# **SPECIAL ARTICLE**



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# A guide on how to develop an International Classification of Functioning, Disability and Health Core Set

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International Classification of Functioning, Disability and Health (ICF) Core Sets are purpose-tailored shortlists of ICF categories from the whole ICF classification for describing functioning and disability. Although the 34 ICF Core Sets developed up to now already cover many health conditions, there may still be a need to develop additional ICF Core Sets that tackle other health conditions and address other purposes. This paper provides a detailed description of the standard process for developing ICF Core Sets that will serve as a guide for future ICF Core Set development projects. ICF Core Sets are developed by means of a three-phase, multi-method scientific process. The process involves four preparatory studies - an empirical multicentre study, a systematic literature review, a qualitative study and an expert survey. The results of the preparatory studies serve as the starting point for a structured decision-making and consensus process at an international conference, during which participating experts decide on the ICF categories to be included in the Comprehensive and Brief ICF Core Sets. The first version of the ICF Core Set may necessitate modifications for specific applications and implementation in specific settings.

**KEY WORDS:** International Classification of Functioning, Disability and Health - Process assessment (Health Care) - Classification - Disability evaluation.

The International Classification of Functioning, Disability and Health (ICF) 1 has become a stand-

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ard classification for the description and assessment of health in which functioning can be understood as the operationalization of health and represents the outcome of the interaction between a person's health condition and his/her contextual factors. The ICF contains more than 1400 categories making its applicability in everyday clinical practice challenging. To address this challenge and facilitate its wider implementation in various settings, the World Health Organization (WHO) and the ICF Research Branch created a scientifically-based process for developing core sets of ICF categories for specific purposes.

#### What is an ICF Core Set?

An ICF Core Set (ICF-CS) is a selection of essential categories from the full ICF classification that are considered most relevant for describing the functioning of a person with a specific health condition or in a specific healthcare context. ICF-CS can serve as a minimal standard for the assessment and reporting of functioning and health in clinical practice and studies.<sup>2</sup>

So far, 34 ICF-CSs have been developed.<sup>3</sup> They are presented in Table I. Three different groups can be distinguished: those for the acute, early post-acute, and long-term context. There are also context-cutting ICF-CSs such as for neurological, musculosk-eletal and cardiopulmonary conditions, spinal cord injury and vocational rehabilitation.

For every ICF-CS there are comprehensive and brief versions. The comprehensive ICF-CS includes those ICF categories that make a comprehensive and exhaustive description of functioning possible.<sup>3</sup> Drawn from the ICF categories of the comprehen-

sive version, the Brief ICF-CS includes the most essential categories that can serve as a minimal standard for describing functioning.

Although the existing ICF-CSs already cover many health conditions, ICF users still see a need to develop additional purpose-tailored ICF-CSs to facilitate the implementation of the ICF in clinical practice and research.

The objective of this paper is, therefore, to detail the standard process for developing an ICF-CS, which should facilitate and guide the development of future ICF-CSs.

# **Development of an ICF Core Set**

General principles

ICF-CSs adhere to three principles. First, the development of ICF-CSs follows an evidence-based process that integrates evidence from preparatory studies that will be introduced later in this paper.

TABLE I.—Currently available ICF Core Sets (ICF-CSs).

Acute*	Early post-acute**	Long-term***
Neurological conditions <sup>25</sup>	Neurological conditions 29	Multiple sclerosis 48 Stroke (also under cardiopulmonary conditions) 45 Traumatic brain injury 56
		Children and youth with cerebral palsy 58
	Spinal cord injury 33	Spinal cord injury 47
Cardiopulmonary conditions 28	Cardiopulmonary conditions 31	Chronic ischemic heart disease <sup>39</sup>
,		Diabetes mellitus 40
		Obesity 41
		Obstructive pulmonary diseases 42
Musculoskeletal conditions <sup>26</sup>	Musculoskeletal conditions 30	Ankylosing spondylitis 46
		Chronic widespread pain 34
		Low back pain 35
		Osteoarthritis <sup>36</sup>
		Osteoporosis <sup>37</sup> Rheumatoid arthritis <sup>38</sup>
A guita inflammataux authuitia 27	For equiptain potionts 32	
Acute inflammatory arthritis <sup>27</sup>	For geriatric patients 32	<b>Bipolar disorders</b> 57 Depression 43
		Breast cancer 44
		Head and neck cancer 49
		Hand conditions 53
		Inflammatory bowel diseases 51
		Sleep 50
		Hearing loss 54
		Vertigo 55
		Vocational rehabilitation 52

ICF-CSs marked in bold and *italics* followed the standard methodology for developing ICF-CSs described in this paper.

\*Acute context is the period of time immediately following an injury or onset of a health condition and preceding the early post-acute context. \*\*Early post-acute context refers to healthcare settings in which initial comprehensive rehabilitation following the acute event is provided. \*\*\*Long-term context is the period during which persons with a health condition live in the community and receive both medical and non-medical care intermittently.

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Secondly, ICF-CSs reflect the perspective not only of health professionals and other experts, but also of persons with the health condition. Thirdly, the health professionals and experts represent a broad range of disciplines, thus enriching the application of ICF-CSs in multidisciplinary settings. Lastly, the consensus and decision-making process is international involving experts from the six WHO world regions (the African, Eastern-Mediterranean, South East Asian, Western-Pacific, the European regions, and the region of the Americas) to enable implementation all over the world.<sup>4</sup> So far, the only exceptions to this internationality approach are the ICF-CSs for the acute and post-acute contexts that were developed, for practicality reasons, with a focus on the German-speaking countries.5

#### Specific steps

ICF-CSs are developed by means of a scientific and multi-method process that includes the phases shown in Figure 1.

The first phase in the process is collecting the evidence. This phase consists of four preparatory studies that capture different perspectives: an empirical multicenter study (clinical perspective), an expert survey (health professionals's perspective), a systematic literature review (researcher's perspective), and a qualitative study (perspective of persons with a health condition). In phase two, the resulting set of "candidate" ICF categories is provided to the experts and health professionals who participate in an international consensus conference during which they decide on the ICF categories to be included in the respective ICF-CS. The final phase in the process involves implementing the first version of the ICF-CS.4, 6, 7

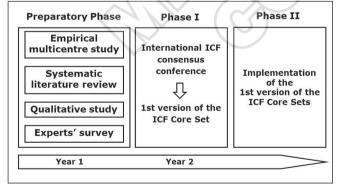


Figure 1.—Process for developing an ICF Core Set.

#### **Preparatory studies**

Systematic literature review

The systematic literature review captures the perspective of researchers on the health condition. The systematic literature review aims to identify the aspects of functioning that are described or evaluated in the scientific literature related to the health condition of interest.8-12 The rationale behind this approach is that we assume that those aspects of functioning that are described, assessed or measured are considered relevant in persons with the health condition under consideration by the researchers carrying out the studies.

The review usually includes scientific literature on the health condition no older than ten years. Internet databases such as Medline, Embase, Psycinfo, Central, CINAHL, etc. can be used depending on the purpose of the ICF-CS. Frequently used inclusion criteria are: peer-reviewed articles in English, the health condition of interest is the primary diagnosis of patients included in the studies, randomized controlled trials, clinical controlled trials, cross-sectional studies, observational studies and qualitative studies. Generally studies to be excluded are psychometric and prevention studies, studies of phase-II clinical trials, studies exclusively with laboratory parameters, animal experiments, letters, comments and editorials. The reason for those exclusions is that those studies usually do not include information about functioning. Inclusion and exclusion criteria as well as the search terms used to identify the studies vary depending on the purpose of the ICF-CS.

Two investigators independently screen the abstracts resulting from the search and based on the inclusion and exclusion criteria identify which abstracts to include for full text screening and data extraction. In case of an overwhelming number of abstracts, a random selection of full articles to read is recommended.<sup>13, 14</sup>.

In reviewing the full articles, the underlying concepts that are contained in the measures and in the article text are identified, and then linked to ICF categories using established linking rules <sup>15</sup> (Figure 2).

A frequency analysis is then done on the linked categories. An ICF category that repeatedly shows up in a publication is counted only once. The ICF categories that are identified in at least 5% of the publications are included in the list of candidate categories.

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#### **Instrument**

Step 1: List each item separately. Each question is one item.	Step 2: Each linker identifies the meaningful concept independently.		Step 3: Independently each linker decides the ICF category that corresponds to the meaningful concept.		Step 4: The linkers discuss incongruency and agree on one category.  *Third linker may be needed to reconcile ongoing disagreement between the two linkers.	
Item	Concept Linker 1	Concept Linker 2	Category Linker 1	Category Linker 2	ICF category agreed on	
How would you describe the pain you usually have from your knee?	Pain in knee	Knee pain	b28016 Pain in joints	b28016 Pain in joints related to s75011 Knee	b28016 Pain in joints	

# Transcript from the qualitative study

Step 1: Divide text when a topic change is discerned.	Step 2-4 are the same as above				
Sometimes I s-s-stutter and can't find the right word to use, but only	sometimes I stutter	sometimes I stutter	b3300 Fluency of speech	b3300 Fluency of speech	b3300 Fluency of speech
when I am around strangers for the first time.	can't find the right word to use	can't find the right word to use	b167 Expression of language	b16710 Expression of spoken language	b16710 Expression of spoken language
	only when I am around strangers for the first time	only when I am around strangers for the first time	d730 Relating with strangers e345 Strangers	d730 Relating with strangers e345 Strangers	d730 Relating with strangers e345 Strangers

Figure 2.—Linking process.

# Empirical multicenter study

common problems experienced by persons with the duct semi-structured interviews with patients.

health condition that are documented in a clinical setting. The study design is a multi-centre cross-sec-The empirical study aims to identify the most tional study during which health professionals conICF CORE SET DEVELOPMENT SELB

Instruments used for data collection are the extended ICF checklist, as well as other health-condition specific measures if deemed by experts as essential in covering the spectrum of functioning of patients living with the health condition. The extended ICF checklist and information about diagnosis and socio-demographic characteristics are integrated in a case record form (CRF) that is provided in the native language of the participating patients.

The ICF checklist 2.1a is a selection of 125 categories that WHO considered most important for clinical practice. <sup>16</sup> To ensure that the ICF checklist is sensitive to functioning specific to the health condition, the ICF Checklist is extended by supplementing it with the categories that are covered by at least one of the most commonly used measures identified in the systematic literature review and that are not already included in the ICF checklist. Ideally the categories resulting from the systematic literature review or at least a preliminary review of the literature should be available before conducting the empirical multicentre study. Experts can additionally be consulted to ensure that no essential category is missed.

The extended ICF checklist requires the investigator to rate the extent of a problem in each of the ICF categories or the extent to which an environmental factor is a facilitator or a barrier using the ICF qualifiers. To help determine the rating, available medical and diagnostic information as well as information gathered through direct observation and in interaction with the patient or the patients' family or caregiver can be taken into account. Although comorbidities should also be documented in the CRF, functioning associated with comorbidities is not linked to the ICF, since ICF-CSs focus on

the primary health condition. Comorbidities can be addressed through the combined use of the corresponding ICF-CS (if available).

The frequency of problems experienced (or barriers or facilitators if an environmental factor) can be analysed using descriptive statistics. An ICF category that is considered a problem, a barrier and/or facilitator at least in 20% of the studied patients is included in the list of candidate categories. The cutoff percentage will depend on the data collected.

#### Qualitative study

The qualitative study aims to identify which aspects of functioning, environmental and personal factors that are most important to persons with the health condition. Focus groups and individual semi-structured interviews may be conducted. The interaction between the focus group participants often enriches the information generated.<sup>17</sup> Although no difference was found in the depth of data generated between focus groups and interviews, focus groups are likely to produce more concepts compared with interviews.<sup>18</sup> Therefore, individual interviews are usually only conducted when the health condition prevents the person from participating in a focus group.

Groups with a maximum of 7 persons with a diverse range of participants should follow the maximum variation strategy. Participants are included in the study until saturation is reached. In each focus group session, a moderator and a group assistant, who have received ICF training, are present. The moderator's role is to ask a set of questions that address the four ICF components (Table II) and facilitate the interview process and group interaction 21.

Table II.—Questions to be asked in the qualitative study and expert survey

Qualitative study	Expert survey	ICF component covered
If you think about your body and mind what does not work the way it is supposed to?	If you think about the body and mind of the person with (health condition) list problems that are relevant to him/her?	Body functions
If you think about your body, in which parts are the problems?		Body structures
If you think about your daily life, what are your problems?	If you think about the daily life of the person with (health condition), what are his/her problems?	Activities and participation
If you think about your environment and living conditions, what do you find helpful or supportive?	If you think about your environment and the living conditions, what is supportive for you?	Environmental factors - facilitator
If you think about your environment and living conditions, what barriers do you experience?	If you think about the environment and the living conditions of the person with (health condition), what is hindering for him/her?	Environmental factors - barrier
If you think about yourself, what is important about you and the way you handle your condition/situation?	If you think about the person with (health condition), what is important about him/her and the way he/she handles his/her condition?	Personal factors

The focus groups or interview are audio-recorded and transcribed. The analysis of the transcript generally follow the method of meaning condensation. The transcript is divided into common themes not necessarily based on linguistic or grammatical considerations but rather where the researcher discerns a shift in meaning. These themes get broken down further into meaningful concepts. The final step is linking these concepts to ICF categories according to the linking rules (Figure 2).

# Expert survey

The expert survey is generally internet-based, and aims to gather opinions of experts on aspects of functioning and environmental factors that are relevant for persons with the health condition. A Delphi study may also be conducted.<sup>24</sup>

To encourage global use of the ICF-CSs and ensure applicability across disciplines, the expert survey includes experts from all six WHO regions and from a wide range of disciplines. Experts who meet the inclusion criteria are those who have at least two years of experience in treating individuals with the health condition and/or in researching the topic. Moreover, the expert must be fluent in English.

The experts are selected in two steps. The first step involves contacting international professional organizations and societies, authors of publications in the field, journal editorial boards, informal networks and peers. These persons and organizations are then asked to name additional experts who could participate in the expert study. A pool of experts who fulfill the selection criteria is stratified by discipline and WHO region. The second step involves drawing a random sample from this expert pool for each discipline and each WHO region. Selected experts are then sent an email invitation to participate in the survey. If an expert declines participation, another expert is randomly drawn from the expert pool. The experts who agree to participate are then emailed the expert survey or the web-link to the survey.

The expert survey consists of open-ended questions, similar to those asked in the qualitative study, about the problems/barriers and facilitators encountered by persons with the health condition (Table II). In addition, socio-demographic information and information about the expert's experience in the field is also recorded.

The experts' response is analyzed like in the qual-

itative study, *i.e.*, themes are identified, then broken down into meaningful concepts and linked to the ICF. A category is counted only once for each expert, even if several answers were given that were linked to the same ICF category. ICF categories that are reported by at least 5% of the experts are normally included in the list of candidate categories provided to the participants at the international consensus conference.

#### International consensus conference

The international consensus conference is central to the development of an ICF-CS. Participants are selected based their experience (at least 5 years) caring for persons with the health condition and/or conducting research on the health condition. Participants reflect an equal distribution across professional disciplines and WHO world regions. Experience from all the consensus conferences to date verifies that the optimal number of participants ranges between 21-24 experts.<sup>4, 5, 25-58</sup>

After the participants are introduced to the ICF, the process of developing ICF-CSs, and to the results of the preparatory studies, participants are provided with the list of candidate categories at the 2<sup>nd</sup> level identified during the preparatory studies. To help participants get familiar with the ICF categories that serve as the basis for discussions and decision-making during the entire conference, they are asked to individually pre-select the categories that reflect the most typical problems experienced by persons living with the health condition. Afterwards the iterative decision-making process begins (Figure 3).

The decision-making process consists of alternating working group (WG) and plenary sessions. The expert participants are divided into three homogenous WGs that reflect an equal representation of professions/disciplines, WHO regions and gender. The WG sessions enable the participants to discuss pros and cons of including each candidate ICF category in the Comprehensive ICF-CS thereby considering factors like commonality between the categories, frequency of a category in the population with the health condition, clinical utility and the results of the preparatory studies. They are then asked whether to include the respective 2<sup>nd</sup> level ICF category. Table III shows how the results of the preparatory studies can be shown to

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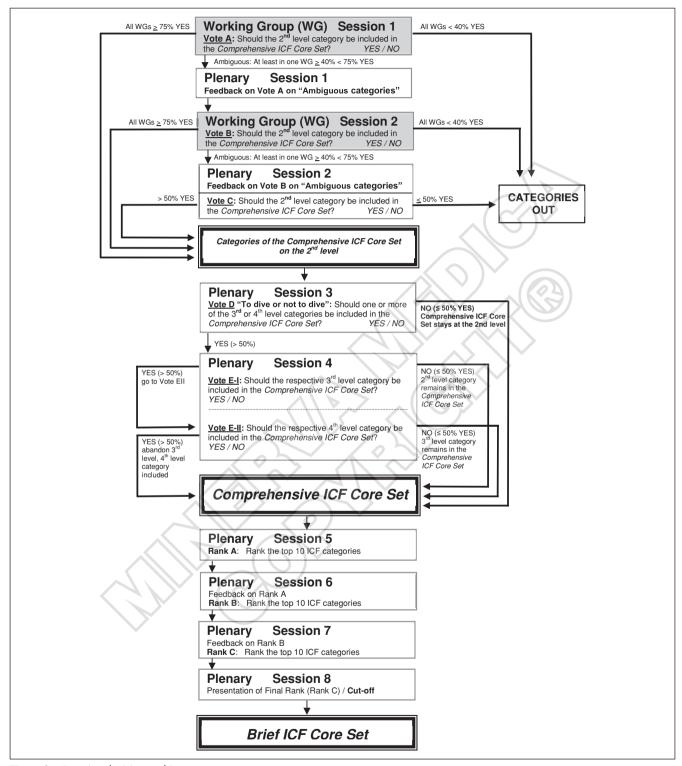


Figure 3.—Iterative decision-making process.

Table III.—Presenting the preparatory results at the consensus conferences.

ICF code level		ICF title	Empirical study (%)	Expert study (%)	Syst. lit. review (%)	Qualitative study (N.)	
2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>		N.=180	N.=63	N.=250	6
+b140			Attention functions	24	16	4	5
b140			Attention functions	14	6	2	4
	b1400		Sustaining attention	18	10	2	4
	b1401		Shifting attention	14	2	0	
	b1402 b1403		Dividing attention Sharing attention	21	2	1	1

This table is an example of how the results of the preparatory studies can be presented to the consensus conference participants for consideration in the voting process. All candidate categories can be listed accordingly in one table. Even if a preparatory study identifies 3rd or 4th level categories, only the corresponding 2nd level category will be voted on in the working group sessions and plenary session 2. However, it is still helpful for the participants to see all of the results for plenary sessions 3 and 4. This table shows the results from all ICF code levels.

the participants by exemplifying one category, *i.e.*, b140 attention functions. All candidate categories can be listed accordingly. Even if a preparatory study identifies 3<sup>rd</sup> or 4<sup>th</sup> level categories, only the corresponding 2<sup>nd</sup> level category will be voted on in the WG sessions and plenary session 2. However, it is still helpful for the participants to see all of the results for later stages of the decision-making process. For this reason, Table III shows the results from all ICF code levels.

ICF categories that were affirmed by at least 75% of the participants in each and all of the WGs will automatically be included in the Comprehensive ICF-CS. ICF categories that were affirmed by less than 40% of the participants in each and all of the WGs will automatically be excluded from the Comprehensive ICF-CS. All other ICF categories are considered "ambiguous". i.e., affirmed by only 40-74% of the WG participants. Even if only one WG considers a category ambiguous, this category will be considered ambiguous altogether. Following WG session 1 and 2, the participants convene in plenary to share the WG results. Only the ambiguous categories are discussed i.e. providing arguments for or against including in the Comprehensive ICF-CS. Up to this point voting of the categories is done only in each WG session and plenary session 2.

The consensus conference has two milestones: the confirmation of the *Comprehensive ICF-CS* and the confirmation of the *Brief ICF-CS*. While the decision-making process up to plenary session 2 examines only the ICF categories at the 2<sup>nd</sup> level, plenary sessions 3 and 4 address the question whether to include more specific ICF categories at the 3<sup>rd</sup> and 4<sup>th</sup> level derived from the 2<sup>nd</sup> level categories already included in the Comprehensive ICF-CS. See Figure

3. Participants are instructed to include a 3<sup>rd-</sup> or a 4<sup>th-</sup> level category only if the additional specification yielded by that category is *essential* to comprehensively describe functioning of persons with the health condition. The first milestone, the Comprehensive ICF-CS, is reached once a decision is made which, if any, 3<sup>rd</sup> and 4<sup>th</sup> level categories are to be added to the 2<sup>nd</sup> level categories already included in the Comprehensive ICF-CS.

The second part of the decision-making process involves deciding on the *Brief ICF-CS*. Participants are requested to rank the most essential ICF categories from the Comprehensive ICF-CSs in three consecutive ranking sessions. In each ranking session, participants are given a sheet listing all of the categories of the Comprehensive ICF-CS and are asked to individually rank the ten most essential categories for each ICF component in order of their importance. Holding three ranking sessions allows the participants to share the reasoning for their ranking decision and gives them an opportunity to re-assess their decision. The result of the individual rankings is statistically calculated and a common ranking arises.

Following the final ranking session, the process of deciding the "cut-off" for each ICF component begins, at which time each participant is asked to decide how many ICF categories per ICF component would be important to include in the Brief ICF-CS. The consensus on the cut-off is then applied to the final ranking results, and the second milestone is reached - the Brief ICF-CS.

Elaborating Comprehensive and/or Brief ICF-CSs for specific age groups may be considered when creating ICF-CSs for health conditions that reflect characteristics of the developing child.<sup>58</sup>

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# Implementation of ICF-CSs

The logical next step after the Comprehensive and Brief ICF-CSs have been established is introducing them into practice. The implementation phase can take form in different ways and address multiple purposes. For example, the Lighthouse Project Hand endeavours to develop and implement ICF-based instruments, documentation forms and treatment guidelines for clinical practice based on the ICF-CS for hand conditions 53 in institutions of the statutory accident insurance in Germany (DGUV) along the continuum of care. It will be the case in point for all the DGUV-hosted institutions to implement the ICF in clinical practice, documentation, health statistics and clinical research for health conditions other than hand conditions.<sup>59</sup> Implementation efforts can also concurrently serve to validate the ICF-CS that is being implemented.60-63

### Generic and disability sets

To complement the health condition-specific ICF-CSs and the ICF-CS for VR, a set of ICF categories

TABLE IV.—Generic and disability sets.

ICF code	Title
Activities and	participation (N.=14)
d230	Carrying out daily routine (G)
d240	Handling stress and other psychological demands
d450	Walking (G)
d455	Moving around (G)
d470	Using transportation
d510	Washing oneself
d540	Dressing
d570	Looking after one's health
d640	Doing housework
d660	Assisting others
d710	Basic interpersonal interactions
d770	Intimate relationships
d850	Remunerative employment (G)
d920	Recreation and leisure
Body function	ns (N.=8)
b130	Energy and drive functions (G)
b134	Sleep functions
b152	Emotional functions (G)
b280	Sensation of pain (G)
b455	Exercise tolerance functions
b640	Sexual functions
b710	Mobility of joint functions
b730	Muscle power functions

called Generic Set (GS) has been developed statistically based on data collected from over 13'000 persons with different health conditions included in the German National Health Interview and Examination Survey 1998 (GHS), the United States National Health and Nutrition Examination Survey 2007/2008 (NHANES), and the ICF-CS studies conducted from 2004 until 2010 3, 64, 65 (Table IV). The GS includes seven categories that were considered relevant in both the clinical (ICF-CS studies) and general population (GHS and/or NHANES surveys), and can be used as key indicators of health and functioning when comparing health across health conditions, settings, contexts, countries and population groups using only a small number of ICF categories. Therefore, it is suggested that the categories from the GS be added to the assessment of functioning, if those categories are not yet included in the ICF-CS being used.

The GS is included in a larger set called Disability Set (DS) that contains 22 categories i.e. the 7 categories of the GS and 15 categories that were found to be statistically relevant solely in the clinical population (ICF-CS studies).<sup>65</sup>

#### Discussion

ICF-CSs are tools tailored for a comprehensive yet efficient application of the ICF for various purposes. In clinical practice, for example, ICF-CSs could be employed as a reference pool of categories to draw from when collecting functioning information that are standard and comparable, and to develop patient functioning profiles that guide intervention planning.3, 57 ICF-CSs also facilitate the joint use of the ICF and the International Classification of Diseases (ICD) by helping to identify so called "functioning properties", i.e., ICF categories relevant for describing the impact of a particular disease concept in terms of functioning. This approach also makes it possible to distinguish health condition severity from its impact. ICF-ICD joint use is purported to improve patient management and reporting of health. 66-69

In research ICF-CSs can serve as an item pool for developing assessment instruments that capture functioning in specific health conditions or contexts comprehensively, confirming content validity of an existing instrument as well as supporting appropriate selection of instruments.<sup>51, 57, 70, 71</sup> When planning studies that focus on functioning ICF-CSs can

be helpful, as they can ensure that all potentially relevant variables are taken into account. Use of ICF-CSs avoids the practice of selecting variables based on convenience or other practical considerations, *e.g.*, based on available instruments or on tradition. Because ICF-CSs are built upon a comprehensive model, it allows researchers to determine what to measure in a top-down, theory-informed manner.<sup>72</sup>

This article details how an ICF-CS can be developed. Professionals interested in developing new purpose-tailored ICF-CSs can refer to this article as a guideline. Following the standard methodology proposed in this paper has the benefit of enabling a robust comparison between ICF-CSs. However, modifications to the process described here are possible to address issues specific to a health-condition, situation or context. In addition, there are other sets of ICF categories that have shown to be useful in research and practice, *e.g.*, EUMASS set.<sup>73, 74</sup>

This standard methodology presented in this paper is the culmination of lessons learned from the first ICF-CSs developed. Of the 34 ICF-CSs developed so far, fourteen followed the standard methodology for developing ICF-CSs described in this paper (Table I). The first 12 ICF-CSs (breast cancer, chronic ischemic heart disease, chronic widespread pain, depression, diabetes mellitus, low back pain, obesity, obstructive pulmonary diseases, osteoarthritis, osteoporosis, rheumatoid arthritis, and stroke) deviated from the standard methodology, since they were developed without conducting a qualitative study in the preparatory phase.34-45 In addition, the ICF-CSs for cardiopulmonary, musculoskeletal and neurological conditions in the acute and post-acute setting as well as for acute inflammatory arthritis and geriatric patients followed an adapted version of the methodology.<sup>5</sup> In these ICF-CSs focus groups with experts and a Delphi process with health professionals were conducted instead of an expert survey, and the patient perspective was integrated in the preparatory phase through empirical data collection from patients in clinics rather than conducting focus groups with patients. Moreover, the ICF-CS for cardiopulmonary, musculoskeletal and neurological conditions in the acute and post-acute setting were decided on in one consensus conference rather than separate conferences for each condition group.

In developing new ICF-CSs it is advisable to consider previous ICF-CS development experience. For example, considering that previous ICF-CS projects show that 2<sup>nd</sup> level categories are generally a good compromise between breadth and depth of coverage of a person's functioning, as reflected in the limited number of ICF-CSs that include 3<sup>rd</sup> and 4<sup>th</sup> level categories,<sup>4, 5, 25-57</sup> ICF-CS developers may decide to include only 2<sup>nd</sup> level categories.

Another lesson learned from previous ICF-CS projects is the value of employing a qualitative study. A qualitative study helps to enrich the data with essential information from the patient perspective, further supporting the patient orientation of ICF-CSs. Based on the experience acquired during the first 12 ICF-CS projects that did not include a qualitative study, it was decided to include patient interviews and/or focus groups as a part of the preparatory phase.<sup>33, 46-58</sup> The numerous ICF-CS publications are a good source for learning from previous ICF-CS development experience as well as recognizing limitations and challenges associated with developing ICF-CSs.

ICF-CSs are designed to cover the whole spectrum of functioning of a person with a specific health condition. Using extraction versus a whole classification is inevitably associated with a risk of omitting an aspect of functioning important for a particular person. To overcome this limitation an ICF-CS can be complemented with additional codes from the classification or used jointly with another ICF-CS.<sup>3</sup>

Another challenge that has been faced in previous ICF-CS projects is ensuring international ap-

Table V.—Overview of what ICF Core Sets are and are not.

An ICF core set...

Does not replace the use of the whole ICF

Does not go back to a causal model of the consequences of disease Has not been developed to be used exclusively in clinical practice

Advises users which aspects of functioning to describe in patients with selected health conditions or specific context

- ...but provides an approach that facilitates the practical use of the ICF.
- ...but addresses functioning in light of a health condition.
- ...but in any context in which a description of functioning is necessary.
- ...but does not tell users how to measure aspects of functioning.

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plicability. This is reflected in the ICF-CSs for the acute hospital and post-acute rehabilitation. Since these ICF-CSs were developed exclusively in a German-speaking context, these ICF-CSs will need to be tested and validated in different WHO regions to optimize their applicability worldwide. The issue of internationality has implications for ICF-CS project planning, particularly in recruiting experts and patients and establishing study centers.

Learning from previous ICF-CS projects would save not only time, but unnecessary effort.

Lastly, some criticize ICF-CSs as a return to the biomedical model in that the starting point of most ICF-CSs is a specific health condition. To address this argument, Table V provides an overview of what ICF-CSs are and are not.3

#### **Conclusions**

This paper is a guide to those interested in developing new ICF-CSs. The ICF-CSs developed following the above-described procedure can be used in a variety of settings and purposes and across country and cultural borders.

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