

ICF CORE SETS FOR OSTEOARTHRITIS

Karsten Dreinhöfer,¹ Gerold Stucki,^{2,3} Thomas Ewert,² Erika Huber,⁵
Gerold Ebenbichler,⁶ Christoph Gutenbrunner,⁷ Nenad Kostanjsek⁴ and Alarcos Cieza³

From the ¹Department of Orthopaedic Surgery, Rehabilitationsklinik, Ulm University, ²Department of Physical Medicine and Rehabilitation, Ludwig-Maximilians-University, Munich, ³ICF Research Branch, WHO FIC Collaborating Center (DIMDI), IMBK, Ludwig-Maximilians-University, Munich, Germany, ⁴Classification, Assessment, Surveys and Terminology Team, World Health Organization, Geneva, ⁵Swiss Association of Physical Therapy, Sursee, Switzerland, ⁶Department of Physical Medicine and Rehabilitation, University of Vienna, Austria ⁷Department of Physical Medicine and Rehabilitation, Medical School Hannover, Germany

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 osteoarthritis.

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 388 ICF categories at the second, third, and fourth ICF levels with 144 categories on *body functions*, 49 on *body structures*; 165 on *activities and participation*, and 43 on *environmental factors*. Seventeen experts from 7 different countries attended the consensus conference on osteoarthritis. Altogether 55 second-level categories were included in the Comprehensive ICF Core Set with 13 categories from the component *body functions*, 6 from *body structures*, 19 from *activities and participation*, and 17 from *environmental factors*. The Brief ICF Core Set included a total of 13 second-level categories (3 on *body functions*, 3 on *body structures*, 3 on *activities and participation*, and 4 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 osteoarthritis. Both the Comprehensive ICF Core Set and the Brief ICF Core Set were defined.

Key words: osteoarthritis, musculoskeletal diseases, outcome assessment, quality of life, ICF.

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*Correspondence address: Gerold Stucki, Department of Physical Medicine and Rehabilitation, University of Munich, DE-81377 Munich, Germany.
Tel: +49 89 7095 4050. Fax: +49 89 7095 8836.
E-mail: gerold.stucki@med.uni-muenchen.de*

INTRODUCTION

Osteoarthritis (OA) is amongst the 3 most disabling conditions having a remarkable public health impact of 4.68×10^6 disability adjusted life years (DALYs) in the developed countries in 1990 (1). In 2001, the prevalence of self-reported arthritis or chronic joint symptoms among US adults was 33%, of physician-diagnosed arthritis 22.4% (2). Because of its high prevalence in the increasing population of elderly people an increase up to 5.6×10^6 DALYs is estimated under the present conditions for 2020 (3). Direct and indirect costs for OA of the knee and hip in the US in 1994 were 12.9 billion US dollars (4).

OA can occur in all joints, but most frequently in the interphalangeal joints, the knee and hip joints. Relatively little is known of the natural history of OA. The disease progress might remain static for a period of time or progress rapidly. A variety of symptomatic conservative therapies are available for OA, including drugs and physical therapy, but they only achieve modest improvements in pain and other further limitations in functioning. In advanced disease, surgery is the only effective intervention and especially total hip and knee replacement has shown its ability to restore function and quality of life (5).

Research and clinical management of patients with OA relies on the sound measurement of pain and functional limitations. The OMERACT (Outcome Measures in Rheumatology Clinical Trials) group has recommended 4 domains to be evaluated: pain, physical function, joint imaging, and patient global assessment (6).

Previous studies showed that hip joint space narrowing was most predictive of hip pain. Progression of hip OA could be defined by a change in joint space narrowing, and narrowing correlated with changes in clinical status (7). There is, however, discordance between radiographs and reports on pain (8). Ten percent of patients with normal radiographs report pain, while only 40–70% of those with advanced radiographic abnormalities complain about pain (9).

Therefore, the OMERACT group advised to always include the domains pain and physical function in phase-III clinical trials and described stiffness as an important optional domain (6). The OMERACT and the 5th WHO/ILAR Task Force (World Health Organisation/International League Against Rheumatism) (10, 11) recommended the use of condition-specific health-status

measures including the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (12) and the Lequesne-Algo-functional Index (13) to measure these domains in clinical research and practice. In the measurement of outcomes in OA it is desirable to include both a generic instrument and a condition-specific instrument (14, 15). These generic health status instruments (SF-36, EQ5D, NHP, MFA) assess domains relevant to patients with OA including dimensions of social function, emotional function, role function, pain and physical function.

Condition-specific measures typically cover only selected aspects of the entire patient experience associated with OA. These measures also vary in the concepts included (2, 16). However, the patient experience of functioning and health goes beyond pain, stiffness and functional limitation with a focus on physical function. Also in contrast to the OMERACT perspective, which focuses on functioning and health as an outcome of the disease process to be evaluated in phase-III trials, functioning and health is not merely an outcome, but the starting point for assessing functioning and health of patients, e.g. in the context of rehabilitation.

With the approval of the new International Classification of Functioning, Disability and Health (ICF, formerly ICIDH-2 <http://www.who.int/classification/icf>) (17, 18) we can now rely on a globally agreed framework and classification to define the typical spectrum of problems in functioning of patients with OA. 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 (19). 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 OA or as Comprehensive ICF Core Set to guide multidisciplinary assessments in patients with OA. 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 OA, the Comprehensive ICF Core Set and the Brief ICF Core Set.

METHODS

The development of the ICF Core Sets for OA involved a formal decision-making and consensus process integrating evidence gathered from preliminary studies including a Delphi exercise (20), a systematic review (21) and an empirical data collection, using the ICF checklist (22). 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.

Seventeen experts from 7 different countries attended the consensus process for OA. The professional background of the experts (13 physicians with various sub-specializations and 4 physical therapists) covered the wide spectrum of limitations in functioning that occurs in patients with OA. The decision-making process for OA involved 3 working groups with 5–6 experts each. The process was facilitated by the condition co-ordinator for OA (KD) and the 3 working-group leaders (EH, GE, CG).

The tables on the preliminary studies presented to the participants included 388 (144 on *body functions*, 49 on *body structures*, 165 on *activities and participation*, and 43 on *environmental factors*) ICF categories at the second, third, and fourth levels.

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

ICF code	ICF category title
b130	Energy and drive functions
b134	Sleep functions
b152	Emotional functions
b280	Sensation of pain
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
b760	Control of voluntary movement functions
b770	Gait pattern functions
b780	Sensations related to muscles and movement functions

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 55 and the total number of categories included in the Brief ICF Core Set is 13. No categories at the third and fourth levels were included in the Comprehensive ICF Core Set or in the Brief ICF Core Set. Table VI summarizes the number and percentage of selected categories on the second level in the Comprehensive ICF Core Set and the Brief ICF Core Set.

Comprehensive ICF Core Set

The 55 categories of the Comprehensive ICF Core Set are made up of 13 categories from the component *body functions*, 6 from the component *body structures*, 19 from the component *activities and participation*, and 17 from the component *environmental factors*.

The 13 categories of the component *body functions* represent 11% 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 3 categories, and chapter 2 *sensory functions and pain* by 1 category.

Table II. *International Classification of Functioning, Disability and Health (ICF)-categories of the component body structures included in the Comprehensive ICF Core Set for osteoarthritis*

ICF code	ICF category title
s720	Structure of shoulder region
s730	Structure of upper extremity
s740	Structure of pelvic region
s750	Structure of lower extremity
s770	Additional musculoskeletal structures related to movement
s799	Structures related to movement, unspecified

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 osteoarthritis*

ICF code	ICF category title
d410	Changing basic body position
d415	Maintaining a body position
d430	Lifting and carrying objects
d440	Fine hand use
d445	Hand and arm use
d450	Walking
d455	Moving around
d470	Using transportation
d475	Driving
d510	Washing oneself
d530	Toileting
d540	Dressing
d620	Acquisition of goods and services
d640	Doing housework
d660	Assisting others
d770	Intimate relationships
d850	Remunerative employment
d910	Community Life
d920	Recreation and leisure

The 6 categories of the component *body structures* represent 11% of the total number of ICF categories at the second level in this component. All of them belong to chapter 7 *structures related to movement*.

The 19 categories of the component *activities and participation* represent 16% 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* (9 categories). Chapter 5 *self care* as well as chapter 6 *domestic life* are represented by 3 categories, chapter 9 *community, social and civic life* by 2 categories, chapter 7 *interpersonal interactions and relationships*, and chapter 8 *major life areas* by 1 category, respectively.

All 5 chapters of the component *environmental factors* are represented in the Comprehensive ICF Core Set for OA. The 17 categories represent 23% of the total number of ICF categories at the second level in this component. Most of the *environmental-factors* categories belong to chapter 1 *products and technology* (6 categories) and chapter 3 *support and relationships* (4 categories). Chapter 4 *attitudes* and chapter 5 *services, systems and policies* are represented by 3 categories, respectively. Chapter 2 *natural environment and human-made changes to environment* is represented by the category e225 *climate*.

Brief ICF Core Set

The Brief ICF Core Set includes a total of 13 second-level categories representing 23% of all categories that were chosen for the Comprehensive ICF Core Set. Three categories from the component *body functions* were selected, representing 21% of the Comprehensive ICF Core Set, in addition 3 (50%) from *body structures*, 3 (16%) from *activities and participation*, and 4 (24%) from *environmental factors*.

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

ICF code	ICF category title
e110	Products or substances for personal consumption
e115	Products and technology for personal use in daily living
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
e310	Immediate family
e320	Friends
e340	Personal care providers and personal assistants
e355	Health professionals
e410	Individual attitudes of immediate family members
e450	Individual attitudes of health professionals
e460	Societal attitudes
e540	Transportation services, systems and policies
e575	General social support services, systems and policies
e580	Health services, systems and policies

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 challenge during the experts' discussion and consensus process was to comprehensively cover the wide spectrum of OA-related functional limitations, body structure changes, activity limitations, and participation restrictions. During the selection process of the categories, the experts were strongly encouraged to identify additional ICF categories of importance not provided in the data from the preliminary studies. Another challenge was to focus on the diagnosis OA and not to pay attention to the related co-morbidities and complications under consideration at all possible stages during the disease.

In the consensus process the varying spectrum of limitations in functioning in OA was addressed. In the early stage of the condition the burden may be limited to minor and only sporadic symptoms. In the later stages patients may experience a wide spectrum of functional impairments, activity limitations, and participation restrictions in addition to now often more severe symptoms. Since ICF Core Sets need to capture the experience of all patients with OA independent of the stage, the joint involved or age, the participants included all categories that were considered relevant for patients with OA at some point. This will allow us to follow patients over time and to detect changes in the pattern of problems over time.

If patients are scheduled for hip or knee replacement surgery the disease is already in a late stage. At that time nearly all patients suffer from pain. More than two-third have severe

Table V. International Classification of Functioning, Disability and Health (ICF)-categories included in the Brief ICF Core Set for osteoarthritis. 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	b710	Mobility of joint functions
	3	b730	Muscle power functions
Body structures	1	s750	Structure of lower extremity
	2	s730	Structure of upper extremity
	3	s770	Additional musculoskeletal structures related to movement
Activities and participation	1	d450	Walking
	2	d540	Dressing
	4	d445	Hand and arm use
Environmental factors	1	e310	Immediate family
	2	e115	Products and technology for personal use in daily living
	4	e580	Health services, systems and policies
	5	e150	Design, construction and building products and technology of buildings for public use

Table VI. Number of relevant International Classification of Functioning, Disability and Health (ICF)-categories on the second level for osteoarthritis in the Comprehensive ICF Core Set and the Brief ICF Core Set and percentage of the overall ICF categories

Components	Second level ICF categories	Comprehensive ICF Core Set	Brief ICF Core Set
Body functions	114	13 (11%)	3 (3%)
Body structures	56	6 (11%)	3 (5%)
Activities and participation	118	19 (16%)	3 (3%)
Environmental factors	74	17 (23%)	4 (5%)
Total	362	55	13

pain when walking. Many patients in this advanced stage report pain at night (23), 1 out of 3 arthritis patients suffers from sleep disturbances (24). Half of the patients have walked in the past 2 weeks less than 1 block, every fourth is only walking in the room. Every second patient needs assistance with walking, about one-third needs assistance with housework or shopping (23). In addition, depression is common in persons with OA (25). All these aspects are represented in the Comprehensive ICF Core Set. In the Brief ICF Core Set *sensation of pain* and *walking* but not *emotional functions*, *sleep*, *doing housework*, and *acquisition of goods and services* are included. Also, according to 1 study, patients may have a high preference regarding the importance of certain problems. For example, public transportation, unequal limb length, concerns about falling, the need to use walking aids, and difficulty with recreational activities may be as important as the problems mentioned above (26). Again, these aspects are represented in the Comprehensive ICF Core Set but not in the Brief ICF Core Set. Two main concerns, concerns about falling and the loss of independence, are only represented indirectly by categories reflecting limitations in *moving around*, *using transportation* and the *environmental factors*, *personal care providers* and *personal assistants*,

individual attitudes of immediate family members, *individual attitudes of health professionals*, and *societal attitudes*. This clearly indicates the need to use the Comprehensive ICF Core Set in the assessment and follow-up of patients considering or undergoing joint replacement surgery.

As could be expected for a musculoskeletal condition, *neuromusculoskeletal- and movement-related functions* are covered in great depth at the *body-functions* level. This is reflected by the fact that 9 of the 11 top-ranked categories in this component belong to chapter 7 *neuromusculoskeletal and movement-related functions*. Consistent with the results of the Delphi (20) and the checklist study (22), *sensation of pain*, *mobility of joint functions*, and *muscle power functions* were considered the most important categories and were included in the Brief ICF Core Set.

Consistent with the definition of OA and their task to focus on the disease and not on the co-morbidity, the experts selected at the *body-structures* level only categories belonging to *structures related to movement*. All second-level categories of this domain, except 2 related to the vertebra, were selected for the comprehensive assessment. Since degenerative, changes in OA also occur in the spine, some experts opted for including *structures of head and neck region* and *structure of trunk*. However, it was decided to limit the definition of OA to joints of the extremities.

Limitations and restrictions in *activity and participation* may indeed be most relevant to patients with OA. This is reflected by the fact that this component is represented by 19 categories, as compared with the 13 *body functions* considered relevant. The areas that are covered represent key issues for patients with OA, including 9 categories of the domain *mobility*. These comprise active changes of body position, but also *using transportation and driving*. Beside the commonly reflected activities such as *lifting and carrying objects*, *walking*, *doing housework* and *self-care (washing oneself, toileting, dressing)*, *recreation and leisure*, *intimate relationships* and *remunerative employment*

were included. While these last categories have not been addressed in most of the prior assessments, they are of great importance at least for a subgroup of patients (27). Three of the 5 highest ranked categories in the Comprehensive ICF Core Set belong to the domain *self-care*. However, the experts decided to include only 1 of these in the Brief ICF Core Set, and so they selected *hand and arm use* since this category is necessary for most of *self-care* and *domestic life-activities*.

It is significant that 17 categories representing 31% of the categories of the Comprehensive ICF Core Set belong to the component *environmental factors*. *Products and technology* as well as *support and relationships* and *attitudes* are highly important to patients with OA because they can serve as either a barrier or a facilitator. While *products and technology for personal use in daily living* (walking aids, etc.) are seen as the latter, *design, construction and building products and technology of buildings for public use* often impress as the former; *immediate family, friends, and societal attitudes* can also be either. Cultural differences will have a serious impact on the applicability of some of the individual categories in different countries. The wide variety in total hip replacement rates, even in OECD countries (28), reflects the different *health services, systems and policies*. However, as the developing world will account for a huge amount of the expected increase in OA prevalence globally, activities for improvement of OA-related health services in the individual countries are disparately required.

While the category *health professionals* obtained rank 3, it was still not included in the Brief ICF Core Set. The experts discussed the greater importance of the *health services, systems and policies* as compared with the individual *health professional*. In addition, the importance of *products and technology* as well as *support and relationships* was expressed by the selection.

The breadth of ICF chapters contained in the Comprehensive ICF Core Set reflects the important and complex impairments, limitations and restrictions of *activity and participation* involved, as well as the numerous interactions with *environmental factors*. 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, it was decided to keep the definition on the second level. This allowed us to limit the ICF Core Sets to a certain number. However, the need for further specification of some second-level categories at least for subsets of patients may be necessary. Also, the ICF may not represent into enough detail some aspects of *body functions* considered relevant in OA. For example, problems in muscle activation, in muscle co-ordination, and automatic muscle responses are not adequately represented, e.g. *muscle power functions*. Similarly, a differentiation of pain to specifically address pain at night instead of referring to *pain* and *sleep functions* to represent this problem would be useful. It is important to note that the ICF does not generally address the issue of time (e.g. rest pain, night pain, pain with activity, etc.). The time perspective needs to be addressed in the measurement of a specific category such as pain.

One limitation of this study is the representation of the experts. The results of any consensus process may differ with different groups of experts. Since most members of the panels live in the Western world, some cultural aspects might have been overlooked or might be under-represented in the ICF Core Sets. As an example, OA of the hip and knee might severely affect the ability to participate in religious ceremonies in some parts of the world. However, the experts did not prioritise this category. This emphasizes the importance of the extensive validation of this first version of the ICF Core Sets from the perspective of different professions and in different countries. The first version of the ICF Core Sets will also be tested in the view of patients 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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