

## ICF CORE SETS FOR CHRONIC WIDESPREAD PAIN

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**Objective:** To report on the results of the consensus process integrating evidence from preliminary studies to develop the first version of a *Comprehensive ICF Core Set* and a *Brief ICF Core Set* for chronic widespread pain.

**Methods:** A formal decision-making and consensus process integrating evidence gathered from preliminary studies was followed. Preliminary studies included a Delphi exercise, a systematic review and an empirical data collection. After training in the ICF and based on these preliminary studies relevant ICF categories were identified in a formal consensus process by international experts from different backgrounds.

**Results:** The preliminary studies identified a set of 365 ICF categories at the second, third and fourth ICF levels with 143 categories on *body functions*, 45 on *body structures*, 125 on *activities and participation* and 125 on *environmental factors*. Thirty experts attended the consensus conference on chronic widespread pain (16 physicians with at least a specialization in physical and rehabilitation medicine, 4 rheumatologists, 2 psychiatrists, 5 physical therapists, one psychologist, one occupational therapist and 1 social worker). Altogether 65 second-level and 2 third-level categories were included in the *Comprehensive ICF Core Set* with 23 categories from the component *body functions*, one from *body structures*, 27 from *activities and participation* and 16 from *environmental factors*. The *Brief ICF Core Set* included a total of 24 second-level categories and 2 third-level categories with 10 on *body functions*, 10 on *activities and participation* and 6 on *environmental factors*. No *body structures* were included in the *Brief ICF Core Set*.

**Conclusion:** A formal consensus process integrating evidence and expert opinion based on the ICF framework and classification led to the definition of *ICF Core Sets* for chronic widespread pain. Both the *Comprehensive ICF Core Set* and the *Brief ICF Core Set* were defined.

**Key words:** pain, outcome assessment, quality of life, ICF.

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## INTRODUCTION

There is a large number of health conditions that present chronic generalized pain or chronic widespread pain (CWP). Although there is not a universally accepted definition of CWP, there is increasing agreement that CWP represents pain involving several regions of the body. This conceptualization has been applied both in the diagnosis of fibromyalgia (1), as well as in epidemiological studies (2).

All conditions associated with CWP carry a high level of burden. Problems in functioning, psychological distress, fatigue, poor sleep quality and difficulties in activities of daily living (ADL) have consistently been reported as related to CWP in the literature (3–7). However, no systematic framework that covers the spectrum of symptoms and limitations in functioning of patients with CWP has been established so far.

Therefore, it would be valuable for clinical practice, research and teaching to define the spectrum of symptoms and limitations in functioning of patients with CWP.

The approval of the new International Classification of Functioning, Disability and Health (ICF) (8) enables us to define the typical spectrum of problems in functioning of patients with CWP, taking into consideration influential environmental factors and using a globally-agreed-upon language of functioning and health. Based on the ICF, generally-agreed-on lists of ICF categories can be defined. Such lists can serve as *Brief ICF Core Set* to rate all patients included in a clinical study with CWP or as *Comprehensive ICF Core Set* to guide multidisciplinary assessments of patients with CWP. The objective of this paper is to report on the results of the consensus process integrating evidence from preliminary studies to develop the first version of the *Comprehensive ICF Core Set* and the *Brief ICF Core Set* for CWP.

## METHODS

The development of the *ICF Core Sets* for CWP involved a formal decision-making and consensus process integrating evidence gathered from preliminary studies including a Delphi exercise (9), a systematic review (10), and an empirical data collection using the ICF checklist (11). After training in the ICF and based on these preliminary studies, relevant ICF categories were identified in a formal consensus process by international experts from different backgrounds.

The principals followed during the consensus conference regarding

Table I. *International Classification of Functioning, Disability and Health (ICF) categories of the component body functions included in the Comprehensive ICF Core Set for chronic widespread pain*

ICF code		ICF category title
2nd	3rd	
b122		Global psychosocial functions
b126		Temperament and personality functions
b130		Energy and drive functions
b134		Sleep functions
b140		Attention functions
b147		Psychomotor functions
b152		Emotional functions
	b1602	Content of thought
b164		Higher-level cognitive functions
b180		Experience of self and time functions
b260		Proprioceptive function
b265		Touch function
b270		Sensory functions related to temperature and other stimuli
b280		Sensation of pain
b430		Haematological system functions
b455		Exercise tolerance functions
b640		Sexual functions
b710		Mobility of joint functions
b730		Muscle power functions
b735		Muscle tone functions
b740		Muscle endurance functions
b760		Control of voluntary movement functions
b780		Sensations related to muscles and movement functions

the organization, recruitment of the participants, training in the ICF and the decision-making process have been described elsewhere (12).

Thirty experts (16 physicians with at least a specialization in physical and rehabilitation medicine, 4 rheumatologists, 2 psychiatrists, 5 physical therapists, one psychologist, one occupational therapist and 1 social worker) from 10 different countries attended the consensus process for CWP. The decision-making process for CWP involved 3 working groups with 10 experts each. The process was facilitated by the condition co-ordinator for CWP (NW) and the 3 working-group leaders (LK, LK, TS).

## RESULTS

The tables on the pre-conference studies (9–11) presented to the participants included 365 ICF categories at the second, third and fourth levels (143 on *body functions*, 45 on *body structures*, 125 on *activities and participation* and 52 on *environmental factors*).

Tables I–IV show the second- and third-level ICF categories included in the *Comprehensive ICF Core Set*. Table V shows the second-level ICF categories that were selected for the *Brief ICF Core Set*, as well as the percentage of experts willing to include the respective category in the *Brief ICF Core Set*.

The number of second- and third-level categories in the *Comprehensive ICF Core Set* is 67, with 65 categories on the second level and 2 categories on the third level. The total number of second- and third-level categories included in the *Brief ICF Core Set* is 26, with 24 categories on the second level and 2 categories on the third level.

Table II. *International Classification of Functioning, Disability and Health (ICF) – categories of the component “body structures” included in the Comprehensive ICF Core Set for chronic widespread pain*

ICF code	ICF category title
s770	Additional musculoskeletal structures related to movement

### *Comprehensive ICF Core Set*

The 67 categories of the *Comprehensive ICF Core Set* are made up of 23 (34%) categories from the component *body functions*, 1 (2%) category from the component *body structures*, 27 (41%) categories from the component *activities and participation* and 16 (24%) categories from the component *environmental factors*.

The 22 categories at the second level of the component *body functions* represent 18% of the total number of ICF categories at the second level in this component. Chapter 1 *mental functions* is represented by 9 categories at the second level and by the third-level category b1602 *content of thought*, which is a specification of the second-level category b160 *thought functions*. Chapter 7 *neuromusculoskeletal and movement-related functions* is represented by 6 and chapter 2 *sensory functions and pain* by 4 categories. Chapter 4 *functions of the cardiovascular, haematological, immunological and respiratory systems* is represented

Table III. *International Classification of Functioning, Disability and Health (ICF) categories of the component activities and participation included in the Comprehensive ICF Core Set for chronic widespread pain*

ICF code	ICF category title
d160	Focusing attention
d175	Solving problems
d220	Undertaking multiple tasks
d230	Carrying out daily routine
d240	Handling stress and other psychological demands
d410	Changing basic body position
d415	Maintaining a body position
d430	Lifting and carrying objects
d450	Walking
d455	Moving around
d470	Using transportation
d475	Driving
d510	Washing oneself
d540	Dressing
d570	Looking after one's health
d620	Acquisition of goods and services
d640	Doing housework
d650	Caring for household objects
d660	Assisting others
d720	Complex interpersonal interactions
d760	Family relationships
d770	Intimate relationships
d845	Acquiring, keeping and terminating a job
d850	Remunerative employment
d855	Non-remunerative employment
d910	Community life
d920	Recreation and leisure

Table IV. *International Classification of Functioning, Disability and Health (ICF) – categories of the component environmental factors included in the Comprehensive ICF Core Set for chronic widespread pain*

ICF code		ICF category title
2nd	3rd	
	e1101	Drugs
e310		Immediate family
e325		Acquaintances, peers, colleagues, neighbours and community members
e355		Health professionals
e410		Individual attitudes of immediate family members
e420		Individual attitudes of friends
e425		Individual attitudes of acquaintances, peers, colleagues, neighbours and community members
e430		Individual attitudes of people in positions of authority
e450		Individual attitudes of health professionals
e455		Individual attitudes of health-related professionals
e460		Societal attitudes
e465		Social norms, practices and ideologies
e570		Social security services, systems and policies
e575		General social support services, systems and policies
e580		Health services, systems and policies
e590		Labour and employment services, systems and policies

by 2 categories, and chapter 6 *genitourinary and reproductive functions* is represented by 1 category, respectively.

The component *body structures* is exclusively represented by 1 category at the second level of the ICF hierarchy, which belongs to chapter 7 *structures related to movement*.

The 27 categories of the component *activities and participation* represent 23% of the total number of ICF categories at the second level in this component. Most of the *activities and participation* categories belong to chapter 4 *mobility* (7 categories). However, with exception of chapter 3 *communication*, all 9 chapters of this component are represented in the *Comprehensive ICF Core Set*. Chapter 6 *domestic life* is represented by 4 categories and chapter 2 *general tasks and demands*, chapter 5 *self care*, chapter 7 *interpersonal interactions and relationships* and chapter 8 *major life areas* by 3 categories, respectively. Chapter 1 *learning and applying knowledge*, and chapter 9 *community, social and civic life* are each represented by 2 categories.

The 15 categories at the second level of the component *environmental-factors* represent 20% of the total number of ICF categories at the second level in this component. Most of the *environmental-factors* categories belong to chapter 4 *attitudes* (8 categories). Chapter 5 *services, systems and policies* and chapter 3 *support and relationships* are represented by 4 and 3 categories, respectively. Chapter 1 *products and technology* is represented by the third-level category e1101 *drugs*.

Table V. *International Classification of Functioning, Disability and Health (ICF) – categories included in the Brief ICF Core Set for chronic widespread pain and percentage of experts willing to include the named category in the Brief ICF Core Set. 50% represent a preliminary cut-off. >50% in bold*

ICF component	%	ICF code	ICF category title	
Body functions	<b>100</b>	<b>b152</b>	<b>Emotional functions</b>	
	<b>100</b>	<b>b280</b>	<b>Sensation of pain</b>	
	<b>100</b>	<b>b455</b>	<b>Exercise tolerance functions</b>	
	<b>86</b>	<b>b147</b>	<b>Psychomotor functions</b>	
	<b>69</b>	<b>b760</b>	<b>Control of voluntary movement functions</b>	
	<b>66</b>	<b>b130</b>	<b>Energy and drive functions</b>	
	<b>66</b>	<b>b134</b>	<b>Sleep functions</b>	
	66	<b>b1602</b>	<b>Content of thought</b>	
	<b>66</b>	<b>b730</b>	<b>Muscle power functions</b>	
	17	b140	Attention functions	
	Activities and participation	<b>100</b>	<b>d230</b>	<b>Carrying out daily routine</b>
		<b>100</b>	<b>d240</b>	<b>Handling stress and other psychological demands</b>
		<b>100</b>	<b>d760</b>	<b>Family relationships</b>
<b>100</b>		<b>d850</b>	<b>Remunerative employment</b>	
<b>97</b>		<b>d770</b>	<b>Intimate relationships</b>	
<b>86</b>		<b>d450</b>	<b>Walking</b>	
<b>86</b>		<b>d920</b>	<b>Recreation and leisure</b>	
<b>69</b>		<b>d175</b>	<b>Solving problems</b>	
<b>66</b>		<b>d430</b>	<b>Lifting and carrying objects</b>	
<b>55</b>		<b>d640</b>	<b>Doing housework</b>	
Environmental factors	<b>100</b>	<b>e1101</b>	<b>Drugs</b>	
	<b>100</b>	<b>e310</b>	<b>Immediate family</b>	
	<b>100</b>	<b>e355</b>	<b>Health professionals</b>	
	<b>100</b>	<b>e410</b>	<b>Individual attitudes of immediate family members</b>	
	<b>100</b>	<b>e570</b>	<b>Social security services, systems and policies</b>	
	17	e420	Individual attitudes of friends	

### Brief ICF Core Set

With respect to the categories contained in the *Comprehensive ICF Core Set*, the *Brief ICF Core Set* includes 9 (43%) categories at the second level and one category at the third level from the component *body functions*, 10 (37%) categories at the second level from *activities and participation*, 5 (33%) categories at the second level and one category at the third level from *environmental factors*. No *body structures* category is included in the *Brief ICF Core Set*.

The 9 categories at the second level of the component *body functions* represent 8%, the 10 categories of the component *activities and participation* 9%, and the 5 categories of the component *environmental factors* 7% of the total number of ICF categories at the second level in their respective components. All those ICF categories taken into account in the final decision process are considered here. However, a preliminary cut-off was established at 50% to reflect the opinion of the majority.

## DISCUSSION

The formal consensus process integrating evidence from preliminary studies and expert knowledge at the third ICF Core Sets Conference led to the definition of the *Brief ICF Core Set* and the *Comprehensive ICF Core Set* for multidisciplinary assessment.

A main challenge during the development of *ICF Core Sets* for CWP was to comprehensively cover the wide spectrum of CWP-related changes in *body functions*, as well as in *activity limitations and restrictions in participation*, while constantly keeping the focus on CWP itself without shifting attention to specific conditions that cause CWP, such as metastatic tumours or rheumatoid arthritis. The 67 categories (65 second-level categories) that were included in the *Comprehensive ICF Core Set* reflect the complex functional problems encountered in patients with CWP and also the crucial influence of patients' surroundings and life situations on their functioning and health.

Further discussion among the experts centred around the ostensible overlap of ICF categories, especially in the chapter *mental functions*. For example, questions such as whether the category *thought functions* or the category *higher-level cognitive functions* should be included in the *Comprehensive ICF Core Set* arose during the decision-making and consensus process. In this case, the experts were referred to the definitions and inclusion/exclusion criteria of the respective categories. Moreover, no concrete instructions were given to the experts regarding whether a determined health area should be included at the functional level or at the activities-and-participation level, i.e. b140 *attention functions* or d160 *focusing attention*. Problems in functioning can be manifested at both levels, reflecting the interrelations between the different components of the ICF.

Within the component *body structures*, only the category *additional musculoskeletal structures related to movement* was included in the *Comprehensive ICF Core Set* in order to cover

bones, joints, tendons, muscles and extra-articular ligaments in an unspecific way. Within this component, the inclusion of the category s710 *structure of head and neck region* was extensively discussed among the different experts, as *axial pain* is mentioned more frequently in publications as the typical localization of chronic pain (13). However, at the end of a long discussion, they decided that the *structure of head and neck region* is a relevant *body structure*, but not an indispensable *body structure* to comprehensively describe the functioning and health of patients with CWP.

Consistent with the main *body functions* affected in CWP, *neuromusculoskeletal- and movement-related functions* and *mental functions* are broadly covered in the *Comprehensive ICF Core Set*. *Energy and drive functions*, *sleep functions* and *emotional functions* are *body functions* widely reported in the literature as being affected by CWP (4, 13–16).

Further *body functions* related to sensory functions, such as *exercise tolerance functions* and *sexual functions*, were also considered sufficiently relevant to be included in a multidisciplinary, comprehensive assessment of patients with CWP. Sensation of pain is also part of the *Comprehensive ICF Core Set* for CWP.

The *body function* b1602 *content of thought*, which includes somatization, was also included in the *Comprehensive ICF Core Set*. The process of somatization has been widely discussed in the literature as a relevant factor in relation to CWP and fibromyalgia (17–19).

The concept generally found in the literature in relation to mental functions affected in CWP is psychological distress, usually understood as depressive mood, anxiety and somatoform disorders (20). It has been shown that CWP has been associated with high levels of psychological distress both in clinical samples and in the general population (14, 21–23). Moreover, research suggests that 40–50% of patients with chronic pain suffer from depression (24) and that anxiety and anger are highly prevalent (25).

Cognitive deficits have been reported in multiple-site musculoskeletal pain (26) and in patients with fibromyalgia (27). Concretely, deficits in performance in complex cognitive tasks (28), reduced psychomotor speed (29) and memory problems have been reported in patients with fibromyalgia. *Psychomotor functions*, *attention functions* and *higher-level cognitive functions* were included in the *Comprehensive ICF Core Set* in order to address these problems.

Based on the results of some studies, it seems, however, important to differentiate between subjective cognitive complaints and objective cognitive performance. Patients with fibromyalgia perceive much more cognitive impairment than is evident in their neuropsychological performance (30, 31). This can be interpreted as a result of the well-known phenomena that pain beliefs and pain coping strategies are central components of the pain experience. According to cognitive-behavioural models of chronic pain, what individuals believe about pain and how they cope with pain play important roles in their adjustment and functioning (32).

Since *personal factors* (which refer to the particular background of the individual's life and living and comprise factors such as gender, race and age, and also lifestyle, habits, past and current experience and coping styles) have not yet been classified in the ICF, it is difficult to address central issues such as pain beliefs and coping strategies, in the current version of the *ICF Core Sets*. This has to be taken into account in the testing and validation studies of this first version of the ICF Core Sets.

Limitations and restrictions in *activity and participation* may, indeed, be most relevant to patients with CWP. This is reflected not only in the fact that 27 categories of this component, as compared with the 23 *body functions* considered relevant, have been included, but also in the fact that 8 of 9 chapters of this component are represented in the *Comprehensive ICF Core Set*. Besides the life areas, such as *mobility, self-care and domestic life*, which have been reported in the literature as areas affected by CWP (20, 21, 33), other issues related to *solving problems, carrying out daily routine, handling stress and other psychological demands, interpersonal interactions and relationships, work and employment and recreation and leisure*, which are frequently reported in the literature in association with other health conditions or under the umbrella term Health-Related Quality of Life (HRQoL) (34) or functional status (4), were considered relevant and selected by the group of experts.

The component *environmental factors* is represented by a considerable number of ICF categories, which reflects the growing awareness of the important influence of patients' surroundings, life situations, and, most importantly, of external attitudes regarding CWP on the functioning and health of patients with this health condition.

*Products and technology*, as well as *services, systems and policies, support and relationships and attitudes* are highly important to patients with CWP because they can serve as either a barrier or a facilitator and may, therefore, influence CWP outcome.

Regarding the category *drugs*, the group felt that, due to the importance of drugs as therapy for CWP, it is worthwhile to have the third-level category *drugs* within the chapter *products and technology*, although other methods of pain relief are also widely used. This view is supported by publications on pain management (35).

Besides clinical studies in which the effectiveness of different medications on patients' pain are studied, the investigations in which the relationship between CWP and the environment has recently been analysed (36, 37) focus on the influence of work tasks and work physical environment on CWP. These aspects of the work environment are reflected in the ICF category *labour and employment services, systems and policies* included in the *Comprehensive ICF Core Set*.

The breadth of ICF chapters contained in the *Comprehensive ICF Core Set* reflects the important and complex "impairments", "limitations in activity" and "restrictions in participation" involved, as well as the numerous interactions with *environmental factors*. In relation to the *Comprehensive ICF Core Set*,

the *Brief ICF Core Set* results in a reduction in the number of chapters represented, as well as a reduction in ICF categories contained in each chapter. The result of this reduction represents a first proposal for a more practical ICF-based tool to be used in clinical studies.

The fact that only 2 categories at the third level of the classification were included reflects that the ICF second-level classification can be specific enough for description of patients with CWP in clinical studies as well as in multidisciplinary assessments.

Regarding the comprehensiveness of the ICF, it is most interesting to note that the panel of experts did not identify problems of patients not contained in the ICF. This emphasizes the validity of the ICF classification, which has been based on a painstaking international development process.

The organizers of the consensus process took much care in the selection of the experts and were successful in recruiting 30 experts with different professional backgrounds from 10 different countries. However, no psychologists were participating. In addition, the results of any consensus process may differ with different groups of experts. This emphasizes the importance of the extensive validation of this first version of the *ICF Core Sets* from the perspectives of different professions and in different countries. The first version of the *ICF Core Sets* will also be tested from the patients' points of view and in different clinical settings. It is important to note that this first version of the *ICF Core Sets* is only recommended for validation or pilot studies.

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