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Validation of the Comprehensive ICF Core Set for Rheumatoid Arthritis: The Perspective of Physicians

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1. Deutsche Zusammenfassung

Hintergrund: Das umfassende ICF Core Set für Rheumatoide Arthritis ist eine klinische Anwendung der Internationalen Klassifikation für Funktionsfähigkeit, Behinderung und Gesundheit (ICF) und stellt das typische Spektrum an Funktionsproblemen von Patienten mit Rheumatoider Arthritis dar.

Ziel: Das Ziel der Studie besteht in der Validierung dieses Core Sets aus der Perspektive von Ärzten.

Methoden: In der Behandlung der Rheumatoiden Arthritis erfahrene Ärzte wurden zu den Problemen und Ressourcen der Patienten, sowie den Umweltfaktoren auf die Ärzte in der Behandlung Einfluss nehmen, befragt. Die Befragung erfolgte in drei Runden nach der Delphi Methode per elektronischer Postzustellung (E-Mail). Die Antworten wurden nach definierten Übersetzungsregeln von zwei darin erfahrenen Mitarbeiterinnen in die Sprache der ICF übersetzt. Der Grad der Übereinstimmung dieser Ergebnisse wurde anhand des statistischen Wertes nach Kappa berechnet.

Resultate: 79 Ärzte aus 41 Ländern nannten 512 Probleme von Patienten, die alle ICF Komponenten abdeckten. 227 ICF Kategorien wurden zu diesen Antworten gelinkt. 16 ICF Kategorien waren nicht im umfassenden ICF Core Set für Rheumatoide Arthritis enthalten, obwohl mindestens 75% der Teilnehmer diese als wichtig erachteten. 19 Sachverhalte wurden nicht durch die ICF Klassifikation abgedeckt und 26 Antworten wurden zu der ICF Komponente „Personenbezogene Faktoren“ gelinkt, die bisher noch nicht in der ICF klassifiziert ist.

Schlussfolgerung: Die Validität der Komponenten „Körperstrukturen“, „Aktivitäten und Teilnahme“ und „Umweltfaktoren“ wurde nahezu vollständig von den Ärzten bestätigt, wohingegen die Validität der Komponente „Körperfunktionen“ geringere Unterstützung fand. Einige Sachverhalte kamen zutage die weiterer Untersuchung bedürfen.

2. Abstract

Objective: The “Comprehensive ICF Core Set for Rheumatoid Arthritis (RA)” is an application of the International Classification of Functioning, Disability and Health (ICF) and represents the typical spectrum of problems in functioning of patients with RA. The objective of this study was to validate this ICF Core Set from the perspective of physicians.

Methods: Physicians experienced in RA treatment were asked about the patients’ problems, patients’ resources and aspects of environment from their scope of practice. This survey was conducted via e-mail in three rounds using the Delphi technique. The responses were linked to the ICF by two trained individuals according to empirically tested linking rules. Consensus of the results was calculated statistically by the statistical Kappa coefficient.

Results: 79 physicians in 41 countries named 512 patients’ problems spanning all ICF components. 227 ICF categories were linked to the physicians’ responses. 16 ICF categories were not represented in the Comprehensive ICF Core Set for RA although at least 75% of the participants have rated them as important. 19 issues were not covered by the ICF classification and 26 answers were linked to the not yet developed ICF component Personal factors.

Conclusion: The validity of the ICF components Body Structures, Activities and Participation and Environmental Factors was well supported by the physicians whereas there was less support for the validity of the component Body Functions. Several issues arose that are not covered and need to be investigated further.

3. INTRODUCTION

3.1 Pathogenesis and clinical picture of rheumatoid arthritis

The first cases of rheumatoid arthritis (RA) seem to go back to 4500 A.C., dated by bone findings of native American inhabitants in Tennessee (www.bms.ch/cps/rde/xchg/SID-3E93EC07-EE3470C5/bmsch_de/hs.xsl/2935.htm). RA represents the most common rheumatic disease with a worldwide prevalence of 1% and mostly affects women. In comparison to men women run a risk twice as high for RA with middle incidence rates of approximately 54/100.00 per year for women respectively 24.5/100.000 per year for men. These prevalence rates are based on estimates of a five-year period from the first onset and with regular assessment of RA criteria. Age-related trends show that there is a significant rise in RA incidence for women above the age of 45 with up to 90/100.000 per year (Klippel, 2001; Ruddy, Harris & Sledge, 2001; Wiles et al., 1999).

Rheumatoid arthritis aetiology is not yet fully resolved. So far specific environmental factors could not be demonstrated to precipitate and cause the development and first time onset of the disease decisively, although heavy cigarette smoking seems to be an influencing factor. Likewise no relevant infectious agents could be identified (Hutchinson et al., 2001). Certain gene polymorphisms, in particular allelic polymorphisms of the HLA-DRB1 gene, reoccur in many studies and their interactions seem to play an important role in the susceptibility for RA as well as the course of the disease (Klippel, 2001).

Considering the pathogenesis of the disease synovial antigen presenting cells and T-cells specifically responding to not yet identified auto- or exogenous antigens in the synovium are of major importance. Antigen mediators and regulators, cytokines and chemokines also play an important role. Proinflammatory cytokines IL-1, IL-6, IL-

8, IL-18 and TNF-α and chemokine CCL18 in particular were demonstrated to have a significantly higher circulation in RA patients compared to healthy controls. On the other hand antagonistic and anti-inflammatory proteins, like IL-18 binding protein and IL-4, show lower levels in RA patients. A similar observation can be made regarding patients with active RA and inactive disease (Klippel, 2001; Lieshout et al., 2007; Sivalingam et al., 2007; Sivalingam et al., 2007). Additionally, the polyclonal B-cell activation triggered production of the rheumatoid factor (RF), an autoantibody specifically interacting with the Fc fragment of IgG, may not be underestimated. One must keep in mind that it can also be found in other conditions than RA, for example chronic bacterial infections, and the healthy population. Rheumatoid factor positive patients, which include approximately 85% of all RA cases, are inclined to show more severe courses and extra-articular manifestation in contrast to RF negative patients. Indeed RF immune complexes can be detected in RA patients' tissues and they may act as contributing agents in the activation of synovial inflammation. The same diagnostic and prognostic value is true for other antibodies, like anti-cyclic citrullinated peptide antibodies (anti-CCP) (Klippel, 2001; Lindqvist et al., 2005).

All of these factors lead to histological changes in articular structures, most important neoangiogenesis of the synovial membrane and an abnormal, probably p53 mutation influenced proliferation of synovial fibroblasts. This effects in the destruction of extracellular matrix forming substances, namely collagen, proteoglycans and others, by proteinases of fibroblastic origin or by synovial macrophages, again controlled by cytokines. Secondary consequences are cartilage and bone degradation. Extra-articular manifestations are discussed in the literature as associated with abnormal T-cell functions following a premature decrease of the thymic function in RA patients (Huber et al., 2006; Klippel, 2001).

The course of RA typically manifests itself first by inflammation of the small hand and foot joints resulting in destruction of joints and consecutive deformity, such as buttonhole deformity and swan neck deformity (Eberhardt, Johnson & Rydgren, 1991). However, the characteristic symmetry of joint manifestations is often missing in the early stages of the disease and appears only after several months. With that in mind and an initial lack of pathological serologic parameters, the first diagnosis of RA is often based on exclusion of other causes for synovitis. With the exception of laboratory parameters, diagnostic tools for this condition generally include: clinical examination, joint aspiration for a detection of synovial leucocytosis and radiological imaging. After several weeks of the disease course results of such a diagnostic strategy usually lead to an accurate diagnosis of the condition (Klippel, 2001).

The course of the disease varies from relapsing-remitting pattern to persistent and even rapidly progressive disease activity (Eberhardt & Fex, 1998). The latter group especially shows damage of larger joints at an early stage of the disease, in particular regarding the hip joint, reaching a degree that often necessitates joint replacement (Eberhardt, 1994). These pathologies result in pain, morning stiffness and functional impairment for the patients. Eventually, this leads to severe difficulties in everyday life, affecting leisure time activity as well as work ability and the general performance of different social roles (Fex, Larsson, Nived & Eberhardt,1998; Geuskens, Burdorf & Hazes, 2007). In 1987 the most frequent of these clinical findings were summarized by the American College of Rheumatology (ACR) in a Classification of Acute Arthritis of Rheumatoid Arthritis which includes the following criteria:

1. Morning stiffness
2. Arthritis of 3 or more joint areas
3. Arthritis of hand joints

4. Symmetric arthritis
5. Rheumatoid nodules
6. Serum rheumatoid factor
7. Radiographic changes

According to the ACR, fulfilment of four out of these seven categories and the persistence of the first four categories for at least six weeks suggest the diagnosis of rheumatoid arthritis (Arnett et al., 1988).

Besides the classic joint manifestations patients suffering from rheumatoid arthritis often show Sjögren Syndrome (keratoconjunctivitis sicca, xerostomia, deficient exocrine secretion) and other comorbidities, like Osteoporosis and Cardiovascular disease (Baskan et al., 2007; Gonzales-Gay et al., 2007; Wankaew et al., 2006). All of these impairments have effects on patients' psychological status, often resulting in emotional distress, severe depression or anxiety related to appearance concerns (Monaghan et al., 2007). The diagnosis of these negative emotions is essential because such patients report significantly higher amount of RA symptoms compared to controls without depression or other emotional distress. These patients also benefited from psychological interventions targeting their rheumatic disease (Katon, Lin & Kroenke, 2007). It was found that personal factors such as coping and general beliefs and attitudes, as well as environmental factors such as social support play an important role in the patient's physical functioning and mental status and need to be observed (Beckham, Rice & Talton, 1994; Demange et al., 2004; Evers et al., 2003).

3.2 Treatment of rheumatoid arthritis with a focus on the role of physicians

The wide scope of life areas influenced by rheumatoid arthritis necessitates a multidisciplinary approach. Psychologists, physical and occupational therapists should be involved in rehabilitation in addition to medical care by rheumatologists and general practitioners to achieve the best physical, psychological, social and economic outcomes of the disease (Uhlig & Christie, 2007; Malcus-Johnson et al., 2005). The cornerstone of both early staged and established rheumatoid arthritis care is pharmacotherapy. Treatment goals are clinical remission for newly onset illness or a disease activity as low as possible for longer courses. Essential substances are NSAIDs and especially disease-modifying anti-rheumatic drugs (DMARDs) like methotrexate, which should be applied as early in the course of illness as possible to guarantee maximum effectiveness. The NSAIDs and DMARDs are used as a monotherapy or in combination with biologicals or steroids. Such a combination was demonstrated to induce clinical remission and to slow down radiological progression in a higher number of patients compared to DMARDs alone. Steroids act on a short-term basis by relieving pain and swelling. Biologic agents like tumor necrosis factor-α inhibitors adalimumab, etanercept and infliximab contribute to long-term effects of the therapy and are especially suitable for refractory conditions (Blom & van Riel, 2007; Chen et al., 2006; Combe, 2007). Surgical interventions, namely arthroscopic debridement, synovectomy, arthrodesis and total joint replacement, constitute an important part of the treatment in addition to the pharmacological approach and physical medicine (Gallo et al., 2008; Simmen et al., 2008). New therapeutical options such as minimal invasive photodynamic treatment of arthritic joints are under investigation (Hansch et al., 2008).

The severity of the disease is also a topic of interest to scientists who are continuously researching new therapy and rehabilitation strategies to optimize clinical

outcome and patients' subjective situation. One of these studies investigated the effectiveness of an interdisciplinary therapy based on the International Classification of Functioning, Disability and Health (ICF). It demonstrated that such an approach modestly improved patients' satisfaction with care, which is an important factor considering the influence of patients' psyche on their overall status (Verhoef et al., 2007). In certain settings, multidisciplinary team practice could be enhanced by the introduction of such an ICF-based rehabilitation model, as it was demonstrated for day-patient care (Verhoef et al., 2008).

3.3 The International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health (ICF) was introduced by the World Health Organization (WHO) in 2001. It is based on a revision of the International Classification of Impairments, Disability and Handicaps (ICIDH), which was published in 1980 and in the following years continuously further developed. The ICF is a representation of inter-related aspects of health and disease and aims to providing a systematic coding scheme and a unified language for the description of health-related functioning for individuals with health conditions in rehabilitation. It also provides a unified framework for all health professionals as well as the public (World Health Organization, 2001). The aim of this classification is a better understanding of the patient's situation and by this an improvement of therapy and rehabilitation. It therefore compliments the use of the International Classification of Diseases (ICD), which is concerned with disease diagnosis, mortality or general health problems (pregnancy, congenital anomalies etc.), because the ICF delivers additional, more specific information. The ICF also serves statistical, research, social policy and educational purposes.

The theoretical approach for the ICF is a biopsychosocial model. An illness, according to the ICF, affects and can be affected by body structures and body functions and the patient's activities and participation in everyday life. The patient's status is also influenced by two contextual factors, namely personal factors as well as environmental factors. 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 two components, the former one of *Body Functions (b)* and *Body Structures (s)* as well as *Activities and Participation (d)* , the latter one of *Environmental Factors (e)* and *Personal Factors*, which are not classified due to their social and cultural variety. The domain *Body Functions* deals with physiological changes, whereas the domain *Body Structures* is about anatomical alterations. Both of them are structured by body areas and organs. *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 (World Health Organization, 2001).

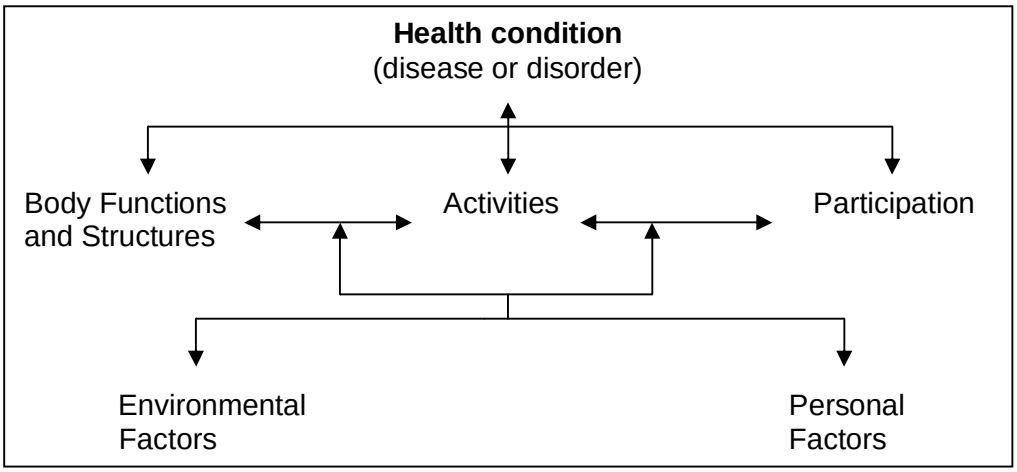

Figure 1: Biopsychosocial model

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 classification. That means that a more detailed higher levelled category covers all the aspects applicable for the lower levelled category, of which it is a member, but not vice versa. To assess the severity of the condition a number ranging from “zero” to “four”, meaning “no” to “complete” problem, is added to the relevant category.

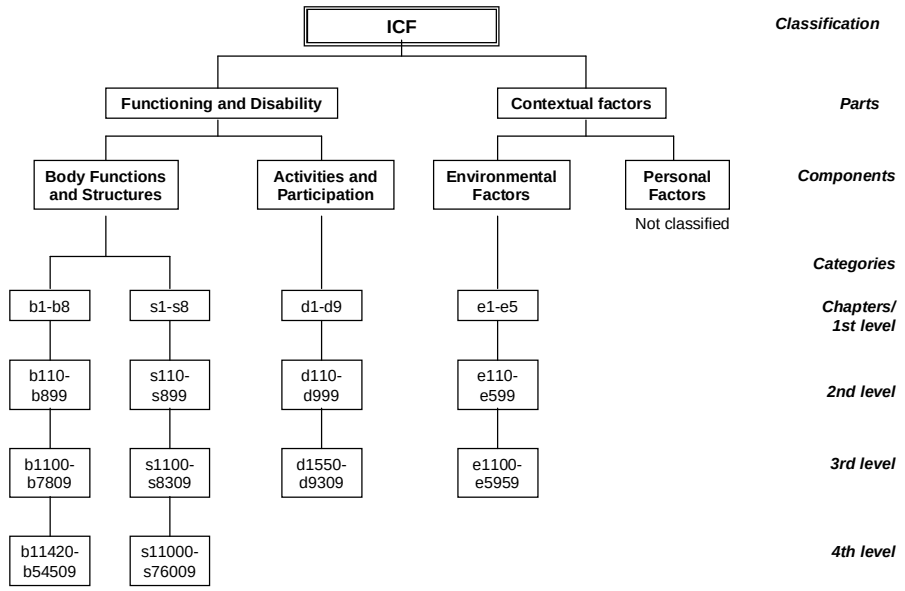

Figure 2: Structure of the International Classification of Functioning, Disability and Health

The value of the ICF for both research and clinical practice by physicians as well as other health professionals is obvious when one considers the structure and content of the ICF and all the issues affected by rheumatoid arthritis (Weigl et al., 2006). The ICF is of significant scientific value for qualitative research and for example as a helpful tool in comparing the content of health status instruments. In the clinical environment it is for example used as a basis for anamnestical questions and as a reference in analyzing and comparing the meaning of patients' statements. It can help to create a functioning profile of RA patients facilitating a follow-up and the management of a coordinated longitudinal care (Cieza & Stucki, 2006; Stamm & Machold, 2007, Steiner et al., 2002). With all of these applications the most important thing to bear in mind about the ICF is that it describes "what" to measure, not "how" it is measured, since the instrument depends on the particular health professional's discipline as well as the aim itself.

Since the classification as a whole is composed of more than 1400 different categories an application in clinical routine is not however feasible. Categories relevant and more specific to certain, mostly chronic conditions needed identification. The resulting categories finally formed the *ICF Core Sets*; one brief version and another comprehensive one, for a variety of diseases, including rheumatoid arthritis (Cieza et al., 2004, Stucki et al., 2004).

The Comprehensive, as well as the Brief Core Set for rheumatoid arthritis was established following a formal decision-making and consensus process on the basis of preliminary studies conducted by health professionals experienced in rheumatology (Stucki et al., 2004). Among these studies, a Delphi exercise was performed, which identified categories typical for rheumatoid arthritis in all ICF components (Weigl et al., 2004). An analysis of outcome measures of 382 randomized trials on rheumatoid arthritis as well as of 48 health status questionnaires concerning rheumatoid arthritis was carried out and the results, namely the extracted concepts, were linked to the ICF (Brockow et al., 2004). Thirdly a multi-centre, cross-sectional study involving samples of rheumatoid arthritis patients was conducted, in which patients' problems were evaluated according to the ICF (Ewert et al., 2004). All in all these studies produced 530 ICF categories covering issues affected by this disease, composed of 203 categories on *Body Functions*, 76 on *Body Structures*, 188 on *Activities and Participation* and 63 on *Environmental Factors*. Based on these findings 17 rheumatology experts, among them seven physicians experienced in rehabilitation and physical medicine and seven rheumatologists, from 12 nations attended a consensus conference to define the final set of categories relevant for RA. In the end 96 categories were included in the Comprehensive Core Set for rheumatoid arthritis, namely 25 categories from the component *Body Functions*, 18 categories on *Body Structures*, 32 categories from *Activities and Participation* as well

as 21 from *Environmental Factors*. Almost 80% are second level categories, only 20% are third and fourth levelled ones. The brief version of the Core Set comprises 39 categories, all of them second levelled (Stucki et al., 2004).

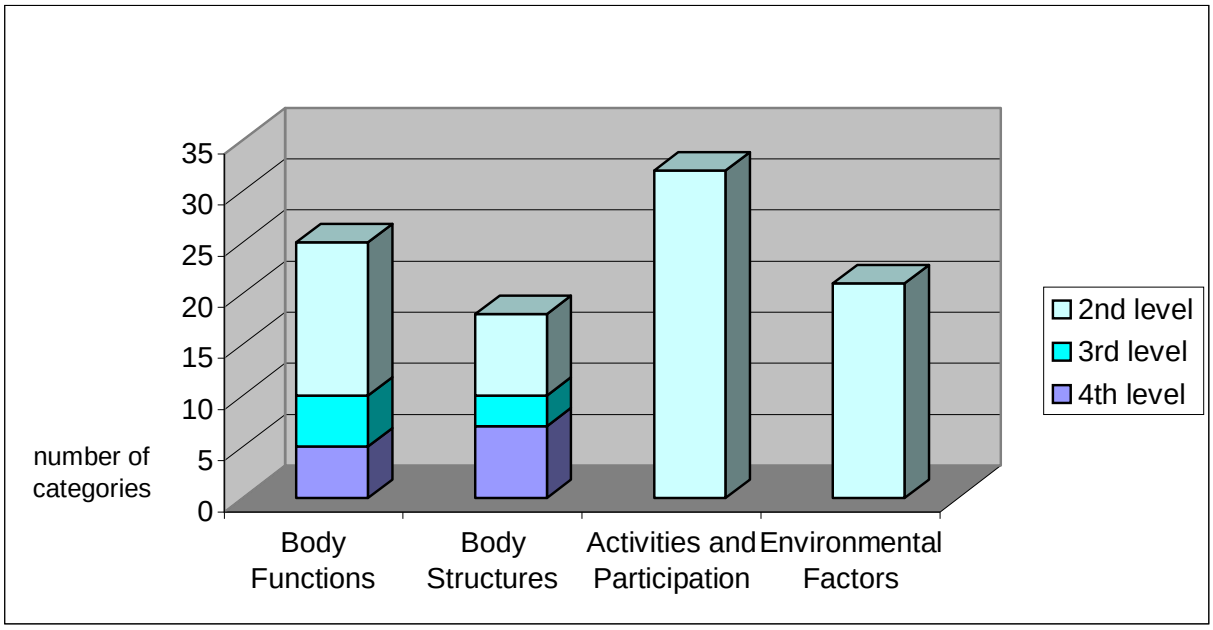

Figure 3: Comprehensive Core Set for rheumatoid arthritis

3.4 Objective

There have been continuous tests and studies investigating the relevance, accuracy and application in clinical practice and research of the Core Sets since their publication in 2004. Among others, the reliability in clinical practice with special regards to the qualifier scale addressing the severity of the patients' problems has been assessed. The results demonstrated that the inter- and intra- rater reliability was only modest indicating that better and more standardized ways of application should be developed (Uhlig et al., 2007). More recently, the major target of studies is the validation of the content of the Comprehensive Core Set for rheumatoid arthritis

from the different perspectives of health professionals involved in therapy and rehabilitation as well as from the patients' point of view (Coenen et al., 2006; Kirchberger & Cieza et al., 2008; Kirchberger & Glässel et al., 2007; Kirchberger & Stamm et al., 2007). This is of particular interest since the ICF and its Core Sets are meant to represent a common basis for multiple professions from physician to psychologist. A specific branch of study was devoted to patients' problems as opposed to the health professionals' goals for rehabilitation, which were considered during the development of the first version of the Core Sets. Using this approach this study firstly intends to identify the patients' problems, resources and aspects of environment treated by physicians and secondly to analyse whether and in what way these issues are represented by the current Comprehensive ICF Core Set for RA.

4. METHODS

4.1 Delphi Method

We conducted a three-round electronic-mail survey of physicians using the Delphi technique (Duffield, 1993; Goodman, 1987; Linstone & Turoff, 1975). The Delphi technique was developed in the 1950s and is of common use in health scientific research since the mid 1970s. Its principal aim is to gain consensus from a panel of individuals, who have knowledge of the topic being investigated (Crisp et al., 1999; McKenna, 1994; Snyder-Halpern et al., 2000). These informed persons are commonly titled ‘experts’. The Delphi method is a multi-stage process where each stage builds on the results of the previous one. In a series of rounds, in this case three rounds, information about a particular participant is both gathered and provided using a questionnaire. The technique is characterized by its anonymity, thus avoiding group dominance and therefore allowing the individual to express freely his or her opinion. It is an iterative process which allows panel members to reconsider and possibly change their opinions in subsequent rounds. Thirdly it represents a controlled feedback showing the distribution of the group’s response as well as the individual response of the previous round (Jones & Hunter, 1995). In contrast to statistical methods, for example meta analysis, consensus methods like the Delphi technique have the advantage of being suitable also in areas where not much published information is available. Moreover they are more appropriate for wider ranges of information than statistical models (Jones & Hunter, 1995).

4.2 Recruitment of participants

The potential participants of the study were selected from of a pool of more than 6000 physicians listed by the EULAR, ACR and other rheumatology associations, as well as international congress participants, cooperation partners of the ICF research branch and personal contacts. Only persons with available email and/or fax number were included. In the first step, if there were more than 10 addresses available for one country in the pool, 10% of these were picked at random, whereas only one physician was selected for countries which showed less than 10 addresses. The United States of America represented a special case since only one participant for every single state was selected to avoid an overrepresentation. Every participant was contacted by e-mail.

To ensure that the participants of the study had sufficient expertise or content knowledge concerning RA treatment, the initial letter noted that participants should be “physicians experienced in the treatment of RA”.

The first contact included an invitation to participate and a detailed description of the projects targets, the Delphi process and the timeline. In case the selected person could not be contacted (e.g. due to wrong address/number), did not reply within one week or declined the participation, in a second step, a similar number of persons was picked at random from the pool and contacted.

Only persons who agreed to participate were included into the expert sample and received the questionnaire of the first Delphi round.

4.3 Delphi Process

The process and verbatim questions of the electronic-mail survey using the Delphi technique are displayed in figure 2. The participants had four weeks to mail

their responses for each round. Reminders were sent in average three days before deadline and one week after the predetermined date.

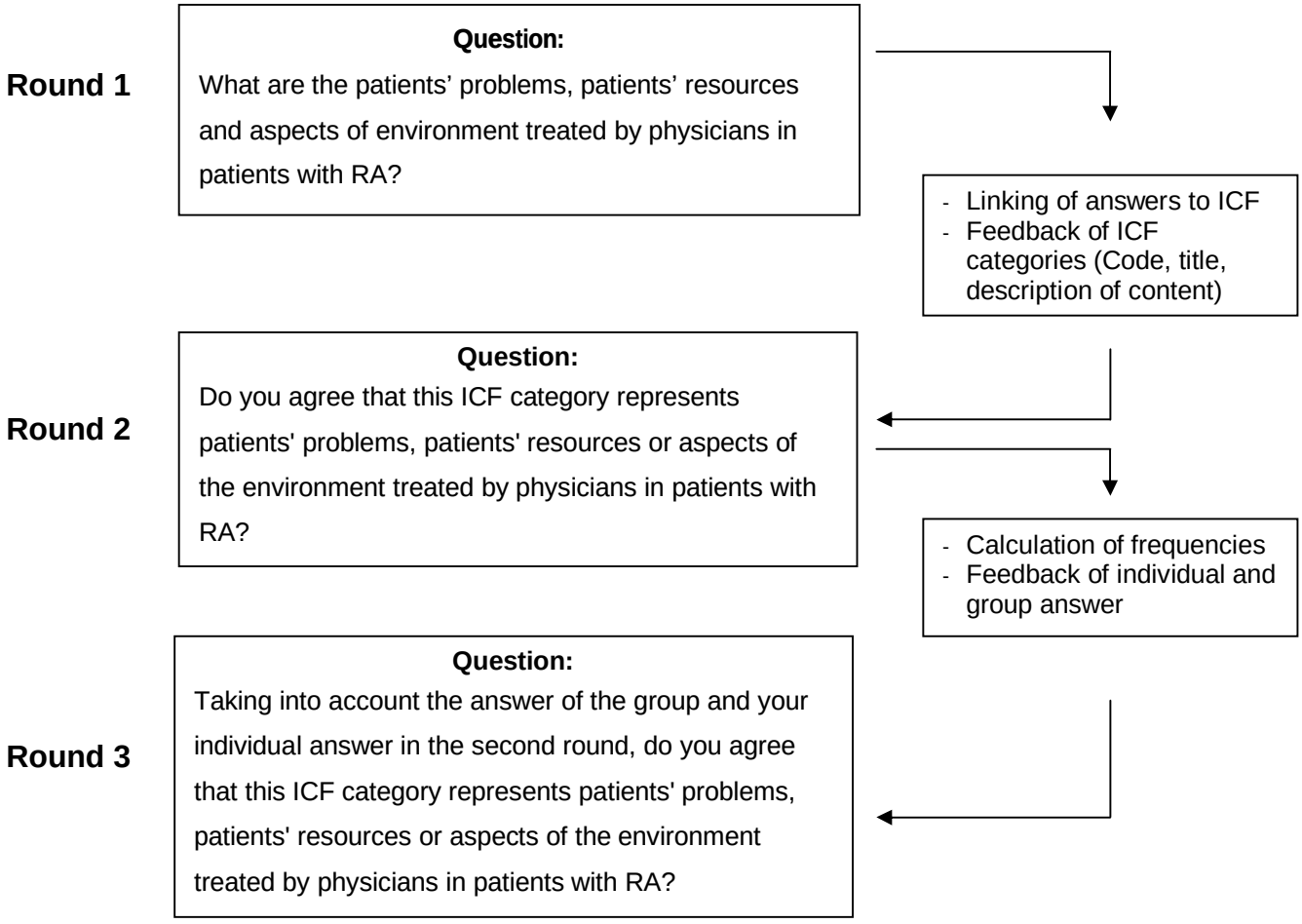

Figure 4: Description of the Delphi-exercise

In **round 1** of the Delphi exercise an information letter including instructions and an Excel file containing an open-ended questionnaire was sent to all experts. In the questionnaire the participants were requested to list all the patients' problems, patients' resources and aspects of environment treated by physicians in patients with RA. Additionally, the participants were asked to complete questions on demographic characteristics like age and gender and professional experience as well as

experience with RA and their self-rated expertise regarding this disease. Responses were collected, the basic concepts identified and linked to the ICF.

In the **second** Delphi round, the participants received a list of the ICF categories linked to the responses of the first round. The categories were ordered according to the structure of the ICF. The responses that could not be linked to an existing ICF category were categorized by the research team and listed as personal factors, health conditions or categories not yet covered by the ICF. The participants were instructed to agree or disagree as to whether the respective ICF category represented patients' problems, patients' resources or aspects of environment treated by physicians in patients with RA.

In order to prevent study dropout the participants of the third Delphi round received only a selection of the ICF categories included in the second round. Scree test was used to identify the categories which did not reach an adequate consensus. 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. The points above and below the scree line indicate high consensus regarding the relevance or irrelevance of the corresponding ICF categories whereas points near the scree line indicate missing consensus (Zoski & Jurs, 1990; Zoski & Jurs, 1991).

In the **third** Delphi round the participants received a list of the ICF categories including the proportion and the identification numbers of the participants who did agree that the categories represent patients' problems, patients' resources or aspects of environment treated by physicians in patients with RA. The participants were requested to answer the same question as in round two taking into account the responses of the group as well as their previous response.

4.4 Linking

An ICF category is coded by the component letter and a suffix of one to five digits. The letters b, s, d and e refer to the components *Body Functions* (b), *Body Structures* (s), A*ctivities and Participation* (d) and *Environmental Factors* (e) (see figure 1). This letter is followed by a one digit number indicating the chapter, the code for the second level (two digits) and the third and fourth levels (one digit each). A higher level (more detailed) category shares the lower level categories of which it is the member, i.e. the use of a higher-level category implies that the lower level category is applicable, but the inverse is not true. The coding of a category concerning alterations of the hand joints, which is included in the Comprehensive Core Set for RA, is coded as follows below:

Component	s	Body Structures
Chapter (1st level)	s7	Structures related to movement
2nd level	s730	Structure of upper extremity
3rd level	s7302	Structure of hand
4th level	s73021	Joints of hand and fingers

Each response of the first Delphi round was linked to the most precise ICF category. Categories containing the expression “other specified” or “not specified”, all ending by the numbers “eight”, respectively “nine”, were not used according to the ten linking rules, established in former studies (Cieza et al., 2002). In such cases a lower levelled, less precise category was applied. Assuming that a concept doesn`t offer enough information, “nd” (= not definable) was applied. Concepts related to health or quality of life in general were classified as “nd-gh” (= not definable-general health) or “nd-qol” (= not definable-quality of life). Moreover, concepts that are not

included in the ICF as a category, but defined as a personal factor by the classification were listed by “pf”. If the concept contained a diagnosis or health state, “hc” (=health condition”) was assigned to it. Lastly, concepts neither included in the ICF nor describing a personal factor were declared “nc” (= not covered). The linkage was performed separately by two trained individuals (linkers), one medical school student and one member of the Institute for Health and Rehabilitation Sciences, according to the linking rules. Every response can contain one or more meaningful concepts and several ICF categories can be linked to each concept. A meaningful concept is a specific part of a text relating to one particular meaning without any interpretation. Consensus between the linkers was used to decide which ICF categories should be linked to each response. In case of disagreements between the two linkers, the suggested categories were discussed by a team consisting of the two linkers and another experienced psychologist. Based on this discussion, a joint decision was made.

Response		*Identification of concepts*		*Linking*
1. side-effects of drugs	→	a) side-effects b) drugs	→	a) nd b) e1101 Drugs
2. doing housework	→	doing housework	→	d630, d640
3. inflammation	→	inflammation	→	nc

Figure 5: Example of the linking procedure

4.5 Statistical methods

Descriptive statistics were used to characterise the sample and frequencies of responses. Kappa statistics with bootstrapped confidence intervals were used to describe the agreement between the two individuals, who performed the linking (Cohen, 1969; Vierkant, 2004).

5. RESULTS

5.1 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 declared undeliverable. The second round resulted in another 45 participants, 13 physicians turned down their involvement in the study and 15 could not be contacted due to technical reasons. At the end of these two rounds 90 physicians agreed to provide information for the research on the Comprehensive ICF Core Set for rheumatoid arthritis.

Seventy-nine out 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 these physicians see table 1. Although the study was conducted in Germany there was no overrepresentation of German physicians (5.1%). During the course of the three Delphi rounds there were no significant changes of demographic sample characteristics except for a diminution of 52.4% of the sample from the WHO region Americas from the first round to the second round.

Table 1: Attrition of participants between the Delphi rounds, demographics and professional experience of the round 1 participants

WHO-Region	Round 1 (n)	Round 2 (n)	Round 3 (n)	Female %	Age Median (Min-Max)	Professional experience years Median (Min-Max)	RA experience years Median (Min-Max)	Self-rating RA expertise[1] Median (Min-Max)	Mainly treating patients in acute situation[2] (n)	Mainly treating patients in post-acute situation[2] (n)	Mainly treating patients in chronic situation[2] (n)
Europe[4]	34	32	29	20.6	51.5 (38-72)	24.5 (7-40)	21.5 (7-35)	4 (3-5)	20	21	28
Americas[5]	21	11	11	33.0	51.0 (38-66)	24.0 (5-36)	21.0 (7-35)	5 (3-5)	13	15	20
Eastern Mediterranean Region[6]	4	4	4	25.0	45.5 (39-60)	17.0 (5-30)	16.5 (8-27)	4 (3-5)	2	2	4
Africa[7]	1	1	1	0	56	32	27	5	missing	missing	missing
South East Asia[8]	2	2	2	0	45.5 (45-46)	19.5 (15-24)	12.5 (5-20)	5 (5)	1	1	2
Western Pacific Region[9]	17	14	14	0	51.0[3] (39-76)	26.0[3] (8-40)	22.0[3] (5-40)	5[3] (4-5)	9[3]	11[3]	14[3]
Total	79	64	61	19.0	51.0 (38-76)	24.0 (5-40)	20.5 (5-40)	5 (3-5)	45	50	68

[1] 1= low 5=excellent
[2] more answers possible
[3] data of two participants missing
[4] Armenia, Austria, Belgium, Czech Republic, Denmark, Germany, Finland, France, Greece, Hungary, Italy, Lithuania, Norway, Poland, Romania, Switzerland, Turkey, United Kingdom
[5] Argentina, Brazil, Canada, Chile, Cuba, Equador, Mexico, Peru, Uruguay, USA
[6] Egypt, Lebanon, Morocco, Qatar
[7] South Africa
[8] India
[9] Australia, China, Japan, Malaysia, New Zealand, Philippines, South Korea

5.2 Delphi process

In the first Delphi round 512 patients' problems, patients' resources and aspects of environment treated by physicians in patients with rheumatoid arthritis were named by 79 out of 90 participants (87.8%). Sixty-four out of 79 (81.0%) participants filled in the second round questionnaire. Of the 272 ICF categories, personal factors and aspects not classified in the ICF, which were part of the second round questionnaire, 193 categories with an agreement between 27% and 80% were selected using Scree test methodology (see figure 5) and presented to the participants in the third round. Sixty-one out of 64 (95.3%) physicians returned the third round questionnaire.

The results including the percentage of agreement among the participants are shown in tables 3-8.

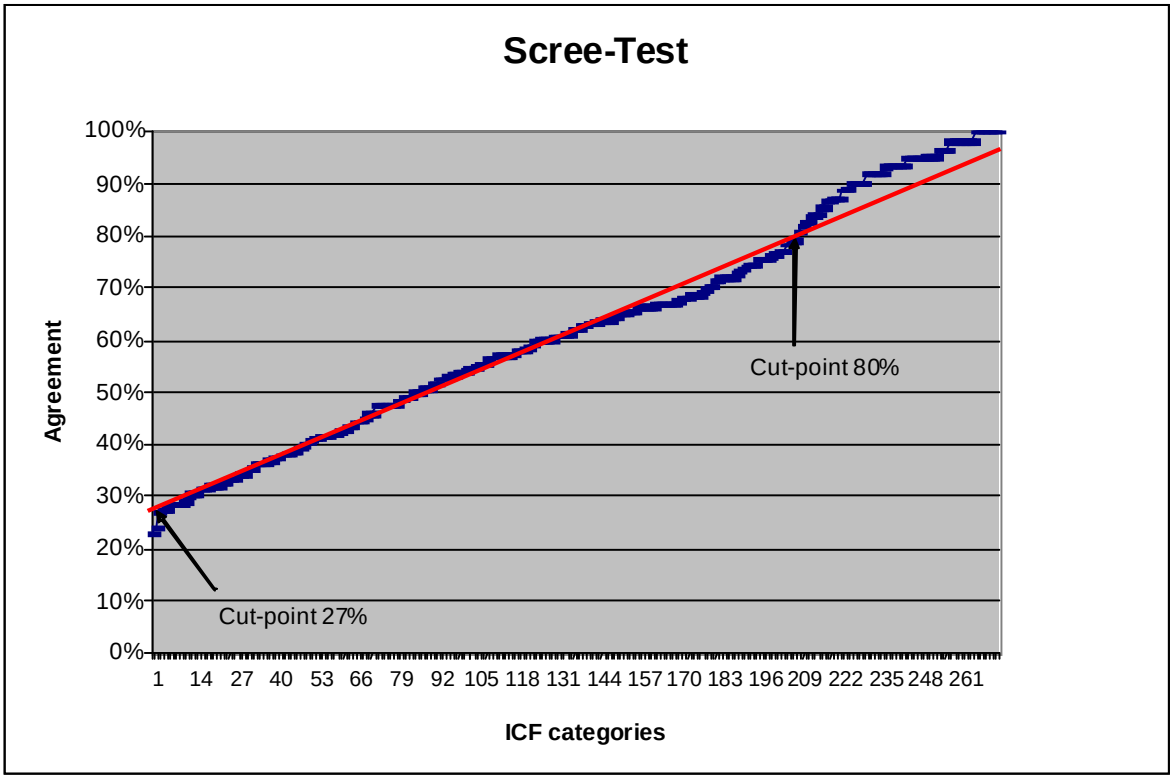

Figure 6: Results of the Scree Test

5.3 Linking of the responses to the ICF

All components of the ICF were represented in the participants' responses (see tables 2-6). Seven fourth level categories, 19 third level categories and 42 second level categories were linked to the component *Body Functions*. Four fourth level categories, eight third level categories and eight 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 *Activities and Participation* and 19 third level categories as well as 26 second level categories were linked to the component *Environmental Factors.* Twenty-six issues were named that could be attributed to the not yet developed component *Personal Factors.* Nineteen responses were declared 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.

Table 2: Representation of identified ICF categories in the Comprehensive ICF Core Sets for rheumatoid arthritis: summary of results

	Body Functions	Body Structures	Activities & Participation	Environmental Factors	Total
Number of categories identified	68	20	94	45	227
*n (%) of categories included in the ICF Core Set at the same level of classification **	19 (27.9%)	8 (40.0%)	25 (26.6%)	16 (35.6%)	68 (30.0%)
*n (%) of categories included in the ICF Core Set at a different level of the classification **	10 (14.7%)	7 (35.0%)	48 (51.1%)	14 (31.1%)	79 (34.8%)
n (%) of categories not included in Core Set with agreement < 75%	24 (35.3%)	5 (25.0%)	20 (21.3%)	15 (33.3%)	64 (28.2%)
n (%) of categories not included in Core Set with agreement ≥ 75%	15 (22.1%)	0	1 (1.0%)	0	16 (7.0%)

* The use of a more detailed ICF category (e.g. b1343 Quality of sleep) implies that the less detailed (lower level) ICF category is applicable.

5.4 Representation of the physicians` responses in the Comprehensive ICF Core Set for RA

5.4.1 Body Functions

Nineteen categories of the component *Body Functions* of the current ICF Core Set for RA were represented in the participants' responses whereas six

categories that are included in the Core Set could not be linked to the responses (see table 3). Half of the latter categories could be linked at a different, namely at a higher level of classification to the issues named by the physicians; these were *b130 Energy and drive functions*, *b180 Experience of self and time functions* and *b2801 Pain in body part*. On the other hand side *b7102 Mobility of joints generalized* and *b28013 Pain in back* were only represented by lower level categories in the participants' responses and *b740 Muscle endurance functions* could not be found at all in the data provided by the study population. Eight categories that were linked to the responses were represented at a higher level of classification in the Core Set, which could be linked to the responses as well, for example *b280 Sensation of pain* and *b2802 Pain in multiple body parts*. Thirty-nine of the participants' categories were found not to be covered at all by the Comprehensive ICF Core Set for RA. Among these 15, namely six categories covering the functions of the cardiovascular and respiratory system (*b410*, *b415*, *b420*, *b4200*, *b440*, *b460*), *b220 Sensations associated with the eye and adjoining structures*, *b435 Immunological system functions*, *b515 Digestive functions*, *b530 Weight maintenance functions*, *b6601 Functions related to pregnancy, b6700 Discomfort associated with sexual intercourse*, *b720 Mobility of bone functions* as well as *b7200 Mobility of scapula* and *b840 Sensations associated with the skin*, showed an agreement among the participants of over 75%. On the remaining 24 linked categories an agreement ranging from 16.4% to 72.1% was reached.

Table 3: ICF component Body Functions: ICF categories included in the ICF Comprehensive Core Set (bold-face letters) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (light-face letters).

Percentage of participants who considered the respective ICF category as relevant in the last round.

ICF Code			ICF Category Title	% Agreement in final round
2nd level	3rd level	4th level		
b122			Global psychosocial functions	65.6%
b130			**Energy and drive functions**	
	b1300		Energy level	78.7%
	b1303		Craving	16.7%
b134			**Sleep functions**	90.2%
b140			Attention functions	18.0%
	b1400		Sustaining attention	20.0%
b152			**Emotional functions**	70.0%
	b1522		Range of emotion	31.7%
b180			**Experience of self and time functions**	
	b1801		**Body image**	68.9%
b210			Seeing functions	33.3%
		b21023	Visual picture quality	16.4%
b215			Functions of structures adjoining the eye	68.9%
b220			Sensations associated with the eye and adjoining structures	82.5%
b265			Touch function	72.1%

2nd level	3rd level	4th level		
	b2702		Sensitivity to pressure	72.1%
b280			**Sensation of pain**	90.5%
	b2800		**Generalized pain**	92.1%
	b2801		**Pain in body part**	
		b28010	**Pain in head and neck**	96.8%
		b28011	Pain in chest	83.9%
		b28012	Pain in stomach or abdomen	88.9%
		b28013	**Pain in back**	
		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%
b410			Heart functions	90.2%
b415			Blood vessel functions	86.9%
b420			Blood pressure functions	93.4%
	b4200		Increased blood pressure	94.9%
b430			**Haematological system functions**	93.3%
b435			Immunological system functions	90.5%
b440			Respiration functions	91.7%
b445			Respiratory muscle functions	65.0%
b450			Additional respiratory functions	41.0%
b455			**Exercise tolerance functions**	86.9%
	b4551		Aerobic capacity	65.6%
	b4552		Fatiguability	85.7%
b460			Sensations associated with cardiovascular and respiratory functions	78.3%
b510			**Ingestion functions**	78.7%
	b5104		Salivation	93.5%
b515			Digestive functions	77.0%

2nd level	3rd level	4th level		
b520			Assimilation functions	24.6%
b525			Defecation functions	42.6%
b530			Weight maintenance functions	87.3%
b535			Sensations associated with the digestive system	42.6%
b540			General metabolic functions	50.8%
b545			Water, mineral and electrolyte balance functions	63.9%
b555			Endocrine gland functions	67.2%
b640			**Sexual functions**	75.0%
b650			Menstruation functions	58.3%
	b6600		Functions related to fertility	68.9%
	b6601		Functions related to pregnancy	88.5%
	b6603		Lactation	58.3%
	b6700		Discomfort associated with sexual intercourse	78.3%
b710			**Mobility of joint functions**	93.5%
	b7102		**Mobility of joints generalized**	
b715			**Stability of joint functions**	91.9%
b720			Mobility of bone functions	90.3%
	b7200		Mobility of scapula	88.3%
b730			**Muscle power functions**	82.0%
	b7300		Power of isolated muscles and muscle groups	88.5%
b740			**Muscle endurance functions**	
b750			Motor reflex functions	36.1%
b755			Involuntary movement reaction functions	31.1%
b760			Control of voluntary movement functions	60.7%
b765			Involuntary movement functions	20.0%
b770			**Gait pattern functions**	86.9%

2nd level	3rd level	4th level		
b780			**Sensations related to muscles and movement functions**	82.0%
	b7800		**Sensation of muscle stiffness**	86.9%
b810			Protective functions of the skin	50.8%
b840			Sensation related to the skin	80.3%

5.4.2 Body Structures

Of the component *Body Structures* 20 ICF categories could be linked to the participants' responses. Among these, eight categories were also represented in the Comprehensive ICF Core Set for RA at the same level of classification. Ten categories, which are part of the Core Set, were found not to be named by the physicians (see table 4); these were very detailed fourth level categories like *s75011 Knee joint* but also more general second level categories, for example *s710 Structure of head and neck region*. The former category, as well as *s73001 Elbow joint* and *s75001 Hip joint*, were represented by lower level categories in the issues raised by the experts. Five categories, that were deemed important by a percentage of 13.3% to 65.6% of the participants, are not part at all of the Comprehensive ICF Core Set for RA, not even as lower levelled categories. However, none of these reached an agreement of at least 75%. Seven categories that are not yet part of the Core Set were regarded as essential by over 75% of the experts, but they were already represented by lower level categories in the Core Set.

Table 4: ICF component Body Structures: ICF categories included in the ICF Comprehensive Core Set (bold-face letters) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (light-face letters).
Percentage of participants who considered the respective ICF category as relevant in the last round.

ICF Code			ICF Category Title	% Agreement in final round
2nd level	3rd level	4th level		
s110			Structure of brain	13.3%
s120			Spinal cord and related structures	57.4%
s140			Structure of sympathetic nervous system	25.0%
s150			Structure of parasympathetic nervous system	23.7%
s299			**Eye, ear and related structures, unspecified**	
s430			Structure of respiratory system	65.6%
s710			**Structure of head and neck region**	
	s7103		Joints of head and neck region	100.0%
s720			**Structure of shoulder region**	
s730			**Structure of upper extremity**	95.1%
		s73001	**Elbow joint**	
		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%
		s75001	**Hip joint**	
	s7502		**Structure of ankle and foot**	96.7%
		s75021	Ankle joint and joints of foot and toes	100.0%
s760			**Structure of trunk**	

2nd level	3rd level	4th level		
	s7600		**Structure of vertebral column**	
		s76000	**Cervical vertebral column**	96.7%
s770			**Additional musculoskeletal structures related to movement**	
	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%

5.4.3 Activities and Participation

Activities and Participation was considered the most important field in which patients experienced problems as far as disability, since 94 categories were linked. The 32 categories of this component that are included in the Comprehensive ICF Core Set for RA were largely supported by the experts whose responses could be linked to 25 categories at the same level of classification (see table 5). Of the remaining seven categories of the ICF Core Set five could be linked at a different level of classification, namely at a higher level, whereas two were not found to be mentioned by the physicians, namely *d449 Carrying, moving and handling objects. other specified and unspecified* and *d859 Work and employment. other specified and unspecified*. Twenty-one categories that were adressed by the participants' responses are not part of the current Comprehensive ICF Core Set for RA, not even at another level of classification, but only one, namely *d435 Moving objects with lower extremities*, reached an agreement of 78.0%.

Table 5: ICF component Activities and Participation: ICF categories included in the ICF Comprehensive Core Set (bold-face letters) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (light-face letters). Percentage of participants who considered the respective ICF category as relevant in the last round

ICF Code			ICF Category Title	% Agreement in final round
2nd level	3rd level	4th level		
d170			**Writing**	34.4%
d230			**Carrying out daily routine**	50.8%
	d2401		Handling stress	43.3%
	d3352		Producing drawings and photographs	18.3%
d360			**Using communication devices and techniques**	
	d3600		Using telecommunication devices	24.6%
	d3601		Using writing machines	27.9%
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%
d415			**Maintaining a body position**	
	d4151		Maintaining a squatting position	67.8%
	d4152		Maintaining a kneeling position	70.0%
	d4153		Maintaining a sitting position	78.7%

2nd level	3rd level	4th level		
	d4154		Maintaining a standing position	83.3%
d430			**Lifting and carrying objects**	
	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%
d435			Moving objects with lower extremities	78.0%
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%
d449			**Carrying, moving and handling objects. other specified and unspecified**	
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%
d470			**Using transportation**	70.0%
	d4701		Using private motorized transportation	60.3%
	d4702		Using public motorized transportation	59.3%
d475			**Driving**	73.3%
	d4750		Driving human-powered transportation	63.3%

2nd level	3rd level	4th level		
	d4751		Driving motorized vehicles	66.7%
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%
d570			**Looking after one`s health**	
	d5701		Managing diet and fitness	59.3%
	d5702		Maintaining one's health	78.0%
d620			**Acquisition of goods and services**	
	d6200		Shopping	25.4%
d630			**Preparing meals**	40.7%
d640			**Doing housework**	61.0%
	d6400		Washing and drying clothes and garments	37.3%
	d6401		Cleaning cooking area and utensils	33.9%
	d6402		Cleaning living area	47.5%
	d6403		Using household appliances	33.9%
	d6404		Storing daily necessities	23.7%
	d6405		Disposing of garbage	25.4%
	d6501		Maintaining dwelling and furnishings	16.9%
	d6505		Taking care of plants, indoors and outdoors	15.3%
d660			**Assisting others**	18.3%

2nd level	3rd level	4th level		
d740			Formal relationships	13.3%
d750			Informal social relationships	13.3%
	d7500		Informal relationships with friends	11.9%
	d7501		Informal relationships with neighbours	11.9%
d760			**Family relationships**	16.7%
d770			**Intimate relationships**	23.3%
	d7702		Sexual relationships	41.7%
d825			Vocational training	25.4%
d830			Higher education	16.7%
d840			Apprenticeship (work preparation)	23.3%
d845			Acquiring, keeping and terminating a job	32.2%
	d8450		Seeking employment	22.0%
	d8451		Maintaining a job	67.8%
d850			**Remunerative employment**	67.2%
d855			Non-remunerative employment	33.9%
d859			**Work and employment, other specified and unspecified**	
d860			Basic economic transactions	11.7%
d870			Economic self-sufficiency	13.3%
	d8700		Personal economic resources	15.0%
d910			**Community life**	25.0%
d920			**Recreation and leisure**	63.8%
	d9201		Sports	55.9%
	d9202		Arts and culture	31.6%
	d9203		Crafts	37.9%
	d9204		Hobbies	23.7%
	d9205		Socializing	28.3%
d930			Religion and spirituality	13.3%
d950			Political life and citizenship	13.6%

5.4.4 Environmental Factors

Of the component *Environmental Factors* 45 categories were linked based on the participants' responses. Among these, 16 categories are included at the same level of classification in the ICF Core Set for RA (see table 6). Three categories of the Core Set were represented by higher levelled categories in the physicians' responses whereas one category of the Core Set, namely *e360 Other professionals* was not found to be mentioned by the experts. There was no aspect of environmental factors the panel of experts missed in the Core Set, since all the 14 newly found categories reached an agreement below 75% each. On the contrary, with an agreement under 25% among the experts in the second Delphi round, one category of the Core Set, namely *e225 Climate*, was not regarded as essential at all, since it represents an area that is not amenable to medical influence.

Table 6: ICF component Environmental Factors: ICF categories included in the ICF Comprehensive Core Set (bold-face letters) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (light-face letters). Percentage of participants who considered the respective ICF category as relevant in the last round.

ICF Code			ICF Category Title	% Agreement in final round
2nd level	3rd level	4th level		
e110			**Products or substances for personal consumption**	
	e1100		Food	21.7%
	e1101		Drugs	76.7%
e115			**Products and technology for personal use in daily living**	61.0%
	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%
e125			**Products and technology for communication**	
	e1251		Assistive products and technology for communication	49.2%
e135			**Products and technology for employment**	25.0%
	e1351		Assistive products and technology for employment	26.7%
e140			Products and technology for culture, recreation and sport	21.7%
e150			**Design, construction and building products and technology of buildings for public use**	25.0%

2nd level	3rd level	4th level		
e155			**Design, construction and building products and technology of buildings for private use**	23.3%
	e1650		Financial assets	23.0%
e225			**Climate**	24.2%
	e2250		Temperature	11.7%
e310			**Immediate family**	32.2%
e315			Extended family	16.7%
e320			**Friends**	18.3%
e325			Acquaintances, peers, colleagues, neighbours and community members	18.3%
e330			People in positions of authority	8.3%
e335			People in subordinate positions	8.3%
e340			**Personal care providers and personal assistants**	65.0%
e355			**Health professionals**	96.7%
e360			**Other professionals**	
e410			Individual attitudes of immediate family members	71.7%
e415			Individual attitudes of extended family members	23.7%
e420			**Individual attitudes of friends**	26.7%
e425			**Individual attitudes of acquaintances, peers, colleagues, neighbours and community members**	21.1%
e450			**Individual attitudes of health professionals**	70.0%
e460			**Societal attitudes**	40.7%
e540			**Transportation services, systems and policies**	28.8%
	e5400		Transportation services	25.0%
	e5401		Transportation systems	23.3%
	e5550		Associations and organizational services	36.7%

2nd level	3rd level	4th level		
	e5600		Media services	35.0%
e565			Economic services, systems and policies	16.9%
e570			**Social security services, systems and policies**	42.4%
	e5700		Social security services	56.7%
	e5702		Social security policies	61.7%
e575			General social support services, systems and policies	56.7%
	e5750		General social support services	56.7%
e580			**Health services, systems and policies**	
	e5800		Health services	90.0%
	e5801		Health systems	83.3%
	e5802		Health policies	77.6%
	e5850		Education and training services	51.7%
e595			Political services, systems and policies	11.9%

5.4.5 Personal Factors

Twenty-six responses were linked to the not yet developed ICF component *Personal Factors* (see table 7). All of these issues addressed comorbid health problems often associated with RA, like *Sjögren syndrome*, *Osteoporosis* and *Cardiovascular diseases*, or factors that influence patients in a negative or positive way or describe the way they deal with their condition like *Coping* and *Knowledge of disease/treatment*. Except for *Intellectual background*, *Resignation* and *Coccydiomycosis*, the participants agreed on the importance of the mentioned factors by a percentage of at least 78%.

Table 7: Responses that were linked to the ICF component Personal Factors. Percentage of participants who considered the respective responses as relevant in the last round.

Answer	% Agreement in final round
Knowledge of disease/treatment	98.4%
Osteoporosis	98.4%
Sjögren 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%

Answer	% Agreement in final round
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%
Coccydiomycosis	59.6%
Resignation	59.3%
Intellectual background	25.4%

5.4.6 Not covered

Nineteen responses of the experts were declared “not covered” since they address issues that are not classified by the ICF (see table 8). Among these, some were considered too vague to be linkable to the ICF like *Inflammation*, *Infections*, *Deformities* and *Exacerbation*, whereas others regarded interventions aimed at the patient’s environment like *Counselling of occupational environment* and *Family counselling*. However, all aspects but one, namely *Incubation*, reached an agreement of over 78%.

Table 8: Responses that could not be linked to a specific ICF category since the concept is not covered by ICF.
Percentage of participants who considered the respective responses as relevant in the last round.

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%

Answer	% Agreement in final round
Patients' Education	92.1%
Monitoring	88.7%
Family counselling	86.4%
Aetiology	84.7%
Prevention	84.7%
Edema	82.5%
Counselling of occupational environment	79.7%
Risk for family members	78.0%
Incubation	17.2%

6. DISCUSSION

6. 1 Body Functions

The current version of the Comprehensive ICF Core Set for RA was supported to a large extent by the panel of experts, especially regarding the components *Body Structures, Environmental Factors* and *Activities and Participation*. However, with regard to the component *Body Functions* some aspects of the disease are not represented in the Core Set.

In particular the involvement of cardiovascular functions may be useful to be considered in the Core Set, since five categories, namely *b410 Heart functions*, *b415 Blood vessel functions*, *b420 Blood pressure functions*, *b4200 Increased blood pressure* and *b460 Sensations associated with cardiovascular and respiratory functions,* reached an agreement over 75% among the experts. This association was the subject of many studies. It was demonstrated that patients affected by inflammatory diseases like RA have an increased risk for cardiovascular morbidity and mortality and should therefore be closely monitored and treated (Chung et al., 2007; Snow & Mikuls, 2005). Among many others, positivity of HLA-DRB1*04 shared epitope alleles and elevated anticardiolipin antibodies in RA patients are currently discussed as causal factors for this higher risk (Gonzales-Gay et al., 2007; Sherer et al., 2007). Glucocorticoids, one of the main substances used in RA therapy, represent an additional risk factor for cardiovascular events in rheumatoid factor positive patients (Davis et al., 2007). Thirdly, physical inactivity, like in the general healthy population, due to functional impairment resulting from RA contributes to the disposition for cardiovascular disease (Turesson & Matteson, 2007). Considering all of these factors rheumatology experts have developed guidelines for the evaluation

and treatment of RA patients aiming at a highest possible control of this excessive burden of cardiovascular morbidity (Pham et al., 2006). Consequently an introduction of the cardiovascular aspect of the disease into the Core Set for RA could be advantageous.

Closely connected with the cardiovascular aspect of the disease is another category that was considered relevant, namely *b530 Weight maintenance functions*. Indeed, it was demonstrated that patients with RA show a higher prevalence of the metabolic syndrome, as it is defined by the WHO and the NCEPIII criteria, than healthy controls which by itself again predisposes patients to cardiovascular events (Chung et al., 2007). A possible reason for struggle in weight maintenance is, amongst other factors, the adipokine resistin which represents an important connection between insulin resistance and obesity and contributes to the inflammatory reactions in rheumatoid arthritis (Bokarewa et al., 2005).
The intake of glucocorticoids is highly predispositional for weight gain.
A lack of physical activity can be a contributor as well as a consequence of rheumatic cachexia, a cell loss predominantly affecting skeletal muscle cells (Walsmith & Roubenoff, 2002).
Since obesity constitutes a risk factor for arthritis (the prevalence is reportedly higher in obese patients than in normal weight or overweight adults) and obese RA patients evidently have a more impaired quality of life compared to lighter patients, it is highly important to address this problem in treatment. It was demonstrated that patients receiving professional advice to lose weight were more likely to go on a diet than patients without motivation from the outside (Garcia-Poma et al., 2007; Mehrotra et al., 2004). Thus, interventions based on nutritional and exercise recommendations constitute another part of rheumatologic treatment and rehabilitation.

Respiration functions and associated sensations, dealt with in the categories *b440 Respiration functions* as well as the already mentioned *b460 Sensations associated with cardiovascular and respiratory functions*, represent another issue potentially interesting for an introduction into the Core Set for RA. A number of studies demonstrated that rheumatoid arthritis is often accompanied by impairments of the airways. These range from morphological changes noticeable in high-resolution computed tomography, like air trapping and bronchiectasis, to functional impairments, like reduced respiratory muscle strength and endurance. This results in a lower aerobic capacity compared to healthy controls (Cimen et al., 2001; Perez et al., 1998). Pulmonary function tests in RA patients frequently show decreases in the forced expiratory fraction (FEF 25%/50%/75%/25-75%) indicating an involvement of the small airways (Cortet et al., 1997). However, the Core Set does not provide any reference to this aspect of the disease.

Over 80% of the experts in this study agreed that *b220 Sensations associated with the eye and adjoining structures* is neglected in the current Core Set although it is one of the targets of interventions. Literature clearly supports a close relationship between RA and ocular symptoms. Particularly a feeling of dryness resulting from secondary Sjogren's Syndrome, a condition that especially correlates with higher titers of rheumatoid factor (Matsuo et al., 1997), is a common problem. Other complications include episcleritis and involvement of the cornea as well as an elevated risk for the development of a cataract due to glucocorticoid side effects. Even in patients not affected by Sjogren's disease microscopical changes of the eye can be observed, which correlate with disease activity. These are the number of activated keratocytes as well as beadlike formations.

Therefore ophthalmic examination, like the performance of the Schirmer's test, which measures the function of the lachrymal glands, is common in clinical routine of RA

patients (Piper et al., 2007; Reddy & Rao, 1996; Shaw et al., 2003; Villani et al., 2008).

A significantly important patients' problem physicians are confronted with is represented by the category *b435 Immunological system functions* according to over 90% of the participants. Considering the autoimmune pathogenesis of RA a general impairment of the patients' immunological system is obvious and thus, a higher susceptibility to infections than the healthy population. Amongst other theories, a deficiency in the functioning of neutrophils is discussed as a contributor to increased risk for bacterial infections (Fairhurst et al., 2007). Beyond this, there is consensus that RA therapy, namely the application of immunosuppressive glucocorticoids and especially TNFα antagonists, is a main risk factor by itself in the development of severe infections, like for example pneumonia caused by opportunistic pathogen pneumocystis carinii (Curtis et al., 2007; Kalyoncu et al., 2007; Kroesen et al., 2003; Strangfeld & Listing, 2006). Efforts are made in clinical practice to diagnose and treat infectious complications and an inclusion of this category in the Comprehensive Core Set for rheumatoid arthritis would be appropriate from the perspective of physicians.

The current Core Set takes into account *b510 Ingestion functions* as an outcome of interventions by rheumatologists, but not *b515 Digestive functions* which was considered relevant by the experts in this study. It is of interest to keep in mind the gastrointestinal tract of patients since a number of substances used in RA therapy have gastrointestinal side effects. Most important are NSAIDs of which dyspepsia and ulcers are main complications. For this reason physicians often intervene by prescribing gastroprotective drugs, particularly proton pump inhibitors, in addition to NSAIDs or switch to COX-2 selective inhibitors like celecoxib. These were demonstrated to be equal in effectiveness and provide superior gastrointestinal tolerability (Chen et al., 2008; Peng & Duggan, 2005; Silverstein et al., 2000).

As the majority of rheumatoid arthritis patients are female and the disease represents no contraindication to pregnancy, 88.5% of participants deemed the category *b6601 Functions related to pregnancy* to be relevant for the Core Set. Recent studies show that women with RA have a higher risk for complications like hypertensive disorder and caesarean section. If a continuation of drug therapy is required, potential adverse outcomes have to be considered and a change in therapy might be necessary. A multidisciplinary approach is recommended to monitor both pregnancy and rheumatoid arthritis and treat problems immediately (Chakravarty et al., 2006; Saar et al., 2006). Thus, it could be useful if the Core Set provides a reference to this aspect since the ICF and the Core Sets are also intended to serve as a tool for the planning of treatment.

The category *b6700 Discomfort associated with sexual intercourse* also reflects a patients' problem that may be addressed by clinical interventions, like a large number of the experts believed. According to several researchers sexual dissatisfaction and a lack of sexual desire is quite common among RA patients. One study estimated that more than 60% of women affected by rheumatoid arthritis suffer from these problems. The reasons are pain, stiffness and also psychological problems like depression and anxiety because of a negatively perceived body image and concerns about health. In men problems with orgasm can additionally appear, triggered by substances influencing the ejaculation function or impotence, which can be a side-effect of methotrexate. Consequently rheumatologists are requested to intervene in this area. In severe cases a consultation of psychologists might be discussed (Abdel-Nasser & Ali, 2006; Aguirre et al., 2002; Gutweniger et al., 1999; van Berlo et al., 2007).

The Comprehensive Core Set for RA provides a detailed range of categories in the component *Body Functions* for the classic manifestations of rheumatoid

arthritis, namely articulations and the individual associated structures. However, the panel of experts identified *b720 Mobility of bone functions* and the more specific category *b7200 Mobility of the scapula,* which are not yet included*.* Actually, changes in bone structure and by that function play an important role for physicians in the management of RA. Bone abnormalities have to be considered and if possible treated for their increased risk of fracture and potential complications in the surgical reconstruction of affected joints (Bogoch & Moran, 1999). It has been demonstrated that patients profit from surgical interventions aimed at the shoulder, if conservative management, like range-of-motion exercises, fails (Clayton & Ferlic, 1975).

Lastly, a large number of physicians named the category *b840 Sensation related to the skin* an area that required their interventions. Pruritus is the main reason for complaints. In most cases it is caused by dryness of the skin due to Sjogren comorbidity (Provost & Watson, 1992). On the other hand pruritus can be a side-effect of oral gold salts, a substance used especially in the past in RA therapy (Bonnetblanc, 1996). The elevated risk for skin cancers, particularly melanoma, caused by biologic therapy and methotrexate, should not be neglected. A dermatological assessment may be part of the treatment and therefore an inclusion in the Core Set might be useful (Buchbinder et al., 2008; Wolfe & Michaud, 2007).

6.2 Body Structures

The main finding in this component is that two categories contained in the Comprehensive Core Set for RA were not mentioned at all by the experts who took part in this study. This is interesting because categories of the component *Body Functions* related with these structures were found to be of particular relevance and should therefore be included in the Core Set in the future. These categories are *s299*

Eye, ear and related structures, unspecified and *s720 Structure of shoulder region*. The former one can be related to the *Body Functions* category *b220 Sensations associated with the eye and adjoining structures*, whereas the latter one seems to be taken into consideration by the body function *b7200 Mobility of the scapula*. In the second case a possible explanation could be the fact that the physicians considered the category *s730 Structure of upper extremity*, which is part of the current version of the Core Set, sufficient. In the first one, however, the disease induced alterations of structures like the cornea or lachrymal glands seem to be neglected all together.

6.3 Activities and Participation

Many of the patients' problems treated by physicians were represented by categories assigned to the component *Activities and Participation.* For the most part these treatment goals are already considered in the current version of the Comprehensive ICF Core Set for RA either by same level categories or by ones on a different level. Only one category, namely *d435 Moving objects with lower extremities* was regarded to be neglected. Indeed, it could be demonstrated that in established RA there is a higher deterioration of the function of lower limbs than upper limbs. Even at an early stage of the disease rheumatoid arthritis patients show impairments in structure and functioning of the feet, like reduced ankle plantarflexion power in contrast to healthy controls. This can lead to disabilities in everyday life like pushing pedals on a bicycle (Ringen et al., 2008; Tuner et al., 2006). In fact, the foot represents the second frequent symptomatic joint complex in RA patients (Grondal et al., 2008). So, analogous to upper extremities, the legs and the feet constitute an important target of clinical interventions and should be taken into account by the ICF Core Set.

6.4 Environmental Factors

It stands out that a large number of categories of the component *Environmental Factors* considered in the current version of the Comprehensive ICF Core Set for RA, namely 11 out of 20, reached a relatively low (< 50%) agreement or were not even mentioned at all, not even by a higher or lower level category. This may indicate that they are usually not target of physicians' interventions. Support for this explanation may be the fact that only five categories were deemed relevant by at least 75% of the participants by a same or different level category.

It is noticeable that several categories assigned to the ICF component *Environmental Factors* were named by the participants in the first Delphi round, but in the following rounds only few of the participants agreed that this category represents a patients' problem, patients' resources or aspect of the environment treated by physicians. This resulted from the fact that some participants did not consider that they should only list patients' problems, patients' resources or aspects of the environment that are *treated by physicians*. This misunderstanding in the first Delphi round did not affect the final results substantially since the participants had the possibility to disagree with the respective categories in the following rounds.

6.5 Personal Factors

A notable number of patients' problems raised by the experts in our study were identified as *Personal Factors.* These represent a component of *Contextual Factors* according to the ICF, but are not yet classified. Personal factors concern an individual's background, ranging from innate features, like age and gender, to characteristics evolving during one's life, like habits, experiences, psychological qualities, coping styles and other health conditions. The latter ones must not be part of the health condition that is to be judged.

All of these factors may play a role in disability (World Health Organization, 2001). There is a clear consensus that especially coping and self-efficacy as well as concomitant health conditions, affecting in particular psychological well-being, like depression, are strongly related to RA patients' health perception, reactions to pain and both positive and negative mood (Conner et al., 2006; Evers et al., 2003; Keefe et al., 1997; Lefebvre et al., 1999). It has been demonstrated that gender differences exist regarding emotion regulation, which again affects health perception and secondarily disability (van Middendorp et al., 2005). However, many of the mentioned personal factors are more likely to require psychological intervention than medical intervention, although they reached a significant agreement among the participants.

A lot of the concomitant health conditions named by the panel of experts, which by definition of the ICF are assigned to *Personal Factors*, are also represented as similarly formulated categories, that were considered relevant, as well. An example for this phenomenon is the personal factor C*ardiovascular diseases* and the categories *b410 Heart functions* and *b415 Blood vessel functions*. Uncertainties of the aetiology of the condition, whether it is caused by the basic disease rheumatoid arthritis or independently of it, may be the reason for this striking finding.

It would be most helpful for physicians if the ICF would create a classification of personal factors, despite their variety in the different cultural and social circumstances. By an introduction of them into the International Classification of Functioning, Disability and Health a systemic and standardized identification of personal factors influencing patients would be possible. Such a classification would facilitate the selection of appropriate diagnostic measures, treatment planning and outcome evaluation.

6.6 The problem of side-effects of rheumatologic treatment

A frequently reoccurring issue raised in this study is the side-effects of pharmacotherapy. These are not to be considered in the Core Sets by definition as discussed by Coenen et al. (2006). In addition, these conditions 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 extra-articular conditions, which are quite uncommon in the regular disease course. That is why they should not be taken into consideration in the Core Set. Nevertheless they do represent a problem that requires physicians' attention as has also been shown in the study addressing patients' perspective regarding the Core Set (Coenen et al., 2006). As a compromise the introduction of a special Core Set for therapy would be useful.

7. Conclusion

The course and the results of the study in general support the application of the Delphi technique for meeting the study objectives. With response rates exceeding 80% in each round the usual attrition rates of approximately 50% reported in literature (Geschka, 1977) could be clearly surpassed.

Participants from all of the six WHO defined regions of the world could be recruited, guaranteeing a wide range of expert opinion. There were some limitations with regards to an even distribution of expert samples and opinion. Only one representative from the African region was included. Further validation research in this region is a direction for future study.

The results of currently finished or ongoing studies involving psychologists, physical and occupational therapists and nurses will further elucidate the validity of the Comprehensive Core Set for rheumatoid arthritis from the perspective of different health professions. The findings regarding this Core Set, as well as for all of the other existing Core Sets for chronic diseases, will be discussed at an International ICF Core Set conference and potentially result in a modified version of the Comprehensive Core Set for RA.

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9. Attachments

9.1 Comprehensive ICF Core Set for Rheumatoid Arthritis

Body Functions

ICF Code			ICF Category Title
2nd level	3rd level	4th level	
b130			Energy and drive functions
b134			Sleep function
b152			Emotional functions
b180			Experience of self and time functions
	b1801		Body image
b280			Sensation of pain
	b2800		Generalized pain
	b2801		Pain in body part
		b28010	Pain in head and neck
		b28013	Pain in back
		b28014	Pain in upper limb
		b28015	Pain in lower limb
		b28016	Pain in joints
b430			Haematological system functions
b455			Exercise tolerance function
b510			Ingestion function
b640			Sexual functions
b710			Mobility of joint functions
	b7102		Mobility of joints generalized
b715			Stability of joint functions
b730			Muscle power functions
b740			Muscle endurance functions
b770			Gait pattern functions
b780			Sensations related to muscles and movement functions
	b7800		Sensation of muscle stiffness

Body Structures

ICF Code			ICF Category Title
2nd level	**3rd level**	**4th level**	
s299			Ear, eye and related structures, unspecified
s710			Structure of head and neck
s720			Structure of shoulder region
s730			Structure of upper extremity
		s73001	Elbow joint
		s73011	Wrist joint
	s7302		Structure of hand
		s73021	Joints of hand and fingers
		s73022	Muscles of hand
s750			Structure of lower extremity
		s75001	Hip joint
		s75011	Knee joint
	s7502		Structure of ankle and foot
s760			Structure of trunk
	s7600		Structure of vertebral column
		s76000	Cervical vertebral column
s770			Additional musculoskeletal structures related to movement
s810			Structure of areas of skin

Activities & Participations

ICF Code			ICF Category Title
2nd level	3rd level	4th level	
d170			Writing
d230			Carrying out daily routine
d360			Using communication devices and techniques
d410			Changing basic body position
d415			Maintaining a body position
d430			Lifting and carrying objects
d440			Fine hand use
d445			Hand and arm use
d449			Carrying, moving and handling objects, other specified and unspecified
d450			Walking
d455			Moving around
d460			Moving around in different locations
d465			Moving around using equipment
d470			Using transportation
d475			Driving
d510			Washing oneself
d520			Caring for body parts
d530			Toileting
d540			Dressing
d550			Eating
d560			Drinking
d570			Looking after ones health
d620			Acquisition of goods and services
d630			Preparing meals
d640			Doing housework
d660			Assisting others
d760			Family relationships
d770			Intimate relationships
d850			Remunerative employment
d859			Work and employment, other specified and unspecified
d910			Community life
d920			Recreation and leisure

Environmental Factors

ICF Code			ICF Category Title
2nd level	3rd level	4th level	
e110			Products or substances for personal consumption
e115			Products and technology for personal use in daily living
e120			Products and technology for personal indoor and outdoor mobility and transportation
e125			Products and technology for communication
e135			Products and technology for employment
e150			Design, construction and building products and technology of buildings for public use
e155			Design, construction and building products and technology of buildings for private use
e225			Climate
e310			Immediate family
e320			Friends
e340			Personal care providers and personal assistants
e355			Health professionals
e360			Other professionals
e410			Individual attitudes of immediate family members
e420			Individual attitudes of friends
e425			Individual attitudes of acquaintances, peers, colleagues, neighbours and community members
e450			Individual attitudes of health professionals
e460			Societal attitudes
e540			Transportation services, systems and policies
e570			Social security services, systems and policies
e580			Health services, systems and policies

9.2 Complete results

Body Functions

ICF Code			ICF Category Title	Round 2 n= 64	Round 3 n= 61
2nd level	3rd level	4th level			
b122			Global psychosocial functions	57.1%	65.6%
b130			**Energy and drive functions**		
	b1300		Energy level	60.3%	78.7%
	b1303		Craving	34.9%	16.7%
b134			**Sleep functions**	73.0%	90.2%
b140			Attention functions	28.6%	18.0%
	b1400		Sustaining attention	34.4%	20.0%
b152			**Emotional functions**	60.3%	70.0%
	b1522		Range of emotion	41.3%	31.7%
b180			**Experience of self and time functions**		
	b1801		**Body image**	57.1%	68.9%
b210			Seeing functions	42.9%	33.3%
		b21023	Visual picture quality	28.6%	16.4%
b215			Functions of structures adjoining the eye	57.1%	68.9%
b220			Sensations associated with the eye and adjoining structures	82.5%	
b265			Touch function	57.1%	72.1%
	b2702		Sensitivity to pressure	55.6%	72.1%
b280			**Sensation of pain**	90.5%	
	b2800		**Generalized pain**	92.1%	

2nd level	3rd level	4th level			
	b2801		**Pain in body part**		
		b28010	**Pain in head and neck**	96.8%	
		b28011	Pain in chest	83.9%	
		b28012	Pain in stomach or abdomen	88.9%	
		b28013	**Pain in back**		
		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%	
b410			Heart functions	64.5%	90.2%
b415			Blood vessel functions	67.7%	86.9%
b420			Blood pressure functions	69.4%	93.4%
	b4200		Increased blood pressure	74.6%	94.9%
b430			**Haematological system functions**	76.2%	93.3%
b435			Immunological system functions	90.5%	
b440			Respiration functions	79.4%	91.7%
b445			Respiratory muscle functions	58.7%	65.0%
b450			Additional respiratory functions	47.6%	41.0%
b455			**Exercise tolerance functions**	79.4%	86.9%
	b4551		Aerobic capacity	54.0%	65.6%
	b4552		Fatiguability	85.7%	
b460			Sensations associated with cardiovascular and respiratory functions	63.5%	78.3%
b510			**Ingestion functions**	66.7%	78.7%
	b5104		Salivation	93.5%	
b515			Digestive functions	63.5%	77.0%
b520			Assimilation functions	36.5%	24.6%
b525			Defecation functions	46.0%	42.6%
b530			Weight maintenance functions	87.3%	

2nd level	3rd level	4th level			
b535			Sensations associated with the digestive system	49.2%	42.6%
b540			General metabolic functions	50.0%	50.8%
b545			Water, mineral and electrolyte balance functions	56.5%	63.9%
b555			Endocrine gland functions	58.1%	67.2%
b640			**Sexual functions**	62.9%	75.0%
b650			Menstruation functions	53.2%	58.3%
	b6600		Functions related to fertility	56.7%	68.9%
	b6601		Functions related to pregnancy	75.8%	88.5%
	b6603		Lactation	54.8%	58.3%
	b6700		Discomfort associated with sexual intercourse	61.3%	78.3%
b710			**Mobility of joint functions**	93.5%	
	b7102		**Mobility of joints generalized**		
b715			**Stability of joint functions**	91.9%	
b720			Mobility of bone functions	90.3%	
	b7200		Mobility of scapula	75.8%	88.3%
b730			**Muscle power functions**	82.0%	
	b7300		Power of isolated muscles and muscle groups	73.8%	88.5%
b740			**Muscle endurance functions**		
b750			Motor reflex functions	49.2%	36.1%
b755			Involuntary movement reaction functions	47.5%	31.1%
b760			Control of voluntary movement functions	59.0%	60.7%
b765			Involuntary movement functions	41.7%	20.0%
b770			**Gait pattern functions**	86.9%	
b780			**Sensations related to muscles and movement functions**	75.4%	82.0%
	b7800		**Sensation of muscle stiffness**	86.9%	
b810			Protective functions of the skin	52.2%	50.8%

2nd level	3rd level	4th level			
b840			Sensation related to the skin	72.1%	80.3%

Body Structures

ICF Code			ICF Category Title	Round 2 n= 64	Round 3 n= 61
2nd level	3rd level	4th level			
s110			Structure of brain	37.7%	13.3%
s120			Spinal cord and related structures	57.4%	57.4%
s140			Structure of sympathetic nervous system	47.5%	25.0%
s150			Structure of parasympathetic nervous system	44.3%	23.7%
s299			**Eye, ear and related structures, unspecified**		
s430			Structure of respiratory system	60.7%	65.6%
s710			**Structure of head and neck region**		
	s7103		Joints of head and neck region	100.0%	
s720			**Structure of shoulder region**		
s730			**Structure of upper extremity**	95.1%	
		s73001	**Elbow joint**		
		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%	
		s75001	**Hip joint**		
	s7502		**Structure of ankle and foot**	96.7%	
		s75021	Ankle joint and joints of foot and toes	100.0%	
s760			**Structure of trunk**		
	s7600		**Structure of vertebral column**		
		s76000	**Cervical vertebral column**	96.7%	
s770			**Additional musculoskeletal structures related to movement**		

2nd level	3rd level	4th level			
	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**	68.9%	78.7%
	s8102		Skin of upper extremity	67.2%	78.7%
	s8104		Skin of lower extremity	67.2%	78.7%

Activities & Participation

ICF Code			ICF Category Title	Round 2 n= 64	Round 3 n= 61
2nd level	3rd level	4th level			
d170			**Writing**	44.3%	34.4%
d230			**Carrying out daily routine**	52.5%	50.8%
	d2401		Handling stress	49.2%	43.3%
	d3352		Producing drawings and photographs	37.7%	18.3%
d360			**Using communication devices and techniques**		
	d3600		Using telecommunication devices	38.3%	24.6%
	d3601		Using writing machines	41.7%	27.9%
d410			**Changing basic body position**	63.9%	83.6%
	d4100		Lying down	67.2%	82.0%
	d4101		Squatting	62.3%	81.4%
	d4102		Kneeling	67.2%	85.0%
	d4103		Sitting	68.9%	86.4%
	d4104		Standing	67.2%	86.7%
	d4105		Bending	62.3%	83.6%
d415			**Maintaining a body position**		
	d4151		Maintaining a squatting position	56.7%	67.8%
	d4152		Maintaining a kneeling position	62.3%	70.0%
	d4153		Maintaining a sitting position	60.7%	78.7%
	d4154		Maintaining a standing position	68.9%	83.3%
d430			**Lifting and carrying objects**		
	d4300		Lifting	70.5%	86.7%
	d4301		Carrying in the hands	72.1%	83.3%

2nd level	3rd level	4th level			
	d4302		Carrying in the arms	72.1%	83.3%
	d4303		Carrying on shoulders, hip and back	67.2%	79.7%
d435			Moving objects with lower extremities	65.6%	78.0%
d440			**Fine hand use**	75.4%	85.0%
	d4400		Picking up	77.0%	83.3%
	d4401		Grasping	76.7%	85.0%
	d4402		Manipulating	73.3%	83.3%
d445			**Hand and arm use**	78.3%	84.7%
	d4452		Reaching	76.7%	83.1%
	d4453		Turning or twisting the hands or arms	72.1%	85.0%
d449			**Carrying. moving and handling objects. other specified and unspecified**		
d450			**Walking**	78.3%	84.7%
	d4500		Walking short distances	72.1%	81.4%
	d4502		Walking on different surfaces	68.3%	76.7%
d455			**Moving around**	66.7%	76.7%
	d4551		Climbing	66.7%	78.3%
d460			**Moving around in different locations**	65.0%	80.0%
d465			**Moving around using equipment**	63.8%	75.9%
d470			**Using transportation**	60.0%	70.0%
	d4701		Using private motorized transportation	53.3%	60.3%
	d4702		Using public motorized transportation	53.3%	59.3%
d475			**Driving**	60.0%	73.3%
	d4750		Driving human-powered transportation	55.0%	63.3%
	d4751		Driving motorized vehicles	58.3%	66.7%
d510			**Washing oneself**	66.7%	83.3%
	d5101		Washing whole body	63.3%	81.4%
d520			**Caring for body parts**	68.3%	81.4%

2nd level	3rd level	4th level			
	d5202		Caring for hair	68.3%	80.0%
d530			**Toileting**	65.0%	81.4%
d540			**Dressing**	71.7%	87.9%
	d5400		Putting on clothes	63.9%	79.7%
	d5401		Taking off clothes	65.6%	81.4%
	d5403		Taking off footwear	68.9%	83.1%
d550			**Eating**	63.9%	78.0%
d560			**Drinking**	65.6%	83.3%
d570			**Looking after one`s health**		
	d5701		Managing diet and fitness	50.8%	59.3%
	d5702		Maintaining one's health	66.7%	78.0%
d620			**Acquisition of goods and services**		
	d6200		Shopping	34.4%	25.4%
d630			**Preparing meals**	45.9%	40.7%
d640			**Doing housework**	54.1%	61.0%
	d6400		Washing and drying clothes and garments	47.5%	37.3%
	d6401		Cleaning cooking area and utensils	42.6%	33.9%
	d6402		Cleaning living area	50.8%	47.5%
	d6403		Using household appliances	44.3%	33.9%
	d6404		Storing daily necessities	39.3%	23.7%
	d6405		Disposing of garbage	47.5%	25.4%
	d6501		Maintaining dwelling and furnishings	37.1%	16.9%
	d6505		Taking care of plants, indoors and outdoors	34.9%	15.3%
d660			**Assisting others**	33.3%	18.3%
d740			Formal relationships	33.9%	13.3%
d750			Informal social relationships	33.3%	13.3%
	d7500		Informal relationships with friends	31.7%	11.9%
	d7501		Informal relationships with neighbours	32.8%	11.9%

2nd level	3rd level	4th level			
d760			**Family relationships**	38.1%	16.7%
d770			**Intimate relationships**	42.9%	23.3%
	d7702		Sexual relationships	45.2%	41.7%
d825			Vocational training	41.0%	25.4%
d830			Higher education	33.3%	16.7%
d840			Apprenticeship (work preparation)	40.3%	23.3%
d845			Acquiring, keeping and terminating a job	41.3%	32.2%
	d8450		Seeking employment	36.5%	22.0%
	d8451		Maintaining a job	55.6%	67.8%
d850			**Remunerative employment**	48.4%	67.2%
d855			Non-remunerative employment	41.9%	33.9%
d859			**Work and employment, other specified and unspecified**		
d860			Basic economic transactions	28.6%	11.7%
d870			Economic self-sufficiency	28.6%	13.3%
	d8700		Personal economic resources	31.7%	15.0%
d910			**Community life**	36.5%	25.0%
d920			**Recreation and leisure**	54.0%	63.8%
	d9201		Sports	57.1%	55.9%
	d9202		Arts and culture	41.9%	31.6%
	d9203		Crafts	47.6%	37.9%
	d9204		Hobbies	32.3%	23.7%
	d9205		Socializing	39.7%	28.3%
d930			Religion and spirituality	27.9%	13.3%
d950			Political life and citizenship	30.0%	13.6%

Environmental Factors

ICF Code			ICF Category Title	Round 2 n= 64	Round 3 n= 61
2nd level	3rd level	4th level			
e110			**Products or substances for personal consumption**		
	e1100		Food	36.5%	21.7%
	e1101		Drugs	65.1%	76.7%
e115			**Products and technology for personal use in daily living**	54.0%	61.0%
	e1151		Assistive products and technology for personal use in daily living	64.5%	85.0%
e120			**Products and technology for personal indoor and outdoor mobility and transportation**	62.9%	75.0%
	e1201		Assistive products and technology for personal indoor and outdoor mobility and transportation	60.3%	75.0%
e125			**Products and technology for communication**		
	e1251		Assistive products and technology for communication	51.6%	49.2%
e135			**Products and technology for employment**	41.9%	25.0%
	e1351		Assistive products and technology for employment	43.5%	26.7%
e140			Products and technology for culture, recreation and sport	38.3%	21.7%
e150			**Design, construction and building products and technology of buildings for public use**	38.7%	25.0%
e155			**Design, construction and building products and technology of buildings for private use**	40.3%	23.3%
	e1650		Financial assets	23.0%	
e225			**Climate**	24.2%	

2nd level	3rd level	4th level			
	e2250		Temperature	32.3%	11.7%
e310			**Immediate family**	43.5%	32.2%
e315			Extended family	30.6%	16.7%
e320			**Friends**	30.6%	18.3%
e325			Acquaintances, peers, colleagues, neighbours and community members	31.7%	18.3%
e330			People in positions of authority	28.6%	8.3%
e335			People in subordinate positions	27.4%	8.3%
e340			**Personal care providers and personal assistants**	54.8%	65.0%
e355			**Health professionals**	77.0%	96.7%
e360			**Other professionals**		
e410			Individual attitudes of immediate family members	58.1%	71.7%
e415			Individual attitudes of extended family members	35.5%	23.7%
e420			**Individual attitudes of friends**	30.6%	26.7%
e425			**Individual attitudes of acquaintances, peers, colleagues, neighbours and community members**	32.3%	21.1%
e450			**Individual attitudes of health professionals**	58.1%	70.0%
e460			**Societal attitudes**	45.9%	40.7%
e540			**Transportation services, systems and policies**	37.1%	28.8%
	e5400		Transportation services	38.7%	25.0%
	e5401		Transportation systems	32.8%	23.3%
	e5550		Associations and organizational services	41.7%	36.7%
	e5600		Media services	47.5%	35.0%
e565			Economic services, systems and policies	29.0%	16.9%
e570			**Social security services, systems and policies**	48.4%	42.4%

2nd level	3rd level	4th level			
	e5700		Social security services	50.0%	56.7%
	e5702		Social security policies	50.8%	61.7%
e575			General social support services, systems and policies	51.6%	56.7%
	e5750		General social support services	52.5%	56.7%
e580			**Health services, systems and policies**		
	e5800		Health services	70.5%	90.0%
	e5801		Health systems	61.3%	83.3%
	e5802		Health policies	60.7%	77.6%
	e5850		Education and training services	50.0%	51.7%
e595			Political services, systems and policies	27.1%	11.9%

Personal Factors

Answer	Round 2 n= 64	Round 3 n= 61
Knowledge of disease/treatment	98.4%	
Osteoporosis	98.4%	
Sjögren 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	74.6%	81.4%
Stamina	60.7%	81.4%
Diabetes	81.0%	
Self-esteem	66.1%	78.0%
Coccydiomycosis	60.3%	59.6%

Answer	Round 2 n= 64	Round 3 n= 61
Resignation	55.6%	59.3%
Intellectual background	38.1%	25.4%

Not covered

Answer	Round 2 n= 64	Round 3 n= 61
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	71.4%	86.4%
Aetiology	74.6%	84.7%
Prevention	74.2%	84.7%
Edema	82.5%	
Counselling of occupational environment	69.8%	79.7%
Risk for family members	66.7%	78.0%
Incubation	32.3%	17.2%

9.3 First round questionnaire

Delphi Exercise Round 1 **Health Profession: Physicians**

What are the problems, resources and aspects of environment treated by physicians in patients with rheumatoid arthritis?

Please list your answers in the following lines.
Please try to use only one line per patients' problem, per patients' resource or per aspect of the environment.

-.....
-.....
-.....

Some information about yourself:

Age _____ **years**
Gender _____

Professional background _____

Specialty _____

Current professional activity _____

Professional experience _____ **years**

Practical experience with RA patients _____ **years**

How many years did you treat RA patients
- exclusively _____ **years**
- predominantly _____ **years**
- frequently _____ **years**
- rarely ? _____ **years**

How would you rate your expertise in the treatment of RA patients?

Please chose an number between 1 (low) and 5 (excellent) _____

9.4 Second round questionnaire

Delphi Exercise Round 2

Physicians

Do you agree that this ICF category represents patients' problems, patients' resources or aspects of the environment treated by physicians in patients with RA?

ICF code	ICF category title	ICF category description	YES/NO
b122	Global psychosocial functions	General mental functions, as they develop over the life span, required to understand and constructively integrate the mental functions that lead to the formation of the interpersonal skills needed to establish reciprocal social interactions, in terms of b	
b1300	Energy level	Mental functions that produce vigour and stamina.	
b1303	Craving	Mental functions that produce the urge to consume substances, including substances that can be abused.	
b134	Sleep functions	General mental functions of periodic, reversible and selective physical and mental disengagement from one's immediate environment accompanied by characteristic physiological changes.	
b140	Attention functions	Specific mental functions of focusing on an external stimulus or internal experience for the required period of time.	
b1400	Sustaining attention	Mental functions that produce concentration for the period of time required.	
b152	Emotional functions	Specific mental functions related to the feeling and affective components of the processes of the mind.	
b1522	Range of emotion	Mental functions that produce the spectrum of experience of arousal of affect or feelings such as love, hate, anxiousness, sorrow, joy, fear and anger.	

9.5 Abbreviations

ACR	American College of Rheumatology
Anti-CCP	Anti-cyclic citrullinated peptide antibodies
COX	Cyclooxygenase
DMARD	Disease-modifying antirheumatic drug
EULAR	European League Against Rheumatism
HLA	Human leukocyte antigen
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
NCEP	National Cholesterol Education Program
NSAID	Non steroidal anti-inflammatory drug
RA	Rheumatoid arthritis
RF	Rheumatoid factor
TNF	Tumor necrosis factor
WHO	World Health Organization

9.6 Curriculum vitae

Name:	Christina Gebhardt
Geburtsdatum:	12. Juli 1982
Geburtsort:	München
Nationalität:	Deutsch

Ausbildung:

2004 – 2009	Technische Universität München, Fakultät Medizin
2002 – 2004	Ludwig- Maximilians Universität München, Fakultät Medizin Physikum
1993 – 2002	Gymnasium Erding, Abitur
1989 - 1993	Grundschule Walpertskirchen

Praktika im Rahmen der medizinischen Ausbildung:

2007- 2008	1. Tertial: Psychiatrie, Uniklinikum Rechts der Isar
(Praktisches Jahr)	2. Tertial: Innere Medizin, Krankenhaus Bogenhausen
	3. Tertial: Chirurgie, Policlinico Tor Vergata, Roma; Italien
August 2006	Famulatur der Allgemeinmedizin, Walpertskirchen
März 2006	Famulatur der Psychiatrie, Bezirksklinikum Taufkirchen
Juli- August 2005	Famulatur der Allgemeinmedizin, Schwabmünchen
März 2005	Famulatur der Chirurgie, Schreiber Klinik für Chirurgie München
September 2003	Krankenpflegepraktikum in der Schreiber Klinik für Innere Medizin München
März 2003	Krankenpflegepraktikum im Kreiskrankenhaus Erding