg Depression Rating Scale	OBS	10
		Hamilton Rating Scale for Depression	SSI	21
		State-Trait Anxiety Inventory	SR	40
		Beck Depression Inventory	SR	21
		Goldberg General Health Questionnaire (Self-completion)	SR	28
		Geriatric Depression Scale	SR	15
		Geriatric Mental State	SSI	30
		Mental Status Questionnaire	SSI	10
		Mental Health Scale of the SF-36	SR	5
b280 Sensation of pain	Shoulder pain Pain (general)	International Spinal Cord Injury Pain Basic Data set	OBS, SSI	16
		International Spinal Cord Injury Pain Basic Data set (self-reported version)	SR	8
		Wheelchair User's Shoulder Pain Index	SR	15
		McGill Pain Questionnaire	SR	20
		McGill Pain Questionnaire - Short Form	SR	15
		Classification System for Chronic Pain in SCI	OBS, SR	36
		Donovan SCI Pain Classification System	SSI	30
		The Multidimensional Pain Inventory - SCI version	SR	50
		Quantitative Sensory Testing	CT	na
		Tunk's Classification Scheme	SSI	various
		Brief Pain Inventory	SR	17
		SCI Secondary Condition Scale	SR	16
		Numeric rating scale	SR	na
		Visual analogue scale	SR	na

[a]Some instruments are available in different lengths and thus number of items; the number of items of the most widely used versions are listed here.

SR: self-report instrument; OBS: observational instrument; SSI: semi-structured interview; CT: clinical test; na: not applicable.

Table III. *Comparison of instruments assessing relevant International Classification of Functioning, Disability and Health (ICF) categories from the component Activities and Participation*

ICF Code	ICF Label	SwiSCI Category Set	FIM	SCIM-SR	IMPACT-S	WHODAS 2.0	USER-P	SCIM-SR & USER-P
d110-d129	Purposeful sensory experiences				×			
d130-d159	Basic learning				×	×		
d160-d179	Applying knowledge		×		×	×		
d210	Undertaking a single task				×			
d230	Carrying out daily routine	×				×	×	×
d240	Handling stress and other psychological demands	×			×			
d310-d329	Communicating - receiving		×		×	×		
d330-d349	Communicating - producing		×		×	×		
d360	Using communication devices and techniques				×		×	×
d410	Changing basic body position	×	×	×	×	×		×
d415	Maintaining a body position	×				×		
d420	Transferring oneself	×						
d430-d449	Carrying, moving and handling objects		×		×			
d445	Hand and arm use	×			×			
d450	Walking	×	×	×	×	×		×
d455	Moving around	×	×	×				×
d460	Moving around in different locations		×	×		×		×
d465	Moving around using equipment	×		×				×
d470-d489	Moving around using transportation	×			×		×	×
d510	Washing oneself	×	×	×	×	×		×
d520	Caring for body parts	×	×	×	×			×
d530	Toileting	×	×	×				×
d540	Dressing	×	×	×	×	×		×
d550	Eating	×	×	×	×	×		×
d560	Drinking	×						
d570	Looking after one's health	×		×				×
d610-d629	Acquisition of necessities				×	×		
d640	Doing housework	×			×	×	×	×
d650	Caring for household objects				×			
d660	Assisting others	×			×			
d710	Basic interpersonal interactions	×			×			
d720	Complex interpersonal interactions							
d730	Relating with strangers					×		
d740	Formal relationships				×			
d750	Informal social relationships				×	×	×	×
d760	Family relationships						×	×
d770	Intimate relationships	×			×	×	×	×
d810-d839	Education				×	×	×	×
d840-d859	Work and employment	×			×		×	×
d860-d879	Economic life				×			
d910	Community life				×	×		
d920	Recreation and leisure	×			×	×	×	×
d930	Religion and spirituality				×	×		
d940	Human rights					×		
d950	Political life and citizenship				×			
	ICF category in SwiSCI Category Set, item included in instrument		10	10	15	11	7	20
	ICF category in SwiSCI Category Set, no item included in the instrument		10	9	1	12	15	3
	ICF category not in SwiSCI Category Set, item included in instrument		4	1	17	10	5	5

Some ICF categories are presented in blocks rather than at the category level in order to facilitate the comprehensiveness, yet simplicity, of the table.

rationale of selecting a specific instrument accounts for aspects beyond the content of an instrument, such as comparability and feasibility.

DISCUSSION

This paper outlines the relevant steps and related methods in the development of a cohort study on functioning based on the ICF. In particular, it specifies how to go from the complex phenomena of functioning to specifying operational variables for consideration in a cohort study on functioning. The steps and methods outlined here ensure that the development of a cohort study is based on the comprehensive perspective of health, as operationalized through functioning in the WHO's ICF, and yet is efficient and feasible to administer.

Using the ICF as a foundation for the development of a cohort study on functioning ensures the operationalization of a comprehensive perspective of health in the specification of which aspects to consider in a given study. At the same time, the methods outlined here do not ignore existing instruments or common practice, but rather try to integrate them into a comprehensive frame of reference. This approach prevents researchers from selecting variables from existing instruments or common practice because of convenience, and ensures comparability with existing clinical and research practice.

Some further points are relevant to the selection of an instrument. First, although instruments may link to the same ICF category, they may adopt different perspectives; for example, one can ask about difficulties in getting dressed, a person's satisfaction with his or her ability to get dressed, or the assistive devices needed for getting dressed. Secondly, instruments and assessment tools may use various approaches to quantify the responses to an item; for example, in terms of the intensity of problems in getting dressed or the frequency of personal assistance needed. The perspectives adopted in existing instruments and the approaches used for quantifying the information are all legitimate and valuable, of course, but for comparability of data it is important to clarify not only whether 2 items link to the same ICF category, but also from which perspective questions about the information are asked and how the information becomes quantified.

The challenge of setting up a cohort study on functioning comes with creating a parsimonious set of categories and related items which, at the same time, is expected to encompass a broad range of ICF categories across all components relevant to human functioning. The ICF Core Sets serve as a starting point to identify those aspects of functioning considered to be most relevant to report and assess. Complementary to that, international scientific communities, such as the International Spinal Cord Society (ISCoS), recommend techniques for assessing some of these ICF categories. For example, ISCoS has proposed standard variables for SCI data sets in order to foster the integration of clinical and research data. Data sets have been developed for specific domains, such as pain, bowel function, urodynamic, and cardiovascular function (21). Each of these data sets contains further questions, as, for example, for the domain pain: severity and frequency of pain, pain location, and quality of pain. In developing a cohort study such as SwiSCI, which captures relevant aspects of functioning across all components of the ICF, it is important to ensure comparability with these existing sets by identifying a succinct standard variable set, while trying to facilitate the development of specific modules or nested projects that enable study of a phenomenon or domain in greater depth. Such an approach makes it possible to establish a comprehensive survey, aligned with international standards and recommendations from relevant international communities, which can also be feasibly administered.

The steps in the development of the data items for SwiSCI answer the call of both the World Report on Disability (30) and the International Perspectives on Spinal Cord Injury (31), for strengthening comparable data. Using the ICF as a foundation to specify what is important to consider, and being transparent in the methods to specify the relevant categories and their translation into operational variables is highly valuable, as it enables the establishment of qualitative and quantitative comparability with any other study. Having the ICF categories of the ICF Generic and Rehabilitation Sets included in the variable set facilitates comparability across health conditions and across settings in the future. These ICF categories can be seen as the minimum standard most relevant for comparability of functioning information across clinical (sub-)populations, across settings along the continuum of care, and across countries.

In conclusion, we have outlined the conceptual and methodological framework for setting up a cohort study on functioning that is also designed to assist comparability with data from existing data sets. The specific steps toward specifying what to assess in rehabilitation practice and research, and how to assess the specified domains are described using SwiSCI as an example. The approach outlined in this paper facilitates bridging classification with existing approaches and methods of assessment. As such, it facilitates, on the one hand, standardized reporting and, on the other hand, comparability with existing clinical practice and research.

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