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ORIGINAL REPORT

VALIDATION OF THE COMPREHENSIVE ICF CORE SET FOR RHEUMATOID ARTHRITIS: THE PERSPECTIVE OF PHYSICIANS

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Objective: **The "Comprehensive ICF Core Set for rheumatoid arthritis" represents the typical spectrum of problems in functioning of patients with rheumatoid arthritis according to the International Classification of Functioning, Disability and Health (ICF). The objective of this study was to validate this ICF Core Set from the perspective of physicians.**

Methods: **Physicians experienced in rheumatoid arthritis treatment were asked about the problems they commonly treat in patients with rheumatoid arthritis in a 3-round survey using the Delphi technique. Responses were linked to the ICF.**

Results: **Seventy-nine physicians in 41 countries named 512 patients' problems. Two hundred and 27 ICF categories were linked to these answers. Twenty-six ICF categories were not represented in the Comprehensive ICF Core Set for rheumatoid arthritis and 19 aspects were not covered by the ICF.**

Conclusion: **The content validity of 3 ICF components was well supported. However, several body functions were identified that are not covered and need to be investigated further.**

Key words: Comprehensive ICF Core Set for rheumatoid arthritis; International Classification of Functioning, Disability and Health (ICF); rehabilitation; rheumatoid arthritis; Delphi method.

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INTRODUCTION

Rheumatoid arthritis (RA), which is the most common rheumatic disease, has a worldwide prevalence of 1% and mostly affects women (1). The course of the disease varies from relapsing-remitting pattern to persistent and even rapidly progressive disease activity (2). Patients' complaints range from pain and morning stiffness to functional impairments, which may lead to difficulties in everyday life, including leisure-time activity, as well as the performance of social roles (3). Furthermore, such impairments affect the patient's psychological status, frequently resulting in depression and anxiety disorders (4).

Considering the variety of areas of life influenced by RA, a multidisciplinary approach is obligatory. Besides medical care offered by rheumatologists and general practitioners, psychologists, physical and occupational therapists are involved in rehabilitation (5). For medical practitioners the cornerstone of treatment is pharmacotherapy with the treatment goal of clinical remission for new-onset illness or a disease activity as low as possible for longer courses (6). Moreover, physical medicine and surgical interventions are part of medical RA treatment.

To optimize interventions aimed at maintaining functioning and minimizing disability, a proper understanding of the patients' functioning and health status is needed. The International Classification of Functioning, Disability and Health (ICF) provides a useful framework for achieving this understanding (7). According to the ICF, a health condition affects and can be influenced by body structures and body functions and the patient's activities and participation in everyday life. Contextual factors, such as environmental and personal factors, modify health states and the development of disability (7). All of these factors are divided according to the classification into two main parts, Functioning and Disability and Contextual Factors. Each of these parts consists of 2 components, the former of Body Functions (b) and Body Structures (s) as well as Activities and Participation (d), the latter of Environmental Factors (e) and Personal Factors, which are not yet classified due to their social and cultural variety. Body Functions and Body Structures are structured by body systems. Activities and Participation represents the capacity and performance of a person to execute tasks and regards both the individual perspective as well as the environmental perspective. The fourth domain, Environmental Factors, is about aspects that either facilitate or worsen functioning and disability, including products, economic and social issues. Each of the classified components consists of consecutively numbered chapters, representing the first level of classification. Within every chapter second, third and fourth levelled classification can be reached, gaining a higher precision the higher the level of classification. This means that a more detailed higher-level category covers

all the aspects applicable for the lower-level category, of which it is a member, but not vice versa.

Both the content and the structure of the ICF indicate its potential value for the health professions involved in RA care (8). However, since the ICF classification as a whole is composed of more than 1400 categories, an application in clinical routine is not feasible. To facilitate the implementation of the ICF in clinical practice, ICF Core Sets for a number of health conditions, including RA (9), have been created. The development of the ICF Core Sets follows a standard approach that includes a formal decision-making and consensus process integrating evidence gathered from preparatory studies by experts consisting of health professionals (10). The Comprehensive ICF Core Set for RA includes a set of 96 categories out of the whole ICF covering the typical spectrum of problems in functioning in patients with RA (9). Based on the Comprehensive ICF Core Set for RA, the impairments, limitations in activities, restrictions in participation and the influential environmental factors of a determined patient can be described and a functioning profile created serving as a reference for follow-up and the management of a co-ordinated longitudinal care among the different health professionals involved (11).

Until now, several studies have tested the feasibility (12), reliability (13), and content validity of the Comprehensive ICF Core Set for RA from the patients' perspective (14) as well as the content validity from the perspective of physical therapists (15), occupational therapists (16), psychologists (17) and nurses (18). However, it remains unclear whether the Comprehensive ICF Core Set for RA is a valid tool from the perspective of physicians. One major aspect of content validity from the perspective of physicians is that their interventions applied to patients with RA are sufficiently represented in the Comprehensive ICF Core Set for RA. Consequently, this study firstly intends to identify the patients' problems, resources and aspects of environment treated by physicians and, secondly, to analyse how these aspects are represented by the current Comprehensive ICF Core Set for RA.

PATIENTS AND METHODS

The Delphi technique was applied in this study to achieve information on the investigated topic from a panel of physicians. It was conducted by e-mail in 3 rounds. The advantages of this technique are anonymity, to avoid dominance of single individuals in a group, as well as controlled feedback, demonstrating the distribution of the group's and each individual's responses. Moreover, it is an iterative process allowing panel members to reconsider their opinions in subsequent rounds (19).

Recruitment of participants

A pool of more than 6000 potential participants was created based on member lists of the European League Against Rheumatism (EULAR), the American College of Rheumatology (ACR) and other rheumatology associations, lists of international congress participants and cooperation partners of the ICF Research Branch as well as personal contacts. An available e-mail and/or fax number was a prerequisite for participation. In a first step, for each country, in case there were more than 10 persons in the pool, 10% were randomly selected; otherwise one was selected. The first contact included an invitation to co-operate and a detailed description of the project's targets, structure and course. If the selected person could not be recruited due to contact problems, refused to participate, or did not meet the deadline of one week, in a second step, another person from the respective country was picked at random from the pool and contacted. To guarantee that the participants in the study were "informed individuals" concerning RA treatment, the initial letter noted that participants should be "physicians experienced in the treatment of RA". Only physicians who agreed to participate received the questionnaire for the first Delphi round.

Delphi process

The process and verbatim questions of the e-mail survey using the Delphi technique are shown in Fig. 1. The participants had 4 weeks to e-mail their responses for each round. Reminders were sent, on average, 3 days before and one week after the predetermined date. In round 1 of the Delphi procedure an information letter and an Excel file containing an open-ended questionnaire requesting a list of all the patients' problems, patients' resources and aspects of environment treated by physicians in patients with RA was distributed. Responses were collected and linked to the ICF. In addition, the demographic characteristics and professional experience of the participants were collected. In the second Delphi round, the physicians received a list

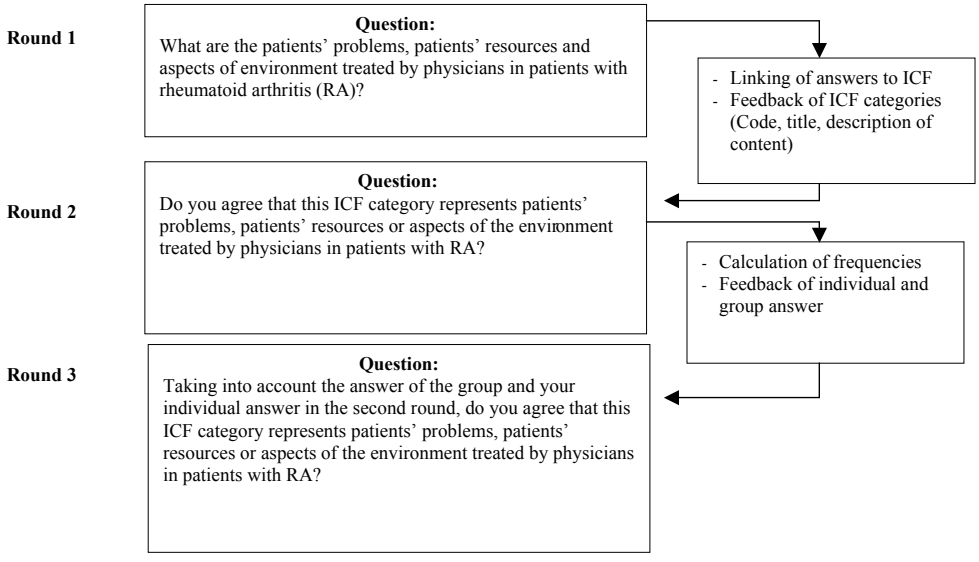

Fig. 1. Description of the Delphi exercise. ICF: International Classification of Functioning, Disability and Health.

of the linked ICF categories resulting from the responses of the first round. The participants were asked to agree or disagree as to whether the respective ICF category represented patients' problems, patients' resources or aspects of the environment treated by physicians in patients with RA.

To maintain a high response rate, the participants in the third Delphi round received only a limited number of the ICF categories included in the second round. This selection was performed using the modified Scree test in order to identify the categories that did not reach an adequate consensus (20). The Scree test includes an examination of a graph of the percentage of agreement among the participants plotted along the ordinate against the ICF categories plotted along the abscissa. A straight edge is placed along the points to see where they form an approximately straight line, the scree line, which divides points above and below the line indicating high consensus regarding the relevance or irrelevance of the corresponding ICF categories or points near the scree line indicating a lack of consensus.

In the third round the selected ICF categories, as well as the proportion and the identification numbers of the participants who have agreed that the categories represent patients' problems, patients' resources or aspects of environment treated by physicians in patients with RA, were sent. The participants were requested to reconsider their previous answers, also taking into account the responses of the group.

Linking

ICF categories are the units of the classification. They are characterized by a specific code consisting of a letter and at least one number. The components Body functions, Body structures, Activities and Participation and Environmental factors (Fig. 2) are represented by the letters b, s, d or e. This letter is followed by a one-digit number indicating the chapter, two additional digits for second level and one digit each for the third and fourth level of precision.

Each concept of the first Delphi round was linked to the most precise ICF category by a trained doctoral student (CG) according to 10 linking rules (21). Thirty percent of the linkage was performed separately by two trained health professionals. Consensus between the health professionals was used to decide which ICF category should be linked to the responses, in case of disagreement with the help of another experienced psychologist (IK) aiming at a joint decision.

Data analysis

The list of ICF categories linked to the participants' responses was compared with the ICF categories included in the Comprehensive ICF Core Set for RA. Only ICF categories that reached a consensus of ≥75% among the participants in the final round were considered. Since no universal agreement on the level of consensus exists (22), based on experience from previous studies (10) this cut-point was considered an appropriate consensus to be achieved. An ICF category identified by the participants was considered as being represented by the Comprehensive ICF Core Set for RA if the identical category or a lower-level category is included in the Core Set. To give an example, the ICF category b1300 Energy level, which was linked to the participants' responses is represented in the Comprehensive ICF Core Set for RA by the second-level category b130 Energy and drive functions.

Statistical methods

Descriptive statistics were used to characterize the sample and frequencies of responses. The agreement between the two individuals, who performed the linking, was described by kappa statistics with bootstrapped confidence intervals (23, 24).

RESULTS

Recruitment and participants

In the first random selection from the expert pool 141 physicians were contacted. Within one week 45 agreed to participate in the study, while 19 refused their participation and 34 e-mail or fax transmissions were undeliverable. The second selection resulted in another 45 participants, 13 physicians turned down their involvement in the study and 12 could not be contacted due to technical reasons (Fig. 3). Seventy-nine of 90 experts (87.8%) who agreed to participate in the study returned a completed first-round questionnaire. For the demographic data and professional information on the participants see Table I.

Delphi process

In the first Delphi round 512 patients' problems, patients' resources and aspects of environment treated by physicians in patients with RA were named. Sixty-four out of 79 (81.0%) participants filled in the second-round questionnaire. From the 272 categories that were included in the second-round

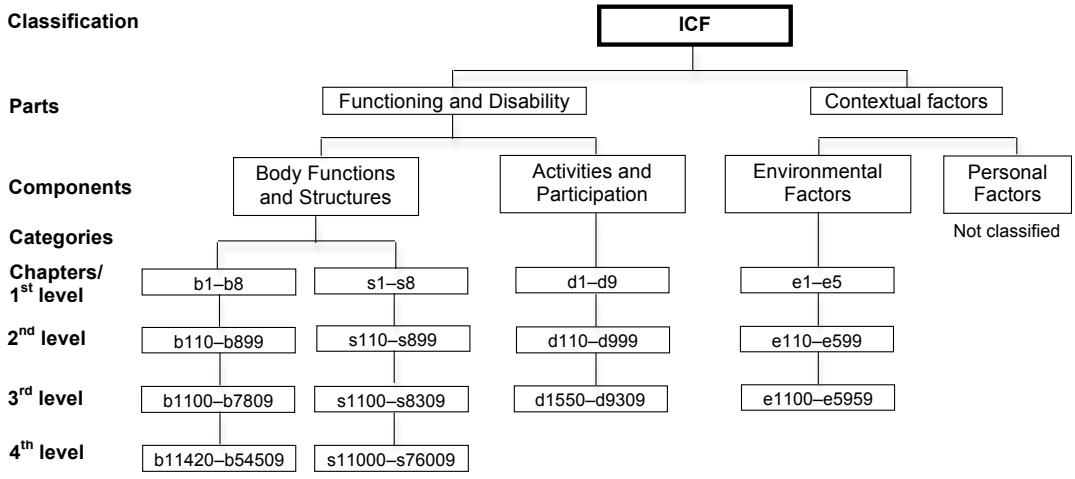

Fig. 2. Structure of the International Classification of Functioning, Disability and Health (7) (permission for reproduction from the World Health Organization).

Table I. *Demographics and professional experience of the round 1 participants*

WHO – Region	Female %	Age Median (Min–Max)	Professional experience years Median (Min–Max)	RA experience years Median[a] (Min–Max)	Self-rating RA Expertise Median (Min–Max)	Mainly treating patients in acute situation[b] (*n*)	Mainly treating patients in post-acute situation[b] (*n*)	Mainly treating patients in chronic situation[b] (*n*)
Europe[d]	20.6	51.5 (38–72)	24.5 (7–40)	21.5 (7–35)	4 (3–5)	20	21	28
Americas[e]	33.0	51.0 (38–66)	24.0 (5–36)	21.0 (7–35)	5 (3–5)	13	15	20
Eastern Mediterranean Region[f]	25.0	45.5 (39–60)	17.0 (5–30)	16.5 (8–27)	4 (3–5)	2	2	4
Africa[g]	0	56.0	32	27	5	Missing	Missing	Missing
South East Asia[h]	0	45.5 (45–46)	19.5 (15–24)	12.5 (5–20)	5 (5)	1	1	2
Western Pacific Region[i]	0	51.0[c] (39–76)	26.0[c] (8–40)	22.0[c] (5–40)	5[c] (4–5)	9[c]	11[c]	14[c]
Total	19.0	51.0 (38–76)	24.0 (5–40)	20.5 (5–40)	5 (3–5)	45	50	68

[a]1 = low 5 = excellent; [b]More answers possible; [c]Data of two participants missing; [d]Armenia, Austria, Belgium, Czech Republic, Denmark, Germany, Finland, France, Greece, Hungary, Italy, Lithuania, Norway, Poland, Romania, Switzerland, Turkey, UK; [e]Argentina, Brazil, Canada, Chile, Cuba, Equador, Mexico, Peru, Uruguay, USA; [f] Egypt, Lebanon, Morocco, Qatar; [g]South Africa; [h]India; [i]Australia, China, Japan, Malaysia, New Zealand, Philippines, South Korea. RA: rheumatoid arthritis.

First random sampling

	EURO	AMER	EMED	AFRI	ASIA	WEPA	Total
Contacted	52	33	14	3	3	36	141
Undeliverable	10	8	7	1	1	7	34
No response	11	8	6	2		16	43
Declined							
– lack of time	4					2	6
– no RA expert	7						7
– lack of interest	1						1
– retired		1					1
– abroad		1					1
– paediatric rheumatologist		2				1	3
Agreed	19	13	1	0	2	10	45

Second random sampling

	EURO	AMER	EMED	AFRI	ASIA	WEPA	Total
Contacted	33	21	13	1	1	27	96
Undeliverable	2	3	3			4	12
No response	7	1	6			12	26
Declined							
– lack of time		2				1	3
– no RA expert		3	1			2	6
– paediatric rheumatologist	2	2					4
Agreed	22	11	3	1	1	7	45

Delphi process

	EURO	AMER	EMED	AFRI	ASIA	WEPA	Total
Total participants first round	41	24	4	1	3	17	90
First Delphi round (Responders)	34	21	4	1	2	17	79
Second Delphi round (Responders)	32	11	4	1	2	14	64
Third Delphi round (Responders)	29	11	4	1	2	14	61

Fig. 3. Description of the sampling and attrition of participants within the Delphi process. EURO: Europe; AMER: Americas; EMED: Eastern Mediterranean Region; AFRI: Africa; ASIA: South East Asia; WEPA: Western Pacific Region.

questionnaire 205 categories were selected for the third-round questionnaire using the Scree test (Fig. 4). Sixty-one out of 64 (95.3%) physicians completed the questionnaire of the third Delphi round.

Linking of the responses to the ICF

All components of the ICF were represented in the participants' responses. Seven fourth-level categories, 19 third-level categories and 42 second-level categories were linked to the component Body functions. Four fourth-level categories, 8 third-level categories and 8 second-level categories were linked to the component Body structures. Fifty-seven third-level categories and 37 second-level categories were linked to the component

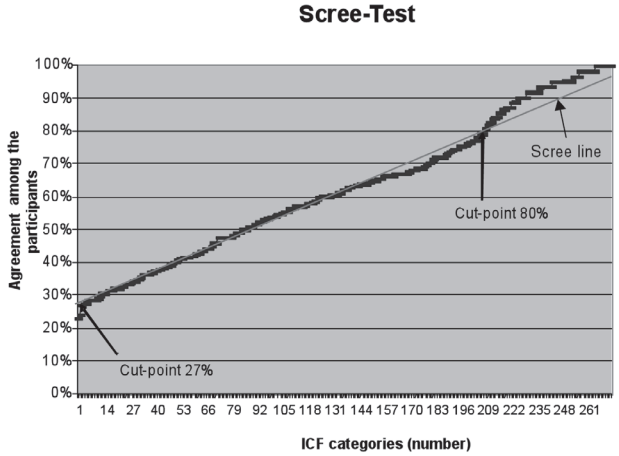

Fig. 4. Selection of International Classification of Functioning, Disability and Health (ICF) categories without clear consensus using the modified Scree test. ICF categories of the second Delphi round were ordered by percentage of expert agreement and plotted. The scree line was placed onto the slope, along the points to determine where they approximately form a straight line. Points close to the scree line indicate an inadequate endorsement. Cut-points were defined as the points were the slope significantly deviates from the scree line. ICF categories with an agreement > 27% and < 80% were included in the third Delphi round.

Table II. *International Classification of Functioning, Disability and Health (ICF) categories that reached an agreement ≥75% among the participants and are represented in the Comprehensive ICF Core Set for rheumatoid arthritis (RA)*

ICF Code				% Agreement in final round
2nd level	3rd level	4th level	Category title	
Body functions				
	b1300		Energy level*	78.7
b134			Sleep functions	90.2
b280			Sensation of pain	90.5
	b2800		Generalized pain	92.1
		b28010	Pain in head and neck	96.8
		b28011	Pain in chest	83.9
		b28012	Pain in stomach or abdomen	88.9
		b28014	Pain in upper limb	98.4
		b28015	Pain in lower limb	98.4
		b28016	Pain in joints	100.0
	b2802		Pain in multiple body parts	91.9
b430			Haematological system functions	93.3
b455			Exercise tolerance functions	86.9
	b4552		Fatiguability	85.7
b510			Ingestion functions	78.7
	b5104		Salivation	93.5
b640			Sexual functions	75.0
b710			Mobility of joint functions	93.5
b715			Stability of joint functions	91.9
b730			Muscle power functions	82.0
	b7300		Power of isolated muscles and muscle groups	88.5
b770			Gait pattern functions	86.9
b780			Sensations related to muscles and movement functions	82.0
	b7800		Sensation of muscle stiffness	86.9
Body structures				
	s7103		Joints of head and neck region	100.0
s730			Structure of upper extremity	95.1
		s73011	Wrist joint	100.0
	s7302		Structure of hand	95.1
		s73021	Joints of hand and fingers	100.0
s750			Structure of lower extremity	95.1
	s7502		Structure of ankle and foot	96.7
		s75021	Ankle joints and joints of foot and toes	100.0
		s76000	Cervical vertebral column	96.7
		s7700	Bones	98.4
		s7701	Joints	100.0
		s7703	Extra-articular ligaments, fasciae, extramuscular aponeuroses, retinacula, septa, bursae, unspecified	96.7
s810			Structure of areas of skin	78.7
	s8102		Skin of upper extremity	78.7
	s8104		Skin of lower extremity	78.7
Activities and participation				
d410			Changing basic body position	83.6
	d4100		Lying down	82.0
	d4101		Squatting	81.4
	d4102		Kneeling	85.0
	d4103		Sitting	86.4
	d4104		Standing	86.7
	d4105		Bending	83.6
	d4153		Maintaining a sitting position	78.7
	d4154		Maintaining a standing position	83.3
	d4300		Lifting	86.7
	d4301		Carrying in the hands	83.3
	d4302		Carrying in the arms	83.3
	d4303		Carrying on shoulders, hip and back	79.7
d440			Fine hand use	85.0
	d4400		Picking up	83.3
	d4401		Grasping	85.0
	d4402		Manipulating	83.3
d445			Hand and arm use	84.7
	d4452		Reaching	83.1
	d4453		Turning or twisting the hands or arms	85.0
d450			Walking	84.7
	d4500		Walking short distances	81.4
	d4502		Walking on different surfaces	76.7
d455			Moving around	76.7
	d4551		Climbing	78.3
d460			Moving around in different locations	80.0
d465			Moving around using equipment	75.9
d510			Washing oneself	83.3
	d5101		Washing whole body	81.4
d520			Caring for body parts	81.4
	d5202		Caring for hair	80.0
d530			Toileting	81.4
d540			Dressing	87.9
	d5400		Putting on clothes	79.7
	d5401		Taking off clothes	81.4
	d5403		Taking off footwear	83.1
d550			Eating	78.0
d560			Drinking	83.3
	d5702		Maintaining one's health	78.0
Environmental factors				
	e1101		Drugs	76.7
	e1151		Assistive products and technology for personal use in daily living	85.0
e120			Products and technology for personal indoor and outdoor mobility and transportation	75.0
	e1201		Assistive products and technology for personal indoor and outdoor mobility and transportation	75.0
e355			Health professionals	96.7
	e5800		Health services	90.0
	e5801		Health systems	83.3
	e5802		Health policies	77.6

*This category is represented in the Comprehensive ICF Core Set for RA by a lower-level (less specific) category.

Activities and Participation and 19 third-level categories as well as 26 second-level categories were linked to the component Environmental factors. Twenty-six aspects were named that could be attributed to the not-yet-developed component Personal factors. Nineteen responses were not covered by the ICF. The kappa statistics for the linking was 0.74 with a 95% bootstrapped confidence interval of 0.72–0.75.

Representation of the physicians' responses in the Comprehensive ICF Core Set for rheumatoid arthritis

In total, from the 227 ICF categories linked to the participants' responses, 102 reached an agreement ≥ 75% in the final round and were considered for comparison with the current Comprehensive ICF Core Set for RA. Seventeen ICF categories of the component Body functions are represented in

the Comprehensive ICF Core Set for RA at the same level of classification. Several responses were linked to more detailed, third- or fourth-level ICF categories, e.g. b28012 Pain in stomach or abdomen, which is represented in the Comprehensive ICF Core Set for RA by the third-level category b2801 Pain in body part (see Table II). Fifteen ICF categories are found to be not represented in the Comprehensive ICF Core Set for RA (Table III).

Of the component Body structures 15 ICF categories reached an agreement of 75% or above. All of them are represented in the Comprehensive ICF Core Set for RA, either at the same level of classification (8 categories) or a lower level (7 categories) (Table II).

Of the 39 ICF categories from the ICF component Activities and Participation, which reached an agreement ≥ 75%, 13 are included at the same level of the classification and 26 more detailed, third-level categories are represented in the Comprehensive ICF Core Set for RA by their corresponding second-level categories (Table II). One ICF category is not represented in the Comprehensive ICF Core Set for RA (Table III).

Of the component Environmental factors 8 categories reached an agreement ≥ 75%. Of these, two categories are included at the same level of classification in the Comprehensive ICF Core Set for RA, whereas 6 categories were represented at a different level of the classification (Table II).

Twenty-three responses were assigned to the not-yet-developed ICF component Personal factors and reached an agreement surpassing 75%. All of these concepts addressed either health conditions that are often associated with RA, such as Sjögren's syndrome, osteoporosis, cardiovascular diseases, and depression or factors that describe the patients' way of dealing with their condition, such as coping and knowledge of disease/treatment (Table IV).

Eighteen responses of the participants, which reached an agreement ≥ 75% were found not to be covered by the ICF (Table V).

DISCUSSION

The components Body structures, Activities and Participation and Environmental Factors of the current version of the Comprehensive ICF Core Set for RA were almost perfectly supported by the participants in our study. However, regarding the component Body functions, some aspects were identified that are not yet included in the Comprehensive ICF Core Set for RA.

A considerable number of those categories could be related to pharmacological side-effects. Cardiovascular dysfunctions and obesity, addressed by the ICF categories b410 Heart functions, b415 Blood vessel functions, b420 Blood pressure functions and b539 Weight maintenance functions, can be associated with the intake of glucocorticoids (25). Furthermore the application of immunosuppressive tumour necrosis factor alpha (TNFα) antagonists is a main risk factor in the development of severe infections, for example pneumonia caused by opportunistic pathogen *Pneumocystis carinii* (26), addressed by the category b435 Immunological system functions. Moreover, a number of substances used in RA therapy, especially non-steroidal anti-inflammatory drugs (NSAIDs), have gastrointestinal

Table III. *International Classification of Functioning, Disability and Health (ICF) categories which reached an agreement ≥ 75% among the participants and are not represented in the Comprehensive ICF Core Set for rheumatoid arthritis*

ICF Code				% Agreement in final round
2nd level	3rd level	4th level	Category Title	
Body functions				
b220			Sensations associated with the eye and adjoining structures	82.5
b410			Heart functions	90.2
b415			Blood vessel functions	86.9
b420			Blood pressure functions	93.4
	b4200		Increased blood pressure	94.9
b435			Immunological system functions	90.5
b440			Respiration functions	91.7
b460			Sensations associated with cardiovascular and respiratory functions	78.3
b515			Digestive functions	77.0
b530			Weight maintenance functions	87.3
	b6601		Functions related to pregnancy	88.5
	b6700		Discomfort associated with sexual intercourse	78.3
b720			Mobility of bone functions	90.3
	b7200		Mobility of scapula	88.3
b840			Sensation related to the skin	80.3
Activities and participation				
d435			Moving objects with lower extremities	78.0

Table IV. *Personal factors that reached an agreement ≥ 75% among the participants*

Answer	% Agreement in final round
Knowledge of disease/treatment	98.4
Osteoporosis	98.4
Sjögren's syndrome	98.4
Amyloidosis	95.2
Feltys syndrome	95.2
Other articular manifestations	95.2
Pulmonary diseases	95.2
Cardiovascular diseases	93.7
Gastrointestinal diseases	93.7
Comorbidities	93.4
Pleural manifestations	92.1
Fever	90.5
Neuropathies	90.5
Risk factors	88.9
Depression	87.3
Fibromyalgia	87.3
Eye-related diseases	85.7
Coping	84.2
Sepsis	84.1
Sexual health	81.4
Stamina	81.4
Diabetes	81.0
Self-esteem	78.0

Table V. *Aspects not covered by the ICF that reached an agreement ≥ 75% among the participants*

Answer	% Agreement in final round
Inflammation	100.0
Treatments	100.0
Deformities	98.4
Swelling	98.4
Diagnosis	95.2
Prognosis	95.2
Skin nodules	95.2
Exacerbation	93.7
Infections	93.7
Educating health professionals	92.1
Patients' education	92.1
Monitoring	88.7
Family counselling	86.4
Aetiology	84.7
Prevention	84.7
Oedema	82.5
Counselling of educational environment	79.7
Risk for family members	78.0

side-effects that require further interventions by physicians, such as prescription of gastroprotective drugs or switch to COX-2 selective inhibitors such as celecoxib (27). Thus, it is not surprising that the ICF category b515 Digestive functions was considered relevant by the participants in this study. Since ICF categories representing side-effects of medication are not merely found to be relevant for physicians but also for patients (14) the question arises whether those ICF categories should be included in the Comprehensive ICF Core Set for RA. As discussed by Coenen et al. (14) one should bear in mind that the ICF Core Sets establish the standards of "what to measure" in patients with RA independent of the treatment. Moreover, as these problems evoked by pharmacotherapy are avoidable by a change in substances, there is a certain risk of biasing the immediate consequences of RA by focusing too much on indirectly related, mainly extraarticular conditions, which are not as common in the regular disease course as articular pathologies and therefore should not be taken into consideration in the Core Set. On the other hand, side-effects of medication belong to the reality of patients with RA and their physicians. Perhaps the development of treatment-specific Core Sets could be a solution for this dilemma.

The respiratory tract and its sensations, addressed by the ICF categories b440 Respiration functions as well as b460 Sensations associated with cardiovascular and respiratory functions, represent another area to which the Comprehensive ICF Core Set for RA does not provide any reference. RA is often accompanied by impairments of the airways, ranging from obstruction and small airways disease to morphological changes such as air trapping and bronchiectasis (28).

Furthermore, more than 80% of the experts in this study agreed that b220 Sensation associated with the eye and adjoining structures is one of the intervention targets of physicians, although it is not included in the Comprehensive ICF Core Set for RA. The literature clearly supports a close relationship between RA and ocular symptoms, including a feeling of dryness resulting from secondary Sjogren's syndrome as well as episcleritis and other ophthalmopathies (29).

As RA affects predominantly females and represents no contraindication to pregnancy, a reference to this aspect by inclusion of b6601 Functions related to pregnancy in the Comprehensive ICF Core Set for RA should be discussed. Recent studies have shown that a multidisciplinary approach to monitor pregnancy and RA is recommendable, since women with RA have a higher risk for complications such as hypertensive disorder and Caesarean section (30). Moreover, potential adverse effects of drug therapy have to be considered and therefore a change in therapy might be necessary.

Sexual dissatisfaction and a lack of sexual desire, as well as difficulties in sexual performance, are quite common among patients with RA. The reasons are pain, stiffness and depressive states. Consequently, rheumatologists are requested to discuss this topic too, which is addressed by the not-yet-included category b6700 Discomfort associated with sexual intercourse (31).

Regarding the classic manifestations of RA, the Comprehensive Core Set for RA provides a detailed range of categories in the component Body functions; however, b720 Mobility of bone functions and b7200 Mobility of the scapula cannot be found. In fact, it is essential that physicians consider bone abnormalities in the management of RA owing to the increased risk of fracture and potential complications in the surgical reconstruction of affected joints (32). It has been demonstrated that patients profit from surgical interventions aimed at the shoulder, if conservative management fails (33).

Lastly, a large number of participants named the category b840 Sensation related to the skin. Pruritus may be both caused by dryness of the skin due to Sjogren's comorbidity and can be a side-effect of oral gold salts (34, 35). Since a dermatological assessment is often part of treatment, an inclusion in the Comprehensive ICF Core Set for RA might be useful.

Many of the patients' problems treated by physicians were represented by categories assigned to the component Activities and Participation and are predominantly already considered in the current version of the Comprehensive ICF Core Set for RA. Only d435 Moving objects with lower extremities is not yet included. Indeed, even at an early stage of the disease patients with RA show impairments in structure and functioning of the feet, such as reduced ankle plantarflexion power, which can lead to restrictions such as pushing pedals on a bicycle (36). On the other hand, problems with riding a bicycle are covered by the ICF category d475 Driving which is already part of the Comprehensive ICF Core Set for RA.

A notable number of the participants' responses were identified as Personal Factors. According to the ICF language personal factors are contextual factors that relate to the individual such as age, gender, character and coping styles (7). There is a clear consensus that coping and self-efficacy as well as concomitant health conditions such as depression, are strongly related to RA patients' health perception, reactions to pain and mood, and therefore influence disability (37, 38). However, although reaching a considerable agreement between the participants, many of the mentioned personal factors are

more likely to require psychological intervention than medical ones (17). Nevertheless, the findings stress the need to develop the ICF component Personal factors to obtain a comprehensive and complete description of relevant aspects influencing a patient's functioning and health.

Regarding methods, the Delphi technique was an appropriate method for this study objective. The response rates exceeding 80% in each round were satisfactory and comparable with the response rates reached in studies with similar design (15–18).

However, the external validity of this study is limited. Participants from all of the 6 world regions defined by the World Health Organization could be recruited, guaranteeing a wide range of expert opinion. Even though the African region seems to be underrepresented by only one participant, this may reflect a potential lack of RA specialists in this region. However, the sample of physicians is not representative for all RA physicians worldwide.

Another limitation refers to the 75% definition of level of consensus. Although no universally agreed definition exists and its selection was based on the experiences with previous ICF studies, it still remains, to some extent, arbitrary and therefore is open to debate.

In conclusion, this study as well as the studies involving the perspectives of other health professionals, such as physical therapists (15), occupational therapists (16), nurses (18), and psychologists (17), largely confirmed the current version of the Comprehensive ICF Core Set for RA on the one hand. On the other hand, each profession identified several ICF categories not yet covered by the Comprehensive ICF Core Set for RA. Some results of this study could be supported by other professions, for example the importance of categories b539 Weight maintenance functions or b435 Immunological system functions, also stressed by nurses (18). Other aspects that were not identified by the panel of physicians, for example b1266 Confidence, were considered important by professions specifically dealing with such issues, such as occupational therapists and psychologists (16, 17). Consequently, two approaches for a further improvement of the Comprehensive ICF Core Set for RA could be discussed: first, an enlargement by adding all identified ICF categories not yet covered, allowing health professionals to select the ICF categories most relevant for their profession, or secondly, the development of profession-specific modules that may be used in addition to the current version of the Comprehensive Core Set for RA.

Besides this decision, future projects should focus on the development of summary scores that combine the information of all single ICF categories into a few numbers to facilitate the application of the Comprehensive Core Set for RA in clinical practice. Data collected within the ongoing international validation study will be used to develop such scores as recently demonstrated for the ICF Core Sets for Osteoarthritis (39). Finally, as the Comprehensive ICF Core Set for RA defines "what to measure" but not "how to measure", future studies could focus on the operationalization of the ICF categories and identify appropriate measures and instruments to assess all single aspects of functioning covered by the Comprehensive ICF Core Set for RA.

REFERENCES

1. Firestein GS. Etiology and pathogenesis of rheumatoid arthritis. In: Ruddy S, Harris ED, Sledge CB, editors. Kelley's textbook of rheumatology. Philadelphia: WB Saunders Co.; 2001, p. 921.
2. Eberhardt K, Fex E. Clinical course and remission rate in patients with early rheumatoid arthritis: relationship to outcome after 5 years. Br J Rheumatol 1998; 37: 1324–1329.
3. Fex E, Larsson BM, Nived K, Eberhardt K. Effect of rheumatoid arthritis on work status and social and leisure time activities in patients followed 8 years from onset. J Rheumatol 1998; 25: 44–50.
4. Monaghan SM, Sharpe L, Denton F, Levy J, Schrieber L, Sensky T. Relationship between appearance and psychological distress in rheumatic diseases. Arthritis Rheum 2007; 57: 303–309.
5. Uhlig T, Christie A. Specialized rehabilitation of patients with rheumatoid arthritis. Tidsskr Nor laegeforen 2007; 127: 313–315.
6. Blom M, van Riel PL. Management of established rheumatoid arthritis with an emphasis on pharmacotherapy. Best Pract Res Clin Rheumatol 2007; 21: 43–57.
7. World Health Organization. ICF – International Classification of Functioning, Disability and Health. Geneva: World Health Organization; 2001.
8. Weigl M, Cieza A, Kostanjsek N, Kirschnek M, Stucki G. The ICF comprehensively covers the spectrum of health problems encountered by health professionals in patients with musculoskeletal conditions. Rheumatology (Oxford) 2006; 45: 1247–1254.
9. Stucki G, Cieza A, Geyh S, Battistella L, Lloyd J, Symmons D, Kostanjsek N, Schouten J. ICF Core Sets for rheumatoid arthritis. J Rehabil Med Suppl 2004; 44: 87–93.
10. Cieza A, Ewert T, Uestün B, Chatterji S, Kostanjsek N, Stucki G. Development of ICF Core Sets for patients with chronic conditions. J Rehabil Med 2004; Suppl 44: 9–11.
11. Steiner WA, Ryser L, Huber E Uebelhart D, Aeschlimann A, Stucki G. Use of the ICF Model as a clinical problem-solving tool in physical therapy and rehabilitation medicine. Physical Ther 2002; 82: 1098–1107.
12. Stucki G, Grimby G. Foreword: applying the ICF in medicine. J Rehabil Med Suppl 2004; 44: 5–6.
13. Uhlig T, Lillemo S, Moe RH, Stamm T, Cieza A, Boonen A, et al. Reliability of the ICF core set for rheumatoid arthritis. Ann Rheum Dis 2007; 66: 1078–1084.
14. Coenen M, Cieza A, Stamm TA, Amann E, Kollerits B, Stucki G. Validation of the International Classification of Functioning, Disability and Health (ICF) Core Set for rheumatoid arthritis from the patient perspective using focus groups. Arthritis Res Ther 2006; 8: R84.
15. Kirchberger I, Gläßel A, Cieza, A, Stucki G. Validation of the Comprehensive ICF Core Set for rheumatoid arthritis: the perspective of physical therapists. Phys Ther 2007; 87: 368–383.
16. Kirchberger I, Stamm T, Cieza A, Stucki G. Does the Comprehensive Core Set for rheumatois arthritis capture occupational therapy practice? A content-validity study. Can J Occup Ther 2007; 74: 267–280.
17. Kirchberger I, Cieza A, Stucki G. Validation of the Comprehensive ICF Core Set for rheumatoid arthritis: the perspective of psychologists. Psychol Health 2008; 23: 639–659.
18. Rauch A, Kirchberger I, Cieza A, Stucki G. Does the Comprehensive International Classification of Functioning, Disability and Health (ICF) Core Set for rheumatoid arthritis capture the nursing practice? A Delphi survey. Int J Nurs Stud 2009; 46: 1320–1334.
19. Linstone HA, Turoff M, editors. The Delphi technique: techniques and applications. London: Addison Wesley; 1975.
20. Zoski K, Jurs S. Priority determination in surveys. An application of the scree test. Evaluation Rev 1990; 14: 214–219.
21. Cieza A, Geyh S, Chatterji S, Kostanjsek N, Üstün B, Stucki G. ICF linking rules: an update based on lessons learned. J Rehabil Med 2005; 37: 212–218.
22. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs 2000; 32: 1008–1015.

23. Cohen J. A coefficient of agreement for nominal scales. Educat Psycholog Measure 1960; 20: 37–46.
24. Vierkant RAA. SAS Macro for calculating bootstrapped confidence intervals about a kappa coefficient. 2004 [cited 2004 Jul 23]. Available from: URL: http://www2.sas.com/proceedings/sugi22/STATS/PAPER295.PDF.
25. Davis JM 3rd, Maradit Kremers H, Crowson CS, Nicola PJ, Ballman KV, et al. Glucocorticoids and cardiovascular events in rheumatoid arthritis: a population-based cohort study. Arthritis Rheum 2007; 56: 820–830.
26. Strangfeld A, Listing J. Infection and musculoskeletal conditions: bacterial and opportunistic infections during anti-TNF therapy. Best Pract Res Clin Rheumatol 2006; 20: 1181–1195.
27. Silverstein FE, Faich G, Goldstein JL, Simon LS, Pincus T, Whelton A, et al. Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis: the CLASS study: a randomized controlled trial. Celecoxib Long-term Arthritis Safety Study. JAMA 2000; 284: 1247–1255.
28. Perez T, Remy-Jardin M, Cortet B. Airways involvement in rheumatoid arthritis: clinical, functional, and HRCT findings. Am J Respiratory Critical Care Med 1998; 157: 1658–1665.
29. Reddy SC, Rao UR. Ocular complications of adult rheumatoid arthritis. Rheumatol Int 1996; 16: 49–52.
30. Chakravarty EF, Nelson L, Krishnan E. Obstetric hospitalizations in the United States for women with systemic lupus erythematosus and rheumatoid arthritis. Arthritis Rheum 2006; 54: 899–907.
31. Abdel-Nasser AM, Ali EI. Determinants of sexual disability and dissatisfaction in female patients with rheumatoid arthritis. Clin Rheumatol 2006; 25: 822–830.
32. Bogoch ER, Moron EL. Bone abnormalities in the surgical treatment of patients with rheumatoid arthritis. Clin Orthopaed Rel Res 1999; 366: 8–21.
33. Clayton ML, Ferlic DC. Surgery of the shoulder in rheumatoid arthritis. A report of nineteen. Clin Orthopaed Rel Rres 1975; 106: 166–174.
34. Provost TT, Watson R. Cutaneous manifestations of Sjogren's syndrome. Rheum Dis Clinics North Am 1992; 18: 609–616.
35. Bonnetblanc JM. Cutaneous reactions to gold salts. Presse Med 1996; 25: 1555–1558.
36. Turner DE, Helliwell PS, Emery P, Woodburn J. The impact of rheumatoid arthritis on foot function in the early stages of disease: a clinical case series. BMC Musculoskel Dis 2006; 7: 102.
37. Conner TS, Tennen H, Zautra AJ, Affleck G, Armeli S, Fifield J, et al. Coping with rheumatoid arthritis pain in daily life: within-person analyses reveal hidden vulnerability for the formerly depressed. Pain 2006; 126: 198–209.
38. Lefebvre JC, Keefe FJ, Affleck G, Affleck G, Armeil S, Fifield J. The relationship of arthritis self-efficacy to daily pain, daily mood, and daily pain coping in rheumatoid arthritis patients. Pain 2006; 80: 425–435.
39. Cieza A, Hilfiker R, Chatterji S, Kostanjsek N, Ustün BT, Stucki G. The International Classification of Functioning, Disability, and Health could be used to measure functioning. J Clin Epidemiol 2009; 62: 899–911.