

The World Health Organisation International Classification of Functioning, Disability and Health: A Conceptual Model and Interface for the OMERACT Process

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ABSTRACT. “What to measure” refers to domains stable over time. “How to measure” is constantly evolving. Lacking a common terminology and common underlying conceptual model of functioning and disability, what and how to measure have been described differently in the various OMERACT Core Sets. With the approval of the International Classification of Functioning, Disability and Health (ICF) by the World Health Assembly in 2001, we now have a universally conceptual model that integrates the biomedical and societal model of functioning and disability. The so-called ICF Core Sets can be used as a basis for the further specification of OMERACT domains addressing aspects of functioning. In line with the successful approach taken by OMERACT, it is suggested to comprehensively specify the domain “function” when defining “what should be measured,” and only then to recommend how to measure or which health status measure to use. We recommend comparing the specifications of domains addressing aspects of functioning of OMERACT Core Sets already established with the ICF Core Sets, and examine whether the ICF Core Sets may be useful for the further specification of these domains. (J Rheumatol 2007;34:600–6)

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OMERACT started in 1992, under the designation, “Outcome Measures in Rheumatoid Arthritis Clinical Trials”¹. The initiative addressed the challenge of improving applicability of clinically relevant endpoints in rheumatoid arthritis (RA) clinical trials. Over the years, it has turned into an informal international network with working groups and gatherings of people interested in outcome measurement that define, through an iterative consensus approach, “what” should be measured and “how” this should be measured across the spectrum of rheumatology intervention and observational studies. OMERACT is led by an organizing committee with members from 3 continents, and is advised by a 15-member scientific advisory committee with international opinion leaders from 9 countries.

“What to measure” is an explicit statement about the outcome domains that patients and their physicians consider relevant. Unless health conditions change their clinical expression or epiphenomena, the domains are stable over time; e.g., the OMERACT domains “pain”^{1,2} and “fatigue”² are not only of concern now but will most likely remain a concern in the future. The same is true for specifications within a domain. For example, the domain “disability” in RA can be further specified by, for example, “fine hand use” and “hand and arm use,” “walking,” “lifting and carrying objects,” “changing

basic body position,” “carrying out daily routine,” “using transport,” and “remunerative employment”¹. Similar to the domain “disability,” these specifications are likely to remain relevant for patients and their healthcare providers in the future.

Different from “what to measure,” the way “how to measure” is constantly evolving. Over the years since OMERACT began, we have witnessed major developments in the fields of clinical and patient-oriented outcome instruments. For example, in RA, magnetic resonance imaging is a promising technique to measure the domains “damage” and/or “inflammation,” and several OMERACT meetings have addressed the application of these measurement techniques^{3,4}. Current developments in the area of patient-reported outcomes include application of item response theory^{5,6} and more efficient practical approaches including computer assisted technologies in the development of instruments⁷.

Any recommendation regarding a specific outcome instrument is likely to soon be outdated. It is a more straightforward strategy to first define “what should be measured,” and only then to recommend how to measure it or which outcome instrument to use. If enough care is taken to define “what should be measured,” it could form the basis for a solid and stable recommendation adhered to for many years. Based on the valid set of recommended domains to be measured, the best available measurement options can be tested and then recommended. This is indeed the approach that has been successfully applied by OMERACT.

Consensus on domains (“what to measure”) has been reached for 6 musculoskeletal conditions. They include RA¹, osteoarthritis (OA)⁸, osteoporosis⁹, ankylosing spondylitis², systemic lupus erythematosus (SLE)¹⁰, and systemic sclerosis¹¹. For some of these conditions, consensus on instruments (“how to measure”) has also been achieved. Ongoing initiatives include psoriatic arthritis, fibromyalgia, gout, and low back pain. In addition, a more generic core set was developed to define which measures need to be included when evaluating patient groups in longitudinal studies¹².

In this report we review first the general OMERACT process of selecting domains and instruments, and second, the current conceptualization and specification of OMERACT domains that address aspects of “functioning and disability.” We then examine how the International Classification of Functioning, Disability and Health (ICF)¹³ may enhance the conceptualization and specification of OMERACT domains by first providing a conceptual model and taxonomy, and second, by serving as an interface between OMERACT domains and candidate instruments.

Selecting domains and instruments

Selection of domains: “what to measure.” The selection of OMERACT domains for disease-specific OMERACT Core Sets was initially guided by the 5 D-domains, “discomfort,” “disability,” “dollar costs,” “drug adverse events,” and

“death”¹⁴. This framework was intended to cover all relevant aspects of a musculoskeletal condition, ranging from the disease process to participation in the community, including, for example, work productivity. Remarkably, these initially proposed 5 “D’s” seemed not to provide a generally applicable frame, and each group introduced their own list of relevant domains. Arguably with the exception of the OMERACT Core Set for longitudinal studies, no conceptual model for human functioning was used to guide the process of selecting domains¹².

Selection of instruments: “how to measure.” Candidate instruments suitable for the measurement of an OMERACT domain have to pass the so-called OMERACT filter that can be summarized with 3 words, “truth,” “discrimination,” and “feasibility”¹⁵. In the OMERACT process, methodological issues to appraise or develop new instruments are explored in depth by the OMERACT working groups. A research agenda on issues that need to be resolved in order to achieve consensus on domains and instruments has been formulated¹⁶.

Current conceptualization and specification of OMERACT domains addressing aspects of “functioning and disability”

At least one domain in all OMERACT Core Sets addresses aspects of “functioning and disability” as defined by the ICF¹³. Lacking a common terminology and lacking a common underlying conceptual model of functioning and disability, these domains have been described differently in the various OMERACT Core Sets. In RA the domain has been called “physical disability”¹, in ankylosing spondylitis “physical function”², in OA “physical functioning”⁸, in osteoporosis “quality of life”⁹, in SLE “health related quality of life”¹⁰, and in systemic sclerosis “function and health related quality of life”¹¹.

Accordingly, it is not obvious whether these domains address the same aspects of human functioning and disability. Also, the specifications characterizing these domains have not been explicitly defined. Implicitly, the specifications are defined by the items of an instrument recommended for the measurement of the respective domain. “What to measure” is therefore left to “how to measure.” This is done without taking into account that the different instruments proposed to measure the same OMERACT domain vary considerably regarding the aspects of functioning they cover¹⁷⁻²².

The ICF: a conceptual model for identification and conceptual description of OMERACT domains

With the approval of the ICF by the World Health Assembly (WHA) in 2001, we now have a universal conceptual model and classification of functioning and disability. According to WHO, the ICF serves as a conceptual model to describe the problems in human functioning associated to a health condition. The conceptual model of the ICF integrates the biomedical and societal model of human functioning and disability.

Figure 1 shows the ICF model. Based on this model, functioning, with its components “Body Functions and Structures” and “Activities and Participation,” is viewed in relation to the health condition under consideration, as well as personal and environmental factors. Functioning denotes the positive aspects, and disability, the negative aspects of the interaction between an individual with a health condition and the contextual factors (environmental and personal factors) of that individual. Thus, disability is an umbrella term for impairments, limitations in activities, and restrictions in participation. This distinction can help when reading the medical literature. Disability is usually the preferred term. However, from the bio-psycho-social perspective, functioning is implicitly addressed when disability is studied, and vice versa²³.

Prior to the ICF, there were 2 major conceptual frameworks in the field of disability: the International Classification of Impairment, Disability and Handicap (ICIDH-1)²⁴ and the “functional limitation” or Nagi framework²⁵. In contrast to the ICIDH, the Nagi framework was not accompanied by a classification.

The 2 frameworks received both positive and negative reviews and were compared extensively. They stimulated discussions of disability concepts and were used widely around the world. Building on the conceptual frameworks of the ICIDH and Nagi, the US Committee on a National Agenda for the Prevention of Disabilities developed a model emphasizing the interaction between the disabling process, quality of life, and individual risk factors²⁶. The “Disablement Process” proposed by Verbrugge and Jette²⁷ also represents an extension of those 2 models.

The ICF addresses many of the criticisms of prior conceptual frameworks and was developed in a worldwide comprehensive consensus process over many years. It is the first model and classification that has been officially approved by the WHA. All these reasons make it likely that the ICF will become the generally accepted conceptual framework to describe a person’s level of functioning and disability.

In the field of musculoskeletal conditions, the ICF has

already served as a framework and common metric for the assessment of severity and the course of the condition [pages 52–54] and for health and economic indicators and for outcome measurement [pages 71–74] in the WHO Technical Report, “The Burden of Musculoskeletal Conditions at the Start of the New Millennium”²⁸. The potential of the ICF for rheumatology research and practice has been described^{29,30}.

As an internationally accepted conceptual model developed in a worldwide consensus process³¹, the ICF is of great interest to OMERACT. It has the potential to become the reference model for the conceptualization of OMERACT domains addressing aspects of functioning and disability.

We therefore encourage the use of the ICF as a conceptual model for identification and conceptual description of new OMERACT domains. We also encourage close examination of current OMERACT domains regarding their compatibility with the ICF and the possibility of revising current domains according to the ICF model and terminology.

The ICF: an interface between OMERACT domains and instruments

Lacking a globally accepted conceptual model for human functioning and lacking an exhaustive classification of human functioning, there has been no explicit specification of the OMERACT domains addressing functioning. With the ICF, which encompasses 1454 so-called ICF categories, this is now possible. The ICF categories are an exhaustive list of globally acceptable descriptions of “what” can be relevant to people with a health condition experiencing decrements in functioning.

The integrative model of functioning and disability guided the development of the ICF. Therefore, the components of the model correspond to the components of the classification. Figure 2 illustrates the structure of the ICF classification. Categories referring to “body functions” are designated “b,” categories referring to “body structures” are designated “s,” categories referring to “daily activities and participation” as “d” and categories referring to environmental factors as “e.”

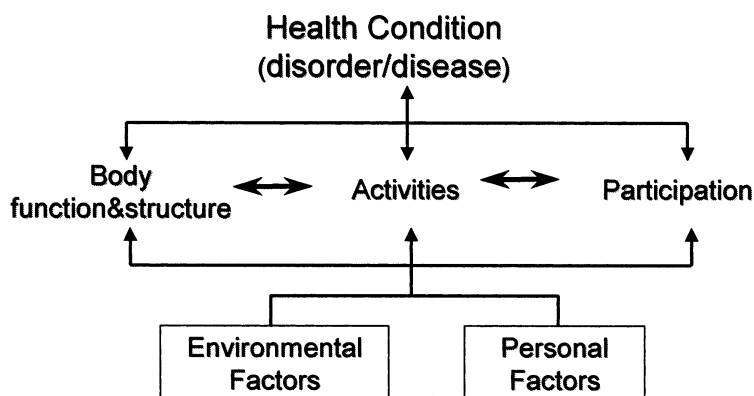


Figure 1. Framework of the International Classification of Function, Disability and Health (ICF).

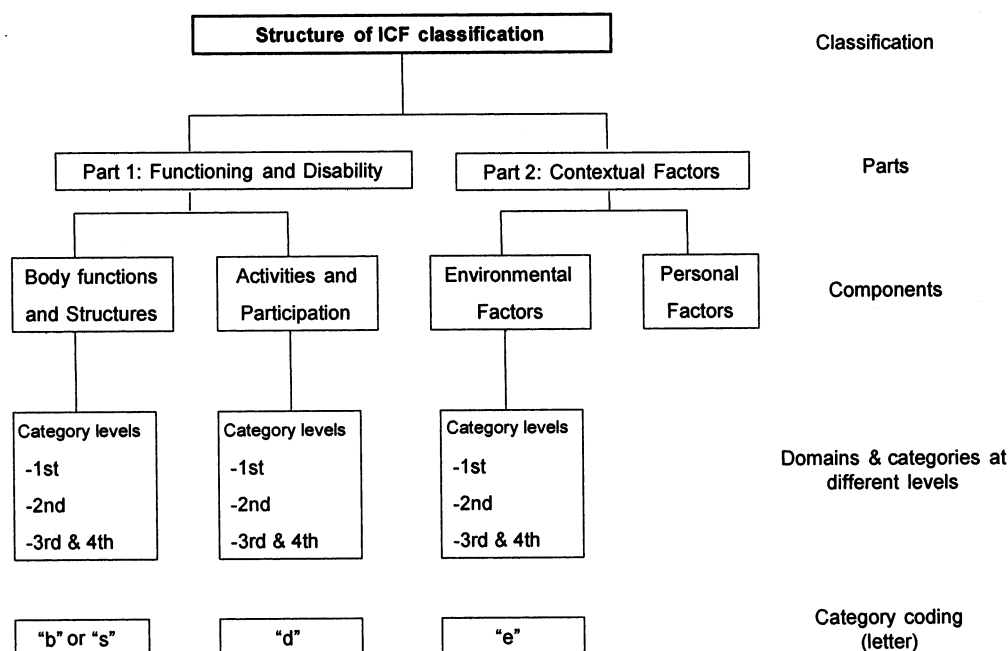


Figure 2. Structure of the International Classification of Functioning, Disability and Health (ICF).

Within each component there is an exhaustive list of ICF categories, which are hierarchically organized and denoted by unique alphanumeric codes. The first level of this hierarchy consists of chapters. Each chapter consists of second-level categories that, in turn, are composed of categories at the third level, which include fourth-level categories. For example, from the component “Body Functions”:

- b2 Sensory functions and pain (first/chapter level)
- b280 Sensation of pain (second level)
- b2801 Pain in body part (third level)
- b28013 Pain in back (fourth level)

Some examples of ICF categories are shown in Table 1.

ICF categories should not be confused with “items” used, for example, in patient-reported outcome measures or health-related quality of life measures. There is a wide range of items that are potentially suitable for the measurement of a specific ICF category or a set of ICF categories. While there is a finite number of ICF categories relevant to people with a specific health condition, there is, at least in principle, an infinite number of items potentially useful to measure these categories.

Similarly, the ICF categories should not be confused with clinical tests. In the OMERACT process, the ICF categories are needed when specifying “what to measure,” while “clinical tests” including imaging, laboratory tests, or capacity tests are needed when specifying “how to measure.”

In the OMERACT process, the ICF categories are therefore needed when specifying “what to measure,” while “items” and “tests” are needed when specifying “how to measure.” The ICF categories identified as relevant to record the experience of functioning and disability of people with a

health condition are unlikely to change much over time. Instead, items, instruments, and tests to measure these categories are undergoing a constant process of improvement.

ICF Core Sets: a way to specify OMERACT domains addressing aspects of functioning

Obviously, not all of the total 1454 ICF categories are relevant for each condition. Clinicians will only need a fraction of the categories found in the ICF³². Therefore, for each condition the categories that are necessary to describe functioning need to be identified in a standardized approach. The number of categories should be as low as possible, but as high as needed to accurately reflect functioning³³ for the particular health condition. In a worldwide iterative and scientifically sound process, the WHO has therefore developed lists of ICF categories relevant for specific conditions (available at the website www.icf-research-branch.org). These lists are called ICF Core Sets^{32,34,35}.

ICF Core Sets are defined during an international consensus conference, based on the evidence from preliminary studies, namely: (a) a systematic literature review regarding the outcomes used in clinical trials and selected observational studies; (b) focus groups/individual interviews involving patients in different world regions; (c) an expert survey with involvement of international clinical experts in the field; and (d) a cross-sectional study involving patients in different world regions.

ICF Core Sets have been developed for 12 chronic “most burdensome” health conditions, including the OMERACT relevant conditions OA³⁶, RA³⁷, low back pain³⁸, chronic wide-

Table 1. ICF codes and description of pain, walking, using transportation, work, and leisure as an example.

Code	Definition
b280 Sensation of pain	Sensation of unpleasant feeling indicating potential or actual damage to some body structure
d450 Walking	Moving along a surface on foot, step by step, so that one foot is always on the ground, such as when strolling, sauntering, walking forwards, backwards, or sideways
d470 Using transportation	Using transportation to move around as a passenger, such as being driven in a car or on a bus, rickshaw, jitney, animal-powered vehicle, or private or public taxi, bus, train, tram, subway, boat or aircraft
d850 Remunerative employment	Engaging in all aspects of work, as an occupation, trade, profession or other form of employment, for payment, as an employee, full or part time, or self-employed, such as seeking employment and getting a job, doing the required tasks of the job, attending work on time as required, supervising other workers or being supervised, and performing required tasks alone or in groups
Recreation and leisure (d920)	Engaging in any form of play, recreational or leisure activity, such as informal or organized play and sports, programs of physical fitness, relaxation, amusement or diversion, going to art galleries, museums, cinemas or theatres; engaging in crafts or hobbies, reading for enjoyment, playing musical instruments; sightseeing, tourism and traveling for pleasure

spread pain³⁹, and osteoporosis⁴⁰. Within the realms of musculoskeletal conditions ICF Core Sets are currently being developed for psoriatic arthritis in cooperation with the Wellington School of Medicine and Health Sciences, University of Otago, for ankylosing spondylitis by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) in cooperation with University Hospital Maastricht and the Ankylosing Spondylitis Assessment Study (ASAS) group, and for SLE and systemic sclerosis in cooperation with the Vienna Medical University⁴¹. They can serve as a basis for further specification of OMERACT domains addressing functioning and disability.

We therefore recommend that OMERACT groups currently involved in the development of OMERACT Core Sets consider the use of these ICF Core Sets as a basis for further specification of OMERACT domains addressing aspects of functioning. Groups with OMERACT Core Sets already established are encouraged to compare the current specification of domains addressing aspects of functioning with the ICF Core Sets, and to examine whether the ICF Core Sets may be useful for further specification of these domains.

ICF linkage: mapping the world of measures to OMERACT domains

The ICF and more specifically the ICF Core Sets can serve as a reference or interface when appraising and comparing candidate instruments in the OMERACT process. The linkage of existing instruments to the ICF using established linking rules^{42,43} provides a new way to study the “truth” component of the OMERACT filter. Linkage represents translation of the contents of a selected instrument to the ICF language. After linking specific and generic candidate condition measures to the ICF, it will be possible to examine whether and to what extent an instrument covers the ICF Core Set categories, or to

examine where they overlap^{19,21,22}. Along this line, the ICF Core Sets can be used as a reference for the development of new instruments to assess functioning for research¹⁵.

We therefore recommend that OMERACT groups currently involved in the selection of instruments for an OMERACT domain consider the linkage to the ICF, relying on the established linkage rules as a new and additional way to examine “truth.”

As shown in different studies^{19,21,44-46}, with only a few exceptions the content of the health status measures is represented by the ICF categories and therefore the ICF can serve as the common framework when comparing health status measures. A detailed documentation of items containing information beyond the scope of the ICF is an integral part of the named linkage rules. The documented information is to be reflected because it can provide substantial information about the instruments.

Perspective: the ICF in OMERACT outcomes research

Adoption of the ICF and the ICF Core Sets will allow OMERACT groups to select, conceptualize, and specify OMERACT domains and provide a reference for the appraisal of candidate instruments to measure the OMERACT domains. The ICF and ICF Core Sets can therefore facilitate the OMERACT process of defining “what to measure” and “how to measure.”

This approach will also open new opportunities in the design, analysis, and reporting of studies. The ICF Core Sets serve as a reference for researchers to be sure that all relevant aspects of functioning are considered in the planning of studies. Depending on the setting of the study (experimental or observational), the study outcomes/endpoints will be selected based on the disease-specific ICF Core Sets that define the OMERACT domain functioning and disability.

In addition to intervention targets, the inclusion of exploratory targets from the ICF Core Sets would help us to enrich our understanding of the mechanisms that lead to an improvement based on an intervention. The target and exploratory categories should be measured by psychometrically sound and responsive health status measures or clinical tests. In addition to these selected categories, all other categories of the ICF Core Set should be described at the start of the study to allow comparison of populations with respect to their functioning profile. This can easily be done by the so-called qualifier scale, a rating scale proposed by WHO to evaluate the extent of the patient's problem in each of the ICF categories.

Healthcare professionals including researchers and healthcare practitioners, but also the editors of medical reports and readers and reviewers of manuscripts, could benefit from this standardization.

Conclusion

The ICF Core Sets can be used as a basis for further specification of OMERACT domains addressing aspects of functioning. In line with the successful approach taken by OMERACT, it is suggested that the domain "function" should be comprehensively specified when defining "what should be measured," and only then can a recommendation be made how to measure or which health status measure to use. It would be worthwhile to compare the specifications of domains addressing aspects of functioning of OMERACT Core Sets already established with the ICF Core Sets, and to examine whether the ICF Core Sets may be useful for the further specification of these domains.

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1. Biomarkers and Surrogate Endpoints
2. Imaging
3. Outcome Measures
4. Workshops and Special Interest Groups

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