

Examining the Similarities and Differences of OMERACT Core Sets Using the ICF: First Step Towards an Improved Domain Specification and Development of an Item Pool to Measure Functioning and Health

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ABSTRACT. *Objective.* To contribute to the discussion on a common approach for domain selection in the Outcomes in Rheumatology Clinical Trials (OMERACT) process. First, this article reports on the consistency in the selection and names of the domains of the current OMERACT core set, and next on the comparability of the specifications of concepts that are relevant within the domains. For this purpose, a convenience sample of 4 OMERACT core sets was used: rheumatoid arthritis (RA), psoriatic arthritis (PsA), longitudinal observational studies (LOS) in rheumatology, and ankylosing spondylitis (AS). Domains from the different core sets were compared directly. To be able to compare the specific content of the domains, the concepts contained in the questionnaires that were considered or proposed to measure the domains were identified and linked to the category of the International Classification of Functioning, Disability, and Health (ICF) that best fit that construct. Large differences in the domains, and lack of domain definitions, were noted among the 4 OMERACT core sets. When comparing the concepts in the questionnaires that represent the domains, core sets differed also in the number and type of constructs that were addressed within each of the domains. Especially for the specification of the concepts within the domains Discomfort and Disability, the ICF proved to be useful as external reference to classify the different constructs. Our exercise suggests that the OMERACT process could benefit from a standardized approach to select, define, and specify domains, and demonstrated that the ICF is useful for further classification of the more specific concepts of “what to measure” within the domains. A clear definition and classification of domains and their specification can be useful as a starting point to build a pool of items that could then be used to develop new instruments to assess functioning and health for rheumatological conditions. (J Rheumatol 2011;38:1739–44; doi:10.3899/jrheum.110395)

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Since its foundation, Outcome Measures in Rheumatology Clinical Trials (OMERACT) has proposed several core sets for outcome measurement in specific rheumatologic diseases, and other core sets are being prepared. OMERACT core sets refer to the minimum number of domains and instruments that are vital to describe outcomes in clinical studies or clinical practice. While “domains” refer to “what” should be measured, instruments specify “how” those domains should be measured. The typical process is that, first, the relevant domains are selected while, second, instruments are identified that measure or assess these domains. Domains are selected by a nominal group consensus process, usually preceded by a Delphi exercise¹. Instruments should satisfy the OMERACT filter of validity, and candidate instruments are usually retrieved after systematic review of the literature. For domain selection, OMERACT has suggested consideration of 5 main

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dimensions (the five “D’s”) of outcome that were proposed by Fries, *et al*, representing Discomfort, Disability, Damage, Drug toxicity, and Dollars². New insights in clinimetric research identified advantages of improving the domain selection by specifying the large domains into the most specific units of “what to measure.” The main reason to revisit domain definition and content specification is the increasing insight that the instruments used at present, although proven useful, have some shortcomings than can be addressed by new methods. Existing instruments often contain items that cover different dimensions (or domains), and more importantly, the individual items often address several concepts, which can result in disordered responses. The first step in instrument development is to again answer the question, “what should be measured.”

Although several approaches for domain definition and domain specification have been developed, the World Health Organization endorsed the International Classification of Functioning, Disability and Health (ICF) as the universal framework and classification system³. The ICF framework supports the biopsychosocial model of functioning and health by recognizing the influence of contextual factors (environmental and personal factors) on functioning and disability. In addition to the framework, the ICF also proposes a classification system and definition of functioning by means of the so-called ICF categories. A total of 1454 categories in the ICF belong to one of the ICF components, namely, Body functions (e.g., pain, energy, sleep, emotion, muscle power); Body structures (e.g., hip joint, ligaments, cervical vertebral column); Activities and participation (such as reaching, walking, self-care, housework, remunerative employment); and Environmental factors (such as drugs, health services, attitudes of family members). Within each component, the categories are grouped within chapters and are further specified as 2nd, 3rd, and 4th level categories, in which 3rd and 4th level are specifications of the 2nd level categories³. As such, ICF categories are units of functioning within health-related domains. Applying this to the OMERACT domains, the ICF categories can be seen as specifications of some of the OMERACT health-related domains, and refine “what can be measured” when addressing functioning and health. Although Personal Factors are included as a component in the ICF framework, they are as yet not defined by a series of categories.

Terminology to understand the relation between OMERACT domains and ICF classification:

OMERACT domain

- vaguely described concept referring to relevant areas of outcome in rheumatology outcome studies. Each area likely consists of a number of (hierarchically ordered) subdomains that specify the domain further

ICF categories

- ICF categories are *the units* that allow us to specify and classify health-related domains (areas)

- ICF categories are assigned an alphanumeric code, a title, and an operational definition. Categories can be target (outcome) or explanatory variables
- each ICF category belongs to one of the ICF components: Body Functions, Body Structures, Activities and Participation, and Environmental factors
- ICF categories are structured hierarchically, lower levels specifying higher levels

Concept

- the idea or abstract principle relating to a specific subject (in the context of this article, ‘how to measure’ the specific concept of the domains (the idea or principle it represents) is often represented in the content of items from questions or questionnaires

The objective of this article is to find out to what extent the domains and concepts (“what to measure”) within the OMERACT core sets for musculoskeletal disease (i.e., arthritis) can be compared, and whether the ICF can be useful in the process of specification of OMERACT domains by providing an external and universal framework of all aspects of functioning.

METHODS

Four OMERACT core sets, psoriatic arthritis (PsA), rheumatoid arthritis (RA), ankylosing spondylitis (AS), and longitudinal observational studies (LOS) in rheumatology^{4,5,6,7}, were conveniently selected and compared. First, the selected domains for each were compared directly. Next, concepts contained in the instruments that were considered or selected to measure the OMERACT domains were linked to the ICF categories, which served as the external reference for comparison^{7,8,9,10}. Linking refers to the procedure that follows established rules and aims to match a domain or concept to the most precise ICF category that represents that concept or domain^{11,12}. Comparability of OMERACT core sets is discussed in view of the difficulties encountered in comparing the domains and concepts.

RESULTS

Table 1 presents the comparison of the “core domains” of the OMERACT core sets for PsA, RA, AS, and LOS in rheumatology^{4,5,6,7}. First, core sets differed in the way in which proposed domains were organized. The RA core set selected one set of domains that represent the minimal to be included in every clinical study, with one additional domain (radiology) that should be included in studies lasting one year or more⁵. The PsA core set distinguished a minimal number of domains to be included in every clinical study, a number of optional domains that can be of further interest, and a number of domains that need further study before including them⁴. The core set for LOS in rheumatology first selected subdomains that were then grouped into broader domains, some of which are optional⁷. Finally, the AS core set distinguished 3 settings — symptom-modifying antirheumatic drugs (or SMARD) or physiotherapy, disease-modifying antirheumatic drugs, and clinical record-keeping — with increasing number of (obligatory) core domains⁶.

Second, a difference in the number of domains or subdomains was seen. For the core set of PsA, 6 core domains

Table 1. Comparison of the domains selected for the OMERACT core sets for psoriatic arthritis, rheumatoid arthritis, longitudinal observational studies, and ankylosing spondylitis.

Common Domains	Psoriatic Arthritis	RA Clinical Trials	Longitudinal Studies in Rheumatology	Ankylosing Spondylitis
Pain	Pain	Pain	Health status: "symptoms"	Pain ^{a,b,c}
Stiffness			Health status: "symptoms"	Spinal stiffness ^{a,b,c}
Fatigue			Health status: "symptoms"	Fatigue ^c
Physical function	Physical function	Physical disability	Health status: "Physical function"	Physical function ^{a,b,c}
Participation	Participation			
HRQOL	HRQOL		Health status: "HRQOL"	
Patient global	Patient global	Patient global assessment	Disease process: "globals"	Patient global activity ^{a,b,c}
Physician global		Physician global assessment	Disease process: "globals"	
Joints	Peripheral joint activity	Swollen joints	Disease process: "Joint tenderness/swelling"	Peripheral joints/entheses ^{b,c}
Psychosocial function			Health status: "psychosocial function"	
Acute-phase reactant		Acute-phase reactants	Disease process: acute-phase reactant	Acute-phase reactant ^{b,c}
Mobility				Spinal mobility ^{a,b,c}
Radiograph		Radiographs of joints (in studies ≥ 1 year duration)	Damage: Radiographic damage	Spine radiograph ^c Hip radiograph ^c
Deformity			Damage: deformity	
Organ damage			Damage: "organ damage"	
Surgery			Damage: surgery	
Skin	Skin assessment			
Mortality			Mortality	
Toxicity			Toxicity/adverse reactions	

^a In core set for symptom-modifying antirheumatic drugs (SMARD) and physiotherapy trials; ^b in core set for disease clinical record-keeping; ^c in core set for disease controlling antirheumatic drugs. HRQOL: health-related quality of life.

were selected, 8 optional domains, and 5 domains for the research agenda; for RA, 7 (8 for studies of more than 1 year); for LOS, 11 subdomains within 5 broader domains (2 of which are optional); and for AS a total of 9 domains for the 3 settings together.

The names of the domains were surprisingly difficult to compare and could not easily be classified under the proposed "five D" structure of domains. Specifically, the domains in the core set for LOS were difficult to compare with other core sets: the starting point of the core set for LOS considered not only the "five D's"² but also included the "impairment→disability→handicap model" or the International Classification of Impairments, Disabilities and Handicaps model of the World Health Organization (ICIDH)¹³, which preceded the ICF and aimed to make a distinction between process versus damage. This resulted in names and subdomains that differed substantially from other core sets. Further, the domain "health-related quality of life" (HRQOL) posed some challenges. In the LOS, HRQOL was synonymous with health state, and together with Disease process and Damage, part of the domain "health." HRQOL (or health status) domains included symptoms, physical function, and psychosocial function. In the PsA core set, HRQOL was selected as a domain in addition to the domains pain, physical function, global assessments, and participation. When taking into account the specifications of the subdomains that were proposed for the (sub)-domains of the LOS core set, then pain, physical function, patient global assessment of disease activity, and joint

assessment were domains common to all 4 core sets. Damage (including radiographic damage) and acute-phase reactants were presented in all core sets except for the PsA core sets, where it is part of the research agenda. Fatigue was a separate domain in the AS core set, was mentioned among the domain "symptoms" of the LOS core set, was not included in the RA core set, and was on the research agenda for the PsA Core Set. The core set for LOS was the only one to include psychosocial function as a specific domain (within HRQOL). The core set for psoriatic arthritis was the only one to include the domain "skin." When considering the "five D" model, it is clear the OMERACT core sets emphasize Discomfort, Disability, and Damage. The LOS was the only one to include Drug toxicity and Death. Costs were included only as an optional domain in the core set for LOS.

When trying to compare the specific concepts of "what to measure" contained in the domains of the different core sets, it was assumed that the content of domains is specified by the concepts included in the items of the selected instruments. However, only for the core set of AS were measures formally selected by consensus¹⁰. Notwithstanding, the PsA core set and the core set for RA, LOS, respectively, considered or proposed measures for domains^{7,8,9}. For the purpose of the present study, these "considered or proposed" measures were linked to the ICF categories. A separate table that represents the full result of this linking exercise is available from the authors on request.

Linking to the ICF revealed that the majority of concepts

Table 2. Comparison of the ICF-linked concepts addressed in the physical component of the Medical Outcomes Study 36-item Short-Form Survey (SF-36), health Assessment Questionnaire (HAQ), and bath Ankylosing Spondylitis Functional Index (BASFI). Concepts from the SF-36 that have a higher load in the calculation of the physical component of the SF-36 are shown in bold type.

ICF Domain (category)	SF-36 (PCS)	HAQ	BASFI	ICF Domain (category)	SF-36 (PCS)	HAQ	BASFI
Body Functions				Self-care			
Mental functions				d5 Self-care		X	
b1300 Energy level	X			d5100 Washing body parts		X	
b152 Emotional functions	X			d5101 Washing whole body	X	X	
Sensory functions and pain				d5102 Drying oneself		X	
b280 Sensation of pain	X	X		d530 Toileting		X	
Activities and participation				d540 Dressing	X	X	
General tasks and demands				d5400 Putting on clothes		X	
d230 Carrying out daily routine	X			d5402 Putting on footwear		X	X
Mobility				d550 Eating		X	
d4 Mobility	X			d560 Drinking		X	
d410 Changing basic body position		X		d5701 Managing diet and fitness			X
d4100 Lying down		X	X	Domestic life			
d4102 Kneeling	X			d620 Acquisition of goods and services		X	
d4103 Sitting		X	X	d640 Doing housework	X		X
d4105 Bending	X	X	X	d6403 Using household appliances		X	
d4154 Maintaining a standing position			X	d6505 Taking care of plants, indoors and outdoors		X	X
d430 Lifting and carrying objects	X			Interpersonal interactions and relationships			
d4300 Lifting		X		d750 Informal social relationships	X		
d4400 Picking up			X	d7500 Informal relationships with friends	X		
d4401 Grasping		X		d7501 Informal relationships with neighbors	X		
d4402 Manipulating		X		d760 Family relationships	X		
d445 Hand and arm use		X		Major life areas			
d4451 Pushing	X			d850 Remunerative employment	X		X
d4452 Reaching		X	X	Community, social and civic life			
d4453 Turning or twisting the hands or arms		X		d9 Community, social and civic life	X		
d450 Walking		X		d9201 Sports	X		X
d4500 Walking short distances	X			d9205 Socializing	X		
d4501 Walking long distances	X			Environmental factors			
d4551 Climbing	X	X	X	Products and technology			
d4552 Running	X			e1 Products and technology		X	
d4602 Moving around outside the home and other buildings		X		e1151 Assistive products and technology for personal use in daily living		X	
d498 Mobility, other specified			X	e1201 Assistive products... for... mobility and transportation		X	

PCS: physical component score.

addressed in the OMERACT domains were pertinent to pain functions, movement/mobility, self-care, and participation. In addition, categories referring to energy and drive and emotional functions were addressed. To illustrate the advantage of linking, Table 2 presents the comparisons of the constructs included in the physical component of the Medical Outcome Study Short-Form 36 (SF-36)¹⁴ (considered in the domain “physical function” of the OMERACT core set for PsA), the Health Assessment Questionnaire (HAQ)² (considered for the domain “physical function” in the RA and LOS core set, and the Bath AS Functional Index (BASFI) (selected for the domain “function” in the OMERACT core sets for AS). Consistent with the development for RA, the HAQ included more activities of the hands and upper limbs, and the BASFI included ICF categories referring to “maintaining and changing body positions,” which is more specific to patients with

back problems. The SF-36 also contained categories on mental function and participation and thus exceeds the “traditional” domain of “physical function.”

DISCUSSION

The comparison of the OMERACT domains and more specific concepts represented within the domains across 4 selected OMERACT core sets proved useful. We learned that “what to measure” is not consistently defined across core sets and lacks specifications. There are 2 findings that we believe are relevant for further discussion within OMERACT.

First, within OMERACT core sets, the domains are grouped and named following different approaches. Although OMERACT suggested the “concept of five dimensions” as the starting point, this is not consistently reflected in the OMERACT core sets. Further, in the core set for LOS, subdomains

are grouped in core domains comprising “health,” “process,” “damage,” “toxicity,” and “death.” Specifically, the domains “process” and “damage” represent a different construct, since it is a human interpretation that goes beyond the experience at the level of the patient. On the other hand, in the core set for AS, domains were grouped according to the setting of application [SMARD studies, disease-controlling antirheumatic therapy (DC-ART) studies, or clinical record-keeping]. Finally, in the core set for PsA and LOS, a number of optional domains are selected in addition to the “core domains.” As a consequence, in the core set for PsA, acute-phase reactant and radiographic damage are not in the core, while they are core domains for RA (radiographs in studies longer than 1 year), for AS (in DC-ART studies and clinical record-keeping) and for LOS (radiographs are a subdomain in the domain “damage”). Specifically challenging was the domain “quality of life” (QOL). While QOL is part of the core set for PsA and LOS, the domain covers different content. In the core set for LOS, HRQOL is the umbrella for “health” and includes symptoms as well as physical and psychological functioning. In the core set for PsA, HRQOL is a domain separate from pain and physical function.

Second, to be able to compare the specific concepts that are represented in the domains using the ICF as external reference, it was aimed to use the constructs in the items of selected questionnaires that need to represent the OMERACT domains. Remarkably, only the core set for AS agreed upon core instruments. Therefore, it was decided to also include in the comparison the instruments that were considered or recommended in the development of the OMERACT core sets. Comparison of the concepts in the items using the ICF again proved to be useful, especially for the domain “physical function.” The ICF allowed us to gain insight into which aspects of functioning are “typical and relevant” across all diseases versus those for specific diseases.

Historically, the choice of OMERACT to define “what to measure” in broad domains was a logical choice. First, a detailed framework that represented all possible aspects of health was not available. Second, the OMERACT process wanted, for domain specification, to make use of existing instruments that had proven usefulness and had been extensively validated. The need addressed by OMERACT was primarily to agree on selected instruments, in order to improve harmonization (uniformity) in the world of outcome measurement.

The question therefore remains whether there is a need to revisit the question “what to measure.” In the new structure of OMERACT, the selection and further specification of domains are given careful attention¹⁵. With improved insight into the “concept of health” and the emergence of new approaches to development of instruments, it appears that reexamining the domains and domain specification makes sense. Despite their proven usefulness for progress in rheumatology, the existing measures also have some drawbacks. Item response theory has already been applied to the HAQ (includ-

ed in the core set for RA and considered for PsA) and BASFI (included in the core set for AS) and showed that although instruments are reasonably unidimensional, neither of them (HAQ or BASFI) are true interval measures and include items that show differential functioning and non-ordered responses^{16,17,18,19}. Moreover, they lack items that help to distinguish between patients with lower levels of disability (i.e., floor effect). The ICF offers a classification by the WHO that is necessary to describe functioning and health. The ICF framework can be used as the external standard and therefore the starting point of defining “what to measure” for either one of the rheumatological conditions or within a particular setting. Moreover, the ICF could facilitate the management of a pool of items that are clinimetrically valid and could be used in the development of new instruments. For AS, effort is going towards the development of a pool of items covering the categories of the ICF core set for AS^{20,21}. In the area of the development of item pools, the Patient Reported Outcomes Measurement System (PROMIS) is sophisticated and useful^{22,23,24}, and it would be a beneficial initiative for OMERACT to look at the active interface between the ICF and PROMIS¹⁵.

Other fertile ground within the OMERACT community is to consider the application of the ICF by way of the so-called ICF core sets. Different from OMERACT core sets, ICF core sets refer to a short list of ICF categories that are relevant to a health condition or health-related event. These are selections of ICF categories that are necessary to classify functioning of an individual using extensive and multiple methodologies. They encompass the perspective of patients, existing research, and health professionals. Such core sets are available for several rheumatologic or musculoskeletal conditions — RA²⁵, AS²¹, osteoporosis²⁶, chronic low back pain²⁷, chronic widespread pain²⁸, and osteoarthritis²⁹. These core sets could be the starting point to specify OMERACT domains.

In addition to the comprehensive core sets, there are current initiatives to develop a statistically derived or combined statistical experts-derived Brief ICF Core Set based on the comprehensive core sets. Although the ICF (Core Sets) can be useful as external reference, we need to recognize that the ICF has limitations, such as the lack of universally agreed operationalization of its categories, and the lack of classification of personal factors. However, these limitations do not outweigh the advantage of having a common conceptual language and classification to measure functioning and disability domains across diseases. The ICF initiative within OMERACT is a starting point to propose for each “domain” the best (set of) concepts (ICF categories) to specify the domain.

In conclusion, we learned, by doing a comparison of some OMERACT core sets, that domain conceptualization and definition vary across diseases and domain specification is insufficient, if not lacking. A common framework to assess outcome and specification of domains could further improve outcome measurement as already addressed in the OMERACT report on domain selection¹⁵. The ICF proved useful in spec-

ifying the domains referring to physical function in the OMERACT core sets, but can also provide specification for domains that are not part of OMERACT core domains but are relevant to outcomes assessment.

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