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ICF CORE SETS FOR LOW BACK 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 low back 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 503 ICF categories at the second, third and fourth ICF levels with 211 categories on *body functions*, 47 on *body structures*, 190 on *activities and participation* and 55 on *environmental factors*. Eighteen experts from 15 different countries attended the consensus conference on low back pain. Altogether 78 second-level categories were included in the Comprehensive ICF Core Set with 19 categories from the component *body functions*, 5 from *body structures*, 29 from *activities and participation* and 25 from *environmental factors*. The Brief ICF Core Set included a total of 35 second-level categories with 10 on *body functions*, 3 on *body structures*, 12 on *activities and participation* and 10 on *environmental factors*.**

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 low back pain. Both the Comprehensive ICF Core Set and the Brief ICF Core Set were defined.**

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

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INTRODUCTION

Low back pain (LBP) has reached epidemic proportions, being reported by about 80% of the population people at some time in their lives (1). Seventy-five percent of people with LBP are between 30 and 59 years of age, i.e. in their most productive years (2). While not a disease, LBP is a major cause of disability (3). The symptoms of LBP and the associated disability bear only a poor relationship to objective data, such as the imaging evidence of degenerative disease of the spine. Therefore, many efforts have been made to try to identify meaningful outcome measures (2).

Condition-specific instruments, such as the North American Spine Society Lumbar Spine Outcome Assessment Instrument (NASS) (4), the Roland-Morris Disability Questionnaire (RMQ) (5) and the Oswestry Low Back Disability Questionnaire (ODI) (6), generic instruments, such as the Medical Outcome Study Short Form 36 (SF-36) (7) and the Nottingham Health Profile (NHP) (8) and pain specific instruments and other dimension specific instruments including scales to address depression, sleep and fatigue have been used in clinical studies to address functioning, disability and health of patients with LBP. However, there is little standardization of the use of these instruments, and comparisons among studies are difficult or impossible (9). Therefore, different recommendations have been proposed recently regarding the outcome measures to be used in studies with patients with LBP.

Deyo et al. (9) as well as Bombardier (10) considered that a Core Set of measures should include the following dimensions: symptoms, function, general well-being, work disability and satisfaction with care. Deyo et al. recommended the use of a 6-item standardized Core Set of questions to be used in all studies for back pain. Additionally, they suggested the use of this set together with an expanded, more precise battery of measures including the RMQ or the ODI, and the SF-12 (11) or the European Quality of Life instrument (EQ-5D) (12) when greater precision in measurement is desirable. Bombardier, on her part, proposes different specific instruments for some of the domains.

The WHO Low Back Pain Initiative recommends the assessment of pain, function, depression, somatic and autonomic perception, and spinal mobility based on a visual analogue pain

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scale, the OID, the Modified Zung Index, the Modified Somatic Perception Questionnaire (MSPQ) (13) and the Modified Schrober's Test for Spinal Mobility, respectively (14).

Guided apparently by practical considerations rather than a theoretical framework, both recommendations vary considerably regarding the domains to be considered and the recommended instruments. It would, thus, be valuable for teaching, clinical practice and research to define what should be measured to comprehensively represent the experience of patients based on an extensive framework that can serve as a universal language understood by health professionals, researchers, policymakers, patients and patient organizations alike.

With the approval of the new International Classification of Functioning, Disability and Health (ICF, formerly ICIDH-2 http:\\www.who.int\classification/icf) (15) we can now rely on a globally agreed framework and classification to define the typical spectrum of problems in functioning of patients with LBP. For practical purposes and in line with the concept of condition-specific health status measures it would thus seem most helpful to link specific conditions or diseases to salient ICF categories of functioning (16). Such generally-agreed-on lists of ICF categories can serve as Brief ICF Core Set to be rated in all patients included in a clinical study with LBP or as Comprehensive ICF Core Set to guide multidisciplinary assessments in patients with LBP. 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 ICF Core Sets for LBP, the Comprehensive ICF Core Set and the Brief ICF Core Set.

METHODS

The development of the ICF Core Sets for LBP involved a formal decision-making and consensus process integrating evidence gathered from preliminary studies including a Delphi exercise (17), a systematic review (18) and an empirical data collection, using the ICF checklist (19). 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.

Eighteen experts (14 with various physicians sub-specializations, 3 occupational therapists and 1 physical therapist) from 15 different countries attended the consensus process for LBP. The decision-making process for LBP involved 3 working groups, with 6 experts, respectively. The process was facilitated by the condition co-ordinator for LBP (RB) and the 3 working-group leaders (PD, WJ and SL).

The tables on the preliminary studies presented to the participants included 503 ICF categories at the second, third, and fourth levels (211 *body functions*, 47 *body structures*, 190 *activities and participation*, 55 *environmental factors*).

RESULTS

Tables I–IV show the second-level ICF categories included in the Comprehensive ICF Core Set. Table V shows the second-level ICF categories included in the Brief ICF Core Set, as well as the rank order by component allotted to the selected ICF categories. The total number of categories in the Comprehensive ICF Core Set is 79, and the total number of categories included in the Brief ICF Core Set is 35. No categories at the third and fourth levels were included in the Comprehensive ICF Core Set or in the Brief ICF Core Set.

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

ICF code	ICF category title
b126	Temperament and personality functions
b130	Energy and drive functions
b134	Sleep functions
b152	Emotional functions
b180	Experience of self and time functions
b260	Proprioceptive function
b280	Sensation of pain
b455	Exercise tolerance functions
b620	Urination functions
b640	Sexual functions
b710	Mobility of joint functions
b715	Stability of joint functions
b720	Mobility of bone functions
b730	Muscle power functions
b735	Muscle tone functions
b740	Muscle endurance functions
b750	Motor reflex functions
b770	Gait pattern functions
b780	Sensations related to muscles and movement functions

The 78 categories of the Comprehensive ICF Core Set consist of 19 (24%) categories from the component *body functions*, 5 (6%) from the component *body structures*, 29 (37%) from the component *activities and participation* and 25 (33%) from the component *environmental factors*.

The 19 categories of the component *body functions* represent 13% of the total number of ICF categories at the second level in this component. Most of the *body-functions* categories belong to chapter 7 *neuromusculoskeletal and movement-related functions* (9 categories). Chapter 1 *mental functions* is represented by 5 categories, chapter 2 *sensory functions and pain* as well as chapter 6 *genitourinary and reproductive functions* by 2 categories, and chapter 4 *functions of the cardiovascular, haematological, immunological and respiratory systems* by one category.

The 5 categories of the component *body structures* represent 9% of the total number of ICF categories at the second level in this component. Four *body-structures* categories belong to chapter 7 *structures related to movement* and one to chapter 1 *structures of the nervous system*.

The 29 categories of the component *activities and participation* represent 25% of the total number of ICF categories

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

ICF code	ICF category title
s120	Spinal cord and related structures
s740	Structure of pelvic region
s750	Structure of lower extremity
s760	Structure of trunk
s770	Additional musculoskeletal structures related to movement

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 low back pain*

ICF code	ICF category title
d240	Handling stress and other psychological demands
d410	Changing basic body position
d415	Maintaining a body position
d420	Transferring oneself
d430	Lifting and carrying objects
d445	Hand and arm use
d450	Walking
d455	Moving around
d460	Moving around in different locations
d465	Moving around using equipment
d470	Using transportation
d475	Driving
d510	Washing oneself
d530	Toileting
d540	Dressing
d570	Looking after one's health
d620	Acquisition of goods and services
d630	Preparing meals
d640	Doing housework
d650	Caring for household objects
d660	Assisting others
d710	Basic interpersonal interactions
d760	Family relationships
d770	Intimate relationships
d845	Acquiring, keeping and terminating a job
d850	Remunerative employment
d859	Work and employment, other specified and unspecified
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 low back pain*

ICF code	ICF category title
e110	Products or substances for personal consumption
e120	Products and technology for personal indoor and outdoor mobility and transportation
e135	Products and technology for employment
e150	Design, construction and building products and technology of buildings for public use
e155	Design, construction and building products and technology of buildings for private use
e225	Climate
e255	Vibration
e310	Immediate family
e325	Acquaintances, peers, colleagues, neighbours and community members
e330	People in positions of authority
e355	Health professionals
e360	Other professionals
e410	Individual attitudes of immediate family members
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours and community members
e450	Individual attitudes of health professionals
e455	Individual attitudes of other professionals
e460	Societal attitudes
e465	Social norms, practices and ideologies
e540	Transportation services, systems and policies
e550	Legal services, systems and policies
e570	Social security services, systems and policies
e575	General social support services, systems and policies
e580	Health services, systems and policies
e585	Education and training services, systems and policies
e590	Labour and employment services, systems and policies

at the second level in this component. Most of the *activities and participation* categories belong to chapter 4 *mobility* (11 categories). Chapter 6 *domestic life* is represented by 5 categories, chapter 5 *self care* by 4 categories, chapter 7 *interpersonal interactions and relationships* as well as chapter 8 *major life areas* by 3 categories, chapter 9 *community, social and civic life* by 2 categories and chapter 2 *general tasks and demands* by one category.

The 26 categories of the component *environmental factors* represent 35% of the total number of ICF categories at the second level in this component. Most of the *environmental-factors* categories belong to chapter 5 *services, systems and policies* (8 categories). However, all 5 chapters of this component are represented in the Comprehensive ICF Core Set. Chapter 4 *attitudes* is represented by 6 categories, chapter 1 *products and technology* as well as chapter 3 *support and relationships* by 5 categories, and chapter 2 *natural environment and human-made changes to the environment* by 2 categories.

With respect to the Comprehensive ICF Core Set, the Brief ICF Core Set includes 10 (53%) categories from the component *body functions*, 3 (60%) from *body structures*, 12 (41%) from *activities and participation* and 10 (38%) from *environmental factors*.

The 10 categories of the component *body functions* represent 7%, the 3 categories of the component *body structures* 5%, the 12 categories of the component *activities and participation* 10% and the 10 categories of the component *environmental factors* 14% of the total number of ICF categories at the second level in their respective components.

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.

One of the main challenges during the development of the ICF Core Sets for LBP was comprehensively to cover the wide spectrum of problems in functioning of patients with LBP without shifting attention to risk factors or predictors. The 79 categories included in the Comprehensive ICF Core Set cover not only aspects directly related to pain but also a wide spectrum of activities, social and environmental factors. This is neither a surprising nor a new insight, yet research until now has always focussed on specific viewpoints and thus specific outcome measures, thereby ignoring to some extent the overall breadth of the problem (20–22).

Although the participants were provided with the option to define the categories not only on the second, but possibly also on the third or fourth levels of the classification, after thorough discussion it was decided to keep the definition on the second

Table V. *International Classification of Functioning, Disability and Health (ICF) – categories included in the Brief ICF Core Set for low back pain. The categories per component are listed according to the conceded rank order*

ICF component	Rank order	ICF Code	ICF category title
Body functions	1	b280	Sensation of pain
	2	b152	Emotional functions
	3	b730	Muscle power functions
	4	b710	Mobility of joint functions
	5	b455	Exercise tolerance functions
	6	b134	Sleep functions
	7	b740	Muscle endurance functions
	8	b735	Muscle tone functions
	9	b715	Stability of joint functions
	10	b130	Energy and drive functions
Body structures	1	s120	Spinal cord and related structures
	2	s760	Structure of trunk
	3	s770	Additional musculoskeletal structures related to movement
Activities and participation	1	d415	Maintaining a body position
	2	d430	Lifting and carrying objects
	3	d410	Changing basic body position
	4	d450	Walking
	5	d850	Remunerative employment
	6	d859	Work and employment, other specified and unspecified
	7	d640	Doing housework
	8	d540	Dressing
	9	d240	Handling stress and other psychological demands
	10	d760	Family relationships
	11	d530	Toileting
	12	d845	Acquiring, keeping and terminating a job
Environmental factors	1	e580	Health services, systems and policies
	2	e570	Social security services, systems and policies
	3	e355	Health professionals
	4	e450	Individual attitudes of health professionals
	5	e410	Individual attitudes of immediate family members
	6	e135	Products and technology for employment
	7	e110	Products or substances for personal consumption
	8	e310	Immediate family
	9	e155	Design, construction and building products and technology of buildings for private use
	10	e550	Legal services, systems and policies

level. This may facilitate the application of the ICF Core Sets in practice as the number of categories keeps within reasonable limits.

Consistent with the main *body functions* affected in LBP, *neuromusculoskeletal- and movement-related functions* are broadly covered in the Comprehensive ICF Core Set. Other *body functions* included in the Comprehensive ICF Core Set, such as *sleep* and *energy and drive functions*, represent also key issues associated to LBP (23, 24).

The inclusion of *mental functions* including *emotional functions*, *temperament* and *personality functions*, and *experience of self* and time functions is consistent with the association between psychological factors and LBP that have been found in various cross-sectional studies (25). These factors include anxiety, depression, somatization symptoms, stressful responsibility, job dissatisfaction, mental stress at work, negative body image, weakness in ego functioning and poor drive satisfaction (26). Especially depressive mood and somatization have been found to play a crucial role in the transition from acute episode to chronic LBP (27). However, the *body function* b1602 *content of thought* which includes in its definition somatization is not included in the Comprehensive ICF Core Set and will be a point for discussion when deciding on the final version of the Brief ICF Core Set.

It is not surprising that at the level of the *body structures*, *structures related to movement* and the *spinal cord* are included. Experimental studies suggest that LBP may originate from many spinal structures, including ligaments, facet joints, the vertebral periosteum, the paravertebral musculature and fascia, blood vessels, the anulus fibrosus and spinal nerve roots. Other common problems include spinal stenosis and disk herniation (28).

Limitations and restrictions in *activities and participation* may indeed be most relevant to patients with LBP. This is reflected by the fact that this component is represented by 29 categories, as compared with the 19 *body functions* considered relevant. The areas covered represent central functional domains of patients with LBP, including *mobility* and *self care* (29).

Personal interactions and relationships as well as *community life* and *recreation and leisure* were also considered relevant to

be included in a comprehensive multidisciplinary assessment by the LBP expert group. In the literature these areas have also been investigated in relation to LBP (30).

Three *activities and participation* categories referring to *work and employment* have also been included in the Comprehensive ICF Core Set. This is in line with the fact that LBP carries a high economic burden (31) being the most common cause of work-related disability in people under 45 years of age and the most expensive cause of work-related disability, in terms of workers compensation and medical expenses (26).

The broad representation of the component *environmental factors* is remarkable. The chapter *services, systems and policies* which had the highest number of categories included was discussed at length because of the important inter-country differences. For example it was argued that in countries where compensation systems cover for LBP limitations and restrictions in work and employment are more frequent as being reported in the literature (2). Acknowledging the importance of education and training programs in the management of LBP, *education and training services*, *systems and policies* was included in the Comprehensive ICF Core Set. In line with our current understanding of functioning and health (32–34) and predictors of disability in patients with LBP (35), *products and technology*, *support and relationships*, *attitudes of significant others*, and *health professionals* were included in the Comprehensive ICF Core Set. The possible influence of factors of the natural environment is reflected by the inclusion of the categories *climate* and *vibration*. The category e110 *products or substances for personal consumption*, which includes drugs in its definition, addresses the importance of pharmacological therapy.

Remarkably, the selection of categories for the Brief ICF Core Set does not result in a bandwidth compression, i.e. the Brief ICF Core Set still contains most of the chapters represented in the Comprehensive ICF Core Set.

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 was based on a rigorous international development process. However, the wording and/or phrasing of the ICF classification sometimes led to prolonged discussions in the working groups, indicating the need for manuals and operationalizations.

The organizers of the consensus process took much care in the selection of the experts and were successful in recruiting 18 experts with different professional backgrounds from 8 different countries. Nevertheless, 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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