

ICF CORE SETS FOR OSTEOPOROSIS

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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 International Classification of Functioning, Disability and Health (ICF) Core Set and a Brief ICF Core Set for osteoporosis.

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 239 ICF categories at the second, third and fourth ICF levels with 72 categories on *body functions*, 41 on *body structures*, 81 on *activities and participation*, and 45 on *environmental factors*. Fifteen experts from 7 different countries attended the consensus conference on osteoporosis. Altogether 67 second-level and 2 third-level categories were included in the Comprehensive ICF Core Set with 15 categories from the component *body functions*, 7 from *body structures*, 21 from *activities and participation*, and 26 from *environmental factors*. The Brief ICF Core Set included a total of 22 second-level categories with 5 on *body functions*, 4 on *body structures*, 6 on *activities and participation*, and 7 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 osteoporosis. Both the Comprehensive ICF Core Set and the Brief ICF Core Set were defined.

Key words: osteoporosis, outcome assessment, quality of life, ICF.

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INTRODUCTION

Osteoporosis (OP) is a disease characterized by low bone mass and microarchitectural deterioration in bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk (1, 2). The diagnosis of OP is based on the bone mineral density (1). Clinically, osteoporosis is recognized by the occurrence of fractures (3). Hip fracture, forearm fracture, and vertebral fractures are the most common, whereas hip fracture is considered the most serious outcome of OP (4). The number of hip fractures is increasing throughout the world, and the projected number for 2050 is 6.3 million worldwide (5). Currently, the majority of hip fractures occur in North America and Europe, but demographic shifts over the next 50 years will lead to a relocation in the burden of disease from the developed to the developing world. Some 75% of hip fractures are expected to occur in the developing world by the year 2050 (6). OP and associated fractures have therefore become a major public health concern, not only in Western Europe and North America, but globally (7).

There may be little or no impact in the pre-fracture stage, apart from that associated with any predisposing condition (8). However, osteoporotic fractures cause significant morbidity, disability, and decrease in quality of life, as well as leading to long-term limitations in functioning (4, 6, 7).

Based on the health domains covered by available generic health-status measures and a qualitative review of the literature, a number of health domains of importance in patients with OP have been suggested in the recent World Health Organisation (WHO) Technical Report on the burden of musculoskeletal conditions (8). The domains include physical health, social health, mental health and handicap/participation. In addition, the WHO Technical Report mentions a number of sub-domains with different levels of importance, such as pain, mobility, self care, activities/roles and need for support, as well as anxiety/depression and loss of self-esteem.

Based on the new International Classification of Functioning, Disability and Health (ICF, formerly ICIDH-2 <http://www.who.int/classification/icf>) (9), it is now possible to define the typical spectrum of problems in functioning of patients with OP under consideration of influential environmental factors in a more systematic way using a globally agreed-upon language

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

ICF code		ICF category title
2nd	3rd	
b134		Sleep functions
b152		Emotional functions
	b1801	Body image
b280		Sensation of pain
b440		Respiration functions
b455		Exercise tolerance functions
b545		Water, mineral and electrolyte balance functions
	b6202	Urinary continence
b710		Mobility of joint functions
b730		Muscle power functions
b740		Muscle endurance functions
b755		Involuntary movement reaction functions
b765		Involuntary movement functions
b770		Gait pattern functions
b780		Sensations related to muscles and movement functions

of functioning and health. Additionally, based on the operational definitions of health and health-related categories provided by the ICF, it is possible to define what is specifically meant and what should be universally understood by each of these categories. The hierarchical structure of the ICF also provides an unambiguous definition of the level of precision with which the health and health-related categories are defined. Thus, the breadth and depth of content covered by each category is explicitly provided.

It would be most helpful to determine the most relevant ICF categories in patients with OP. Such a generally-agreed-upon list of ICF categories can serve as Brief ICF Core Sets to be rated in all patients included in a clinical study with OP or as Comprehensive ICF Core Sets to guide multidisciplinary assessments in patients with OP. 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 OP, the Comprehensive ICF Core Set and the Brief ICF Core Set.

METHODS

The development of the ICF Core Sets for OP involved a formal decision-making and consensus process integrating evidence gathered from preliminary studies including a Delphi exercise (10), a systematic review (11), and an empirical data collection, using the ICF checklist (12). 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.

Fifteen experts (10 physicians with various sub-specializations and 5 physical therapists) from 7 different countries attended the consensus process for OP. The decision-making process for OP involved 3 working groups with 5 experts each. The process was facilitated by the condition co-ordinator for OP (NW) and the 3 working-group leaders (JM, TS, AW).

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

ICF code	ICF category title
s430	Structure of respiratory system
s720	Structure of shoulder region
s730	Structure of upper extremity
s740	Structure of pelvic region
s750	Structure of lower extremity
s760	Structure of trunk
s770	Additional musculoskeletal structures related to movement

RESULTS

The tables on the pre-conference studies (10–12) presented to the participants included 239 ICF categories at the second, third, and, fourth levels (72 on *body functions*, 41 on *body structures*, 81 on *activities and participation*, and 45 on *environmental factors*).

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

The number of second- and third-level categories in the Comprehensive ICF Core Set is 69, with 67 categories on the second level and 2 categories on the third level. The total number of second-level categories included in the Brief ICF Core Set is 22. No third-level category was selected for the Brief ICF Core Set.

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 osteoporosis*

ICF code	ICF category title
d410	Changing basic body position
d415	Maintaining a body position
d430	Lifting and carrying objects
d445	Hand and arm use
d450	Walking
d455	Moving around
d465	Moving around using equipment
d470	Using transportation
d475	Driving
d510	Washing oneself
d540	Dressing
d620	Acquisition of goods and services
d630	Preparing meals
d640	Doing housework
d710	Basic interpersonal interactions
d770	Intimate relationships
d850	Remunerative employment
d855	Non-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 osteoporosis*

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
e240	Light
e310	Immediate family
e320	Friends
e325	Acquaintances, peers, colleagues, neighbours and community members
e340	Personal care providers and personal assistants
e355	Health professionals
e360	Health-related professionals
e410	Individual attitudes of immediate family members
e420	Individual attitudes of friends
e430	Individual attitudes of people in positions of authority
e440	Individual attitudes of personal care providers and personal assistants
e450	Individual attitudes of health professionals
e455	Individual attitudes of health related professionals
e460	Societal attitudes
e535	Communication services, systems and policies
e540	Transportation 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

Comprehensive ICF Core Set

The 69 categories of the Comprehensive ICF Core Set are made up of 15 (22%) categories from the component *body functions*, 7 (10%) from the component *body structures*, 21 (30%) from the component *activities and participation*, and 26 (38%) from the component *environmental factors*.

Thirteen of the 15 categories of the component *body functions* are at the second level and 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* (7 categories). Chapter 1 *mental functions* is represented by 2 categories at the second-level of the classification and by the third-level category b1801 *body image*, which is a specification of the second-level category b180 *experience of self and time functions*. Chapter 4 *functions of the cardiovascular, haematological, immunological and respiratory systems* is represented by 2 categories at the second level. Chapter 2 *sensory functions and pain* as well as chapter 5 *functions of the digestive, metabolic and endocrine systems* are each represented by one category. Chapter 6 *genitourinary and reproductive functions* is represented by the third-level category b6202 *urinary continence*, which is a specification of the second-level category b620 *urination functions*.

The 7 categories of the component *body structures* represent 13% of the total number of ICF categories at the second level in this component. With exception of the category s430 *structure of respiratory system* which belongs to chapter 4 *structures of the cardiovascular, immunological and respiratory systems*, all other 6 categories refer to chapter 7 *structures related to movement*.

Table V. *Brief ICF Core Set for osteoporosis and the percentage of experts willing to include the named category in the Brief ICF Core Set. 50% represent a preliminary cut-off. >50% is in bold typeface*

ICF component	%	ICF code	ICF category title
Body functions	100	b280	Sensation of Pain
	79	b730	Muscle power functions
	79	b710	Mobility of joint functions
	57	b152	Emotional functions
	14	b765	Involuntary movement functions
Body structures	100	s760	Structure of trunk
	79	s750	Structure of lower extremity
	21	s730	Structure of upper extremity
	14	s770	Additional musculoskeletal structures related to movement
Activities and participation	100	d450	Walking
	71	d430	Lifting and carrying objects
	71	d920	Recreation and leisure
	36	d410	Changing basic body position
	21	d640	Doing housework
	7	d470	Using transportation
Environmental factors	93	e580	Health services, systems and policies
	71	e110	Products or substances for personal consumption
	64	e355	Health professionals
	43	e310	Immediate family
	14	e155	Design, construction and building products and technology of buildings for private use
	7	e115	Products and technology for personal use in daily living
	7	e225	Climate

The 21 categories of the component *activities and participation* represent 18% of the total number of ICF categories at the second level in this component. Most of the categories belong to chapter 4 *mobility* (9 categories). Chapter 6 *domestic life* and chapter 8 *major life areas* are represented by 3 categories, respectively. Chapter 5 *self-care*, chapter 7 *interpersonal interactions and relationships*, and chapter 9 *community, social and civic life* are each represented by 2 categories.

The 26 categories of the component *environmental factors* represent 37% of the total number of ICF categories at the second level in this component. Most of the categories belong to chapter 4 *attitudes* (7 categories). Chapter 1 *products and technology* and chapter 3 *support and relationships* are represented by 6 categories, respectively. Chapter 5 *services, systems and policies* is represented by 5 categories and chapter 2 *natural environment and human-made changes to the environment* by 2 categories. All 5 chapters of this component are represented in the Comprehensive ICF Core Set.

Brief ICF Core Set

The Brief ICF Core Set includes a total of 22 second-level categories, which represents 6% of all second-level categories that were chosen in the Comprehensive ICF Core Set. Five categories were chosen from the component *body functions* (representing 38% of selected second-level categories in the Comprehensive ICF Core Set), 4 from *body structures* (representing 57% of selected second-level categories in the Comprehensive ICF Core Set), 6 from *activities and participation* (representing 29% of selected second-level categories in the Comprehensive ICF Core Set), and 7 from *environmental factors* (representing 9% of selected second-level categories in the Comprehensive ICF Core Set).

All ICF categories taken into account in the final decision process are presented in Table V. However, a preliminary cut-off was established at 50% to reflect majority opinion.

DISCUSSION

The formal consensus process integrating evidence from preliminary studies and expert knowledge at the first ICF Core Set Conference resulted in the definition of the Brief ICF Core Set and the Comprehensive ICF Core Set for multidisciplinary assessment.

One main challenge during the decision-making and consensus process was to focus on the diagnosis OP. Participants were instructed not to heed related co-morbidities and complications while considering all possible disease stages, with and without fracture, even in the absence of symptoms or pain at the onset of OP.

All ICF components are represented in both ICF Core Sets. This result underscores the need to widely address not only *body functions* and *body structures* and *activities and participation*, but also *environmental factors* when defining the limitation of abilities in patients with OP. Thus, the categories of the ICF Core Sets for OP go beyond the list of health-related domains

and sub-domains relevant to osteoporosis that were considered in the WHO Technical Report (8), in which only the subdomain “support” was considered as a possible part of the environment. All sub-domains considered relevant in the WHO Technical Report were included in the Comprehensive ICF Core Set. However, the Comprehensive ICF Core Set is more specific. For example, while “mobility” is a subdomain included in the list of relevant health domains in the WHO Technical Report, specific ICF categories, such as *walking, using transportation, and lifting and carrying objects* are included in the Comprehensive ICF Core Set. All above-mentioned categories belong to the chapter *mobility* within the ICF structure.

Within the ICF component *body functions, neuromusculoskeletal and movement-related functions* are broadly covered in the Comprehensive ICF Core Set. Some of these body functions were widely discussed. *Involuntary movement reaction functions* was selected, since the concepts of functions of postural, and balance reactions, as well as supporting and defensive reactions, are included in its definition. Changes in posture leading to alterations of the body’s centre of gravity, as well as problems of balance and co-ordination due to neuromuscular or vestibular impairment, for example, have to be regarded as major yet underestimated and undertreated complications in OP. They are among the leading causes of falls and fractures (13).

Since participants felt that reduced joint mobility seriously affects patients’ functioning (14), while diminished mobility of bone functions, such as the scapula, the pelvis, carpal and tarsal bones are of minor importance, *mobility of joint functions* and not *mobility of bone functions* was included in the Comprehensive ICF Core Set.

Other body functions included in the Comprehensive ICF Core Set, such as *sleep, emotional functions, and body image*, also represent key issues associated with OP (15). Pain with loss of physical function is the major outcome of any fracture (4, 16, 17). Thus, b280 *pain* was also included within the component *body functions*. Further body functions, such as *water, mineral and electrolyte balance functions, urinary continence, exercise tolerance, and body respiration functions* were also considered sufficiently relevant to be included in a multidisciplinary, comprehensive assessment.

Consistent with the main body structures affected in OP, all structures included in the Comprehensive ICF Core Set, with the exception of structures of the respiratory system, belong to the ICF chapter *structures related to movement*. The *structure of the respiratory system* was selected since the experts felt that changes in posture due to height loss and kyphosis in patients with OP not only influence respiratory function, but also lead to structural changes in the respiratory tract (15). The ICF category *additional musculoskeletal structures related to movement* was included in the Comprehensive ICF Core Set to cover bones, joints, tendons, muscles, and extra-articular ligaments in an unspecific way.

Limitations and restrictions in *activities and participation* are, indeed, of great relevance to patients with OP. The areas covered

represent central functional domains of patients with OP, including *mobility*, *self-care*, and *domestic life* (8). As pointed out by Cummings & Melton (4) based on further literature, limitations in the ability to walk is the most important long-term impairment following hip fracture. Furthermore, 1 year after the event, half of the women who had lived independently before their hip fractures remain in long-term care or need help with the activities of daily living. Not only fractures of the hip, but also fractures of the spine and the distal forearm cause 7% of women to become dependent in the basic activities of daily living and necessitate nursing-home care in a further 8% (18).

Further life areas, such as *employment*, *community life*, *recreation and leisure*, *basic interpersonal interactions*, and *intimate relationships* were also considered relevant and were selected for the Comprehensive ICF Core Set. These life areas are also contained, although with a different terminology, in the list of relevant health-related domains suggested in the WHO Technical Report on the burden of musculoskeletal conditions (8). Therefore, it is remarkable that the impact of OP in the above-named life areas has scarcely been reported in the literature. This may be due to the fact that the named areas are frequently included under the umbrella term Health-Related Quality of Life (HRQL), which has been increasingly studied in relation to OP during the last few years (19–24). Nevertheless, most investigative energy has been primarily spent on testing the psychometric properties of HRQL instruments. The identification of problematic areas in HRQL in patients with OP has received less attention (25).

The component *environmental factors* is represented by 26 ICF categories in the various ICF chapters, which proves the growing awareness of the important influence of patients' surroundings and life situations on their functioning and health. *Products and technology*, as well as *services, systems and policies, support and relationships*, and *attitudes*, are highly important to patients with OP because they can serve either as barriers or facilitators and may influence OP outcome.

The chapter *products and technology* includes matters such as assistive devices, means of transportation, or the features of buildings. These environmental factors evidently play a significant role for patients' functioning, whereas no study could be found showing associations between barriers in the physical environment, accessibility and technology on the one hand and limitations in functioning on the other hand. Medication (e110 *products or substances for personal consumption*) is also included in this chapter, which may influence OP patients' functioning as a barrier due to side-effects and/or as a facilitator by preventing fractures.

The possible influence of factors in the natural environment is reflected by the inclusion of the categories *climate*, which refers to all seasonal conditions encountered when leaving the house, and *light*, which includes day and electrical light. After an extensive discussion, the experts decided to include both categories in the Comprehensive ICF Core Set because they constitute important risk factors for falls in the elderly,

easily leading to fractures in patients with OP (26, 27). Especially during the discussion on *climate* and *light*, the importance of keeping the exact definition of ICF categories in mind during the consensus process became obvious. As soon as inclusion and exclusion criteria of each of these 2 categories were read aloud, participants agreed on their importance for OP.

The importance of the social environment (*social support and attitudes*) for patients' functioning has not been investigated in relation to OP. Nevertheless, its importance is widely accepted and recognized. The experts included 13 categories in the chapter *support and relationships and attitudes*. In the WHO Technical Report (8) support and interaction are also referred to as 2 health-related subdomains relevant to patients with OP.

With regard to the influence of *services, systems, and policies* on the functioning of patients with OP, there is little research. However, clinical experience clearly indicates a considerable impact of these environmental factors on OP outcomes. Thus, it is not surprising that the expert panel regarded the category e580 *health services, systems, and policies* among the most important environmental factor and also included it in the Brief ICF Core Set for OP.

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 in a reduction regarding the 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.

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 is 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 15 experts with different professional backgrounds from 7 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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