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IDENTIFYING THE CONCEPTS CONTAINED IN OUTCOME MEASURES OF CLINICAL TRIALS ON MUSCULOSKELETAL DISORDERS AND CHRONIC WIDESPREAD PAIN USING THE INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH AS A REFERENCE

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Objectives: **To systematically identify and compare the concepts contained in outcome measures of clinical trials on low back pain, chronic widespread pain, osteoarthritis, osteoporosis and rheumatoid arthritis using the International Classification of Functioning, Disability and Health (ICF) as a reference.**

Methods: **Randomized controlled trials carried out between 1991 and 2000 were identified using MEDLINE and selected according predefined criteria. The outcome measures were extracted and the concepts contained in the outcome measures were linked to the ICF.**

Results: **One hundred and twenty-nine trials on low back pain, 42 trials on chronic widespread pain, 176 trials on osteoarthritis, 107 trials on osteoporosis and 382 trials on rheumatoid arthritis were included. Fifty-nine different health status questionnaires were extracted in low back pain, 29 in chronic widespread pain, 29 in osteoarthritis, 3 in osteoporosis and 48 in rheumatoid arthritis. Across conditions at least 77% (range 77–88%) of the extracted concepts could be linked to the ICF. In low back pain, chronic widespread pain and osteoarthritis the most used ICF-categories were *sensation of pain* (b280), in osteoporosis *structure of trunk* (s760) and in rheumatoid arthritis *additional musculoskeletal structures related to movement* (s770). The most used category across conditions was *sensation of pain* (b280) except for osteoporosis.**

Conclusion: **The ICF provides a useful reference to identify and quantify the concepts contained in outcome assessment used in clinical trials.**

Key words: low back pain, chronic widespread pain, osteoarthritis, osteoporosis, rheumatoid arthritis, outcome assessment, systematic review, ICF.

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INTRODUCTION

Musculoskeletal disorders and chronic widespread pain vary in their clinical expression, yet each has a major effect on functioning and health.

Functioning is central to the patient experience in musculoskeletal conditions including low back pain (LBP) (1), chronic widespread pain (CWP) (2), osteoarthritis (OA) (3), osteoporosis (OP) (4) and rheumatoid arthritis (RA) (5). It can be both an outcome of the disease process and a target of rehabilitation and prevention interventions (6).

Accordingly, a large number of clinical tests (7) as well as generic (8, 9), symptom or dimension- (10) and condition-specific (11–14) health status measures have been developed and are used in clinical trials on musculoskeletal disorders and chronic widespread pain to describe and evaluate functioning and health.

Based on the new International Classification of Functioning, Disability and Health (ICF) (15) which was endorsed by the Word Health Assembly in May 2001 and provides a common language of functioning and health, it is now possible to identify and compare the concepts contained in different outcome measures (16).

The objective of this systematic review therefore was to identify and compare the frequency of concepts contained in the outcome measures of randomized controlled trials (RCTs) for interventions in musculoskeletal disorders and CWP using the ICF as a reference tool.

METHODS

Study design

A systematic review was performed using the following 3 steps: step 1, selection of studies; step 2, outcome measures extraction; and step 3, linkage of the concepts contained within the outcomes measures to the corresponding categories of the ICF. All steps were carried out by 2 independent reviewers.

In step 1, selection of studies, RCTs between the years 1991 and 2000 were located in MEDLINE®, Silver Platter, 2000 Edition, using Dickersin et al.'s (17) highly precise search strategy (sets 1–8).

Thereafter, the Dickersin search was combined with 5 condition-specific search strategies using the "and" operator.

To locate LBP trials, the subject heading "back pain" and the title and abstract terms "back pain" and "backache" were combined using the "or" operator (18). To locate CWP trials, the explode function for "fibromyalgia" with all subheadings and the title and abstract terms "fibromyalgia" and "somatoform pain disorder" were combined using "or" operator. The terms "generalized pain disorder", "generalized chronic pain" or "chronic widespread pain" did not lead to additional information. To locate OA trials, the explode function for "osteoarthritis" including all subheadings except "spinal osteophytosis" and the title and abstract terms "osteoarthr*", "degenerative near arthritis", "degenerative near joint or hip or knee or shoulder or ankle or wrist or elbow or hand" were combined by the "or" operator. To locate OP-trials, the explode function for "osteoporosis" including all subheadings and the title and abstract term "osteop*" were combined using the "or" operator. To locate RA trials, the explode function for "arthritis-rheumatoid" including all subheadings and the title and abstract terms "polyarthritis near chronic" and "arthritis near rheumatoid" were combined using the "or" operator.

All searches were limited to English articles. The abstracts were checked applying general and condition-specific eligibility criteria. For the selected trials the original study reports were ordered and reviewed applying again the same eligibility criteria. The finally included studies entered step II of the review.

A study met general eligibility, if the study design was a RCT, the experimental intervention had a therapeutic aim, and the outcome measures had to be evaluated on patients, and if none of the following exclusion criteria were fulfilled: reviews, secondary analyses, psychometric studies, primary prevention studies (healthy population at risk), mode of action studies, and studies with heterogeneous population (e.g. back pain and neck pain). In the case of multiple publication, the paper with the highest impact factor was included.

To identify the appropriate study population in each health condition condition-specific eligibility criteria were applied. To select persons with LBP, the term LBP has to be reported to describe the study population. Specific populations with LBP caused by aetiopatholgical entities such as osteoporosis, seronegative spondylarthropathies, infection, fracture, neoplasm, metastasis, as well as LBP in pregnancy or postpartum were excluded. To select persons with CWP, the terms fibromyalgia or somatoform pain disorder has to be reported to describe the study population. Populations with headache including migraine as well as any populations with specific or localized pain were excluded. To select persons with OA, the diagnosis of OA has to be reported to describe the study population. Arthritis other than primary and secondary osteoarthritis was excluded. To select persons with OP, the diagnosis of OP has to be reported to describe the study population. Bone diseases other than primary and secondary osteoporosis were excluded. To select persons with RA, the diagnosis of either RA or chronic polyarthritis (in the meaning of RA) has to be stated to describe the study population. Patients with juvenile rheumatoid arthritis, rheumatic fever, gout, skin and connective tissue diseases, seronegative spondylarthropathies, reactive arthritis, and infectious arthritis were excluded. Persons aged below 18 years were excluded in each health condition considered.

In step 2, outcome measures extraction, all types of outcome measures including clinical tests, single item measures on different domains, biochemical, physiological, imaging tests, biopsy and questionnaires were extracted. If the items of a questionnaire were not specified in the publication, we attempted to obtain the questionnaire by reference checking, searches in databases or books on health status measures (19, 20), email-consultation with the developers of the questionnaire in question, and internet searches, and then the items were extracted. Only questionnaires available in English were included. Additionally, study population characteristics (disease duration, disease-subsets, etc.) and the type of experimental intervention (drug-, surgery-, non-pharmacological treatment including complex rehabilitative, physical, complementary, nutritional, educational and psychological therapy, and combination of these categories) were extracted.

In step 3, linkage of the concepts contained within the outcome measures to the corresponding categories of the ICF, the concepts contained within the outcome measures were extracted and linked to the most specific ICF category by 2 independent health professionals according to a recently developed set of 10 linking rules (16). Concepts of outcome measures that could not be linked to the ICF were documented and classified in 2 ways: (i) If a concept of an outcome measure was not sufficiently specified to make a decision which ICF category the concept should be linked to, the "not definable" option was chosen (linking rule 9). To give an example, unspecified concepts such as "functional status", "health", "disability" or "symptoms" were considered not to be definable for linking. (ii) If a concept of an outcome measure was not represented by the ICF, the option "not covered" was chosen (linking rule 10). To give an example, concepts such as "wanted to be alone", "blaming yourself for things" extracted from the Hopkins Symptom Checklist (21) or "seeming as though fate and other factors beyond my control affect my condition" extracted from the Rheumatology Attitudes Index (22) were considered not to be covered by the ICF.

Consensus between the 2 health professionals was used to decide which ICF category should be linked to each item/concept of the questionnaires. To resolve disagreements between the 2 health professionals concerning the selected categories, a third person trained in the linking rules was consulted. In a discussion led by the third person, the 2 health professionals that linked the item stated their pros and cons for the linking of the concept under consideration to a specific ICF category. Based on these statements, the third person made an informed decision.

Additionally, to control the plausibility of the linkage procedure the concepts of the outcome measures assigned to the same single ICF category were analysed (e.g. the concepts "not able to make a start", "having little interest in things", "feeling full of pep", "having trouble resisting one's craving" which were linked to the ICF category "energy and drive functions" (b130)).

Analyses

Descriptive statistics were used to examine the frequency of ICF categories linked to the concepts contained in the outcome measures. Large-scale cross tables generated from a SQL-database (Structured Query Language Server 2000) were thereby analysed. If one and the same ICF-category was assigned repeatedly in a study, the category was counted only once.

ICF-categories are presented on the second level. If a concept of an outcome measure was linked to a third or fourth level ICF-category, the overlying second level category was considered. The ICF is organized in a hierarchical scheme, so that the lower-level category shares the attributes of the higher-level category (15). Only ICF-categories with a frequency equal or greater than 10% are shown (preset frequency).

RESULTS

In step 1, for LBP 2297 studies were located by the search strategy, 199 studies were preliminarily selected by abstract checking and 129 were included into the review by screening the respective original papers. For CWP 88 studies were located, 53 studies were preliminarily selected, and 42 studies were included. For OA 517 studies were located, 271 trials were preliminarily selected and 176 studies were included. For OP 685 studies were located, 234 trials were preliminarily selected and 107 studies were included. For RA 817 studies were located, 465 trials were preliminarily selected and 382 studies were included.

In step 2, for LBP 59 different questionnaires (different versions of a questionnaire were considered as one and the same questionnaire) including 13 condition-specific questionnaires, 36 dimension-specific questionnaires (on dimensions such as pain, locus of control, depression, anxiety, coping, etc.) and 10 generic questionnaires were chosen as outcome measures. At least 1 health status questionnaire per trial was selected in 83 (64%) studies. The most frequently used questionnaires were

the Oswestry Low Back Pain Disability Questionnaire (23) and the Roland Morris Disability Questionnaire (11) with a prevalence of 20% (26 studies) and 17% (22 studies), respectively. Further frequent outcome measures were clinical tests on "spinal mobility" and "muscle functions" as well as single item measures on "pain", "health care utilization" and "work status" (data not shown). Non-pharmacological treatment was the most frequently used intervention type with a prevalence of 67% ($n = 87$ studies).

In CWP 29 different questionnaires, including 1 condition-specific questionnaire (13), 25 dimension-specific questionnaires and 3 generic questionnaires were chosen as outcome measures. At least 1 health status questionnaire per trial was selected in 32 (67%) studies. The most frequently used questionnaires were the Fibromyalgia Impact Questionnaire (13) and the Beck Depression Inventory (24) with a prevalence of 24% (10 studies) and 17% (7 studies), respectively. Frequently used outcome measures were clinical tests on tender point count as well single item measures on "pain" "sleep" and "morning stiffness" (data not shown). Drug treatment was the most frequently used intervention type with a prevalence of 69% ($n = 29$ studies).

In OA 29 different questionnaires, including 2 condition-specific questionnaires (12, 25), 20 dimension-specific questionnaires and 7 generic questionnaires were chosen as outcome measures. At least 1 health status questionnaire per trial was selected in 21 (12%) of the studies. The most frequently used questionnaires were the Lequesne Algofunctional Index (25) and the WOMAC-Osteoarthritis Index (12) with a prevalence of 7% ($n = 12$ studies) and 2% ($n = 4$ studies), respectively. Frequent outcome measures were single item measures on "pain" "joint mobility", "muscle strength", "stiffness" and "walking" (data not shown). Drug treatment was the most frequently used intervention type with a prevalence of 67% ($n = 118$ studies).

For OP 3 different questionnaires were chosen as outcome measures. The Food Frequency Questionnaire (26) was used in 2 studies, the Modified Health Assessment Questionnaire (27) and the Katz Index of Activities of Daily Living (28) in 1 study each. Frequent outcome measures were imaging for the assessment of bone mineral density and fractures, biochemical markers of bone formation and resorption and bone biopsy for structural assessment. Drug treatment was the most frequently used intervention type with a prevalence of 94% ($n = 101$ studies).

For RA 48 different questionnaires, including 39 dimension-specific questionnaires and 9 generic questionnaires were chosen. At least 1 health status questionnaire per trial was selected in 121 (32%) of the studies. The most frequently used questionnaires were the Health Assessment Questionnaire (10) and the Arthritis Impact Measurement Scales (29) with a prevalence of 24% (91 studies) and 6% (24 studies), respectively. Frequent outcome measures were clinical tests on joint swelling, joint pain/tenderness, and grip strength, measures of inflammation, imaging for structural assessment, and single item measures on morning stiffness (data not shown). Drug intervention was the most frequently used intervention type with a prevalence of 77% ($n = 87$ studies).

In step 3, at least 77% (range 77–88%) of the extracted concepts could be linked to the ICF across all 5 conditions. At most 22% (range 10–22%) of the concepts were considered not to be definable, and at most 5% (range 0–5%) of the concepts were considered not covered by the ICF.

In LBP a total of 7865 concepts were extracted from the outcome measures; 7008 or 89% of concepts could be linked to the ICF, 449 or 6% of concepts were considered not to be sufficiently specified for an assignment to the ICF ("not definable option"), and 408 (5%) of concepts were considered to be not covered by the ICF. In CWP a total of 3308 concepts were extracted, 2812 concepts (85%) could be linked to the ICF, 360 concepts (11%) were considered not to be sufficiently specified, and 136 concepts (4%) were considered to be not covered by the ICF. In OA a total of 3089 concepts were extracted; 2363 concepts (77%) could be linked to the ICF, 693 concepts (22%) were considered not to be sufficiently specified, and 33 concepts (1%) were considered to be not covered by the ICF. In OP a total of 1169 concepts were extracted; 1025 (88%) concepts could be linked to the ICF, 142 concepts (12%) were considered not to be sufficiently specified, and 2 concepts (0.2%) were considered to be not covered by the ICF. In RA a total of 18 193 concepts were extracted. 15 271 (84%) concepts could be linked to the ICF, 2738 concepts (15%) were considered not to be sufficiently specified and 184 concepts (1%) were considered not to be covered by the ICF.

Tables I–IV show the relative frequency in percentage of ICF categories linked to the concepts contained within the outcome measures for each ICF component and health condition.

DISCUSSION

Using the ICF as a reference it was possible to identify and quantify the concepts within the outcome measures used in RCTs for interventions in LBP, CWP, OA, OP and RA. Most concepts within the outcome measures could be linked to the ICF and those that could not be linked were mostly not specified in enough detail for an assignment. Only a very small portion of concepts was considered not covered by the ICF. In these cases the content of the concepts did not lie in the defined universe of the ICF. Most importantly, personal factors are not covered by the current ICF and could therefore not be linked. Concepts referring to personal factors included "locus of control", "coping" or "personality". Similarly, aetiological concepts and concepts on patient satisfaction are beyond the ICF and could not be linked.

In LBP, CWP and OA the most used categories were *sensation of pain* (b280), in OP *structure of trunk* (s760) and in RA *additional musculoskeletal structures related to movement* (s770). The most used ICF-category across conditions was the body function *sensation of pain* (b280) except for OP. The most prevalent body function in OP was *functions of the joints*

Table I. *Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) categories linked to the concepts contained in the outcome measures for the ICF component body functions*

ICF code	ICF category title	LBP (n = 129)	CWP (n = 42)	OA (n = 176)	OP (n = 107)	RA (n = 382)
b110	Consciousness functions		19			
b130	Energy and drive functions	29	69			
b134	Sleep functions	60	81	17		11
b140	Attention functions	12	29			
b144	Memory functions		14			
b147	Psychomotor functions	10	26			
b152	Emotional functions	40	79			12
b156	Perceptual functions		17			
b160	Thought functions	21	55			
b164	Higher-level cognitive functions		19			
b240	Sensations associated with hearing and vestibular function	18	14			
b270	Sensory functions related to temperature and other stimuli		69	20		62
b279	Additional sensory functions, other specified and unspecified					14
b280	Sensation of pain	83	88	79	16	72
b289	Sensation of pain, other specified and unspecified	66		42		
b298	Sensory functions and pain, other specified					12
b330	Fluency and rhythm of speech functions		24			
b340	Alternative vocalization functions	12				
b410	Heart functions		24			
b420	Blood pressure functions		10			
b430	Haematological system functions		12		22	33
b435	Immunological system functions					26
b440	Respiration functions		19			
b455	Exercise tolerance functions		43			
b460	Sensations associated with cardiovascular and respiratory functions		24			
b510	Ingestion functions	10	12			
b515	Digestive functions		19			
b525	Defecation functions	14	31			
b530	Weight maintenance functions		36			
b535	Sensations associated with the digestive system	16	31			
b540	General metabolic functions				28	
b545	Water, mineral and electrolyte balance functions				63	
b555	Endocrine gland functions		10			
b610	Urinary excretory functions					20
b620	Urination functions		24			
b640	Sexual functions	10	43			
b710	Mobility of joint functions	41		31		11
b729	Functions of the joints and bones, other specified and unspecified				73	
b730	Muscle power functions	19	14			44
b735	Muscle tone functions	11				
b740	Muscle endurance functions	10				
b760	Control of voluntary movement functions		12			
b765	Involuntary movement functions		21			
b780	Sensations related to muscles and movement functions		43	22		58
b789	Movement functions, other specified and unspecified				13	
b830	Other functions of the skin		10			

LBP = low back pain; CWP = chronic widespread pain; OA = osteoarthritis; OP = osteoporosis; RA = rheumatoid arthritis.

Table II. *Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) categories linked to the concepts contained in the outcome measures for the ICF component body structure*

ICF code	ICF category title	LBP (n = 129)	CWP (n = 42)	OA (n = 176)	OP (n = 107)	RA (n = 382)
s120	Spinal cord and related structures	14				
s410	Structure of cardiovascular system		10			
s430	Structure of respiratory system		10			
s710	Structure of head and neck region					37
s720	Structure of shoulder region					40
s730	Structure of upper extremity				26	46
s750	Structure of lower extremity			26	21	44
s760	Structure of trunk				82	35
s770	Additional musculoskeletal structures related to movement				35	81

LBP = low back pain; CWP = chronic widespread pain; OA = osteoarthritis; OP = osteoporosis; RA = rheumatoid arthritis.

Table III. *Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) categories linked to the concepts contained in the outcome measures for the ICF component activities and participation*

ICF code	ICF category title	LBP (n = 129)	CWP (n = 42)	OA (n = 176)	OP (n = 107)	RA (n = 382)
d177	Making decisions	11	38			
d230	Carrying out daily routine	11				13
d330	Speaking		21			
d360	Using communication devices and techniques		12			
d410	Changing basic body position	57	52	17		30
d415	Maintaining a body position	51	12	11		
d420	Transferring oneself	21				
d430	Lifting and carrying objects	36	21			30
d440	Fine hand use		29			30
d445	Hand and arm use	12	29			30
d450	Walking	46	52	32		36
d455	Moving around	52	55	16		30
d460	Moving around in different locations		10			
d470	Using transportation		14			
d475	Driving	11	38			
d498	Mobility, other specified	44		14		30
d510	Washing oneself		29			21
d520	Caring for body parts		12			
d540	Dressing	53	33	14		30
d550	Eating		24			26
d570	Looking after one's health	14	17			
d620	Acquisition of goods and services		48			28
d630	Preparing meals		36			
d640	Doing housework	33	52			29
d650	Caring for household objects	13	43			25
d699	Domestic life, unspecified					21
d760	Family relationships	13	12			
d770	Intimate relationships	36				
d850	Remunerative employment		14			
d855	Non-remunerative employment		10			
d859	Work and employment, other specified and unspecified	33				
d870	Economic self-sufficiency		10			
d920	Recreation and leisure	39	57			
d930	Religion and spirituality		10			

LBP = low back pain; CWP = chronic widespread pain; OA = osteoarthritis; OP = osteoporosis; RA = rheumatoid arthritis.

and bones, other specified and unspecified (b729), which was used to link "alkaline phosphatase". This reflects the fact that drug treatment was the intervention type in 101 (94%) of the studies.

Within the *activities and participation* component the most prevalent categories were *changing basic body position* (d410) in LBP, *recreation and leisure* (d920) in CWP, and *walking* (d450) in OA and RA. Interestingly, OP was not represented in any domain of the *activities and participation* component with a frequency of at least 10%. Additionally, the domains d7-d9 which addresses *interpersonal interactions and relationships, education, work and employment, community, social and civic*

Table IV. *Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) categories linked to the concepts contained in the outcome measures for the ICF component environmental factors*

ICF code	ICF category title	LBP (n = 129)	CWP (n = 42)	OA (n = 176)	OP (n = 107)	RA (n = 382)
e110	Products or substances for personal consumption	56	24		11	14
e115	Products and technology for personal use in daily living		21			25
e120	Products and technology for personal indoor and outdoor mobility and transportation	30	24			26
e310	Immediate family		10			
e320	Friends		10			
e355	Health professionals	13	12			
e398	Support and relationships, other specified	15				
e580	Health services, systems and policies	20				

LBP = low back pain; CWP = chronic widespread pain; OA = osteoarthritis; OP = osteoporosis; RA = rheumatoid arthritis.

life were not endorsed by a frequency of at least 10% in OA and RA.

Similarly, in OA, OP, and RA the *environmental factors* domains e2–e5, covering *natural environment, support and relationships, attitudes* and *services, systems and policies*, were not covered by a frequency of at least 10% in the studies.

The broadest spectrum of ICF-categories was found in RA, the narrowest in OP (data not shown). In RA all domains were represented by at least 1 ICF category except for the domain *structures of the nervous system* (s1). Conceptually, we would have expected a spectrum in CWP as broad as in RA. The reason might be that only 42 studies could be included into the review in CWP compared to 382 studies in RA.

The outcome measures used in the studies influence the spectrum and frequency of concepts linked to the ICF categories. Also the choice of an outcome measure may depend on the intervention studied or the subset of disease included. The results of this systematic review therefore have to be interpreted with caution and have to be put in the perspective. For example, for LBP and CWP the spectrum and frequency of concepts may better reflect the burden of the disease than in OP. The validity of our findings for LBP, CWP, RA and OA is underlined by the fact that the most frequent outcome measures corresponded to the most widely used and recommended condition-specific health status measures (1, 2, 30, 31). Instead, in OP the majority of studies were drug trials focusing on bone density and alkaline phosphatase and not functioning. Therefore, the results for OP are difficult to interpret.

It is beyond the scope of this paper to discuss whether the outcome measures used and therefore the concepts linked to the ICF in this study are appropriate for specific study questions and whether or not they adequately represent the patient experience. However, our findings indicate a need to define "what should be measured" in RCTs to allow for a more comprehensive and comparable comparison of patient populations across studies and interventions. In OP there seems to be a need to include patient-oriented measures.

In conclusion, the ICF provides a useful reference to identify and quantify the concepts within the outcome measures used in RCTs for interventions in LBP, CWP, OA, OP and RA. The spectrum of concepts was widest for RA and narrowest for OP.

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