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Developing a method to validate the WHO ICF Core Sets from the patient perspective: rheumatoid arthritis as a case in point

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Content

1 Background

1.1 Rheumatoid arthritis and disability

Rheumatoid arthritis (RA) is a chronic disabling disease. The prevalence of RA in most industrialized countries varies between 0.3% and 1%, whereas in developing countries it is at the lower end of this range [1]. Patients with RA may have a shorter life expectancy [2,3] and disability in RA patients may be serious [4,5,6,7]. It frequently affects patients in their most productive years and thus disability results in a major economic loss [8,9]. In a comprehensive review it was found that at least 75% of the total costs of this illness are due to the indirect costs of the relatively high work disability rate. Moreover, the range of costs in the studies is remarkably similar, with direct costs of between $4 and $6000 per year in constant dollars and indirect costs of between $12 and $24,000 [8].

The RA disease process may lead to impairments in functions and structures of the body including musculoskeletal pain, fatigue, joint stiffness, joint swelling, loss of range of motion, muscular weakness, and joint damage. Such impairments are followed by limitations of physical activities [10] and restrictions in participation [11]. The relationships between impairments, activity limitations and participation restrictions can in turn be influenced by the disease process itself and by contextual factors including social support and job demands [11]. Current recommendations regarding assessment of the disease and disease consequences, for example in trials of anti-rheumatic drugs include the recommendation to measure functioning mainly referring to physical function [12]. Accordingly, measures of function such as the Health Assessment Questionnaire (HAQ) [13], the Arthritis Impact Measurement Scales (AIMS) [14], or the McMaster Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR) [15] are increasingly used in RA studies [16]. However, condition-specific measures, arguably with the exception of the AIMS [14,17], which can be considered a generic instrument specific for RA, typically cover only selected aspects of the whole patient experience associated with RA. Also, the measures vary quite considerably regarding the concepts included [18]. It is also important to recognize that these measures have been developed to measure the disease consequences but not to measure functioning and health not only associated with the disease process of RA but also with environmental and personal factors [19]. These instruments have been developed according to the medical perspective and in line with the current concept in outcomes and quality-of-life research of condition-specific measures [20], i.e., they are based on the assumption that different conditions are associated with salient patient problems in functioning. The individual influence of the environment and personal factors is, however, rarely taken into account [21,22]. In addition, widely used RA-specific health-status measures, like the HAQ, mainly address activities far more than participation [23]. However, the patients’ experience of functioning is determined by their interaction with the environment and their own personal characteristics and not only by the health condition [24,25,26,27]. RA is also very much associated with the inability to continue working, ultimately leading to the experience of restriction in participation [4,28,29,30]. Thus, a very comprehensive approach is required when addressing RA. Therefore, these measures may not be ideal for rehabilitation where functioning and health is not primarily an outcome but the starting point in the diagnosis or the assessment of a patient. It would therefore be valuable for teaching, clinical practice and research to define what should be measured to represent comprehensively the experience of patients with RA. To achieve this goal, we need a comprehensive framework and classification, which can serve as a universal language understood by health professionals, researchers, policymakers, patients, and patient organizations.

1.2 The International Classification of Functioning, Disability and Health (ICF)

Precise knowledge of patients’ RA related disability and functioning is necessary in health services provision and research. Clinical management, but also epidemiological and clinical research, depend on the careful detection of functioning problems, as well as resources, in patients with a chronic health condition.

With the approval of the World Health Organization’s (WHO) *International Classification of Functioning, Disability and Health* (ICF) [31], we can now rely on a globally agreed framework and classification to define the typical spectrum of problems in functioning of patients with RA. The ICF provides a comprehensive conceptual framework and a unified standardized language to describe health and health related states, both at the individual, as well as at population levels. It establishes the basis for a more comprehensive description of the experience of patients suffering from a determined disease. The ICF has been developed to complement the diagnostic information provided by the *International Statistical Classification of Diseases and Related Health Problems (ICD-10)* [32].

The ICF is based upon a biopsychosocial perspective, which aims to integrate different perspectives of health into one unified and coherent view. The model relates to six components of health: the *Health Condition*, *Body Functions and Structures*, *Activities*, *Participation*, *Environmental Factors*, and *Personal Factors*. The central concepts within this biopsychosocial perspective are functioning and disability. Functioning is an umbrella term for intact body functions and body structures, activities and participation. Functioning denotes the positive or neutral outcome of the bidirectional complex interaction between an individual with a health condition and his or her context. The complementary term disability is an umbrella term to denote impairments of body functions and structures, activity limitations and participation restrictions. Disability is the negative outcome of the interaction between an individual with a health condition and his or her context. The current understanding of the interactions of the components of functioning, disability and health within a biopsychosocial perspective is depicted in Figure 1 [31].

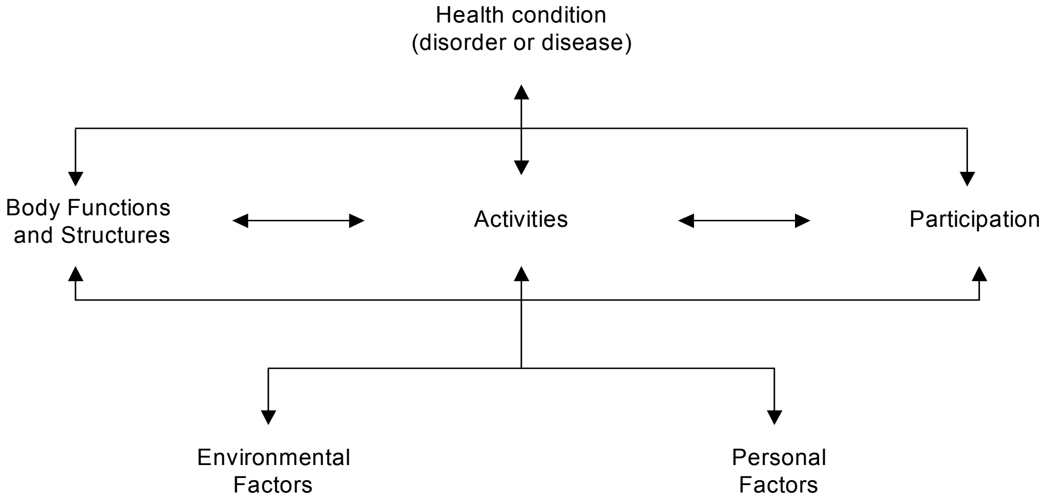

Figure 1 The biopsychosocial perspective of functioning, disability and health [31]

The ICF as a classification reflects the underlying biopsychosocial perspective. The ICF provides a list of *Body Functions*, a list of *Body Structures*, a joint list of *Activities and Participation*, and a list of *Environmental Factors*. *Personal Factors* are not implemented as a part of the classification, yet. Moreover, health conditions are not classified by the ICF, but are classified by the ICD-10 [32]. The ICF as a classification is a listing of categories, which are the units of the classification. The ICF contains more than 1400 so-called ICF categories, each allotted to the named components according to the biopsychosocial perspective with the exception of the component *Personal Factors*. Each ICF category is denoted by a code composed by a letter that refers to the components of the classification (b: *Body Functions*; s: *Body Structures*; d: *Activities and Participation* and e: *Environmental Factors*) and is followed by a numeric code starting with the chapter number (one digit), followed by the so-called 2nd level (two digits) and the 3rd and 4th levels (one digit each). All ICF categories are accompanied by definitions, examples, inclusion, and exclusion criteria. The ICF categories are organized within a hierarchically nested structure. Consequently, a lower level category shares the higher level category of which it is a member, i.e., the use of a lower level (more detailed) category automatically implies that the higher level category is applicable, but not the other way round. An example from the component *Body Functions* is presented in the following:

b	*Body Functions*	(ICF component)
b2	*Sensory functions and pain*	(1st level = ICF chapter)
b280	*Sensation of pain*	(2nd level ICF category)
b2801	*Pain in body part*	(3rd level ICF category)
b28010	*Pain in head and neck*	(4th level ICF category)

The endorsement of the ICF by the Word Health Assembly (WHA) in May 2001 marks an important milestone in health services provision and research and especially in the field of rehabilitation [33]. Since the ICF has been developed in a worldwide, comprehensive consensus process over the last few years and was endorsed by the WHA as a member of the WHO Family of International Classifications, it is likely to become the generally accepted framework to describe functioning and health. The potential uses of the ICF are numerous. With the ICF, not only an etiologically neutral framework, but a globally-agreed-on language and a classification is available to describe functioning both on the individual and the population levels and from both the patient perspective and that of the health professionals. Therefore, the ICF provides a universal terminology to describe functioning and disability, which is applicable independent of a specific disease or health condition, etiology and pathogenesis, of the profession or specialization of the user, of time, place, culture, country, or health care system. The ICF is a multipurpose flexible tool that allows describing health in individuals or groups, comparing different health conditions, persons, defined groups, time points, countries, and health care systems. It represents a useful common platform to communicate in a multi-professional team, between different departments or facilities, between clinicians and scientists, politicians, decision-makers, and not least, to communicate with the patients [18,31,34,35]. The ICF can be used in clinical practice and rehabilitation to structure and to lead through, thus to facilitate the rehabilitation process. It can provide a standardized frame for rehabilitation understood as a problem solving process with its steps: assessment and goal setting, assignment, intervention, and evaluation [19,36]. It can be used in teaching and education of health professionals [37,38] but also to aggregate information, e.g. for health reporting purposes, public health information systems and epidemiology to build the necessary evidence basis for individual clinical, population-based institutional, or political decisions [39]. Also, the ICF is a useful tool for research, e.g. to select and to describe study populations, and also as a heuristic tool to clarify concepts, to generate and test hypotheses, or to explain health states.

All member states of the WHO are now called upon to implement the ICF in multiple sectors that include, among other things health, education, insurance, labour, health-and-disability policy, statistics, etc. However, the ICF has to be tailored to suit these specific applications [33]. In the clinical context, the main challenge is the length of the highly comprehensive classification with it’s over 1400 categories. This comprehensiveness is a major advantage and strength of the ICF. But at the same time it is the major challenge to its practicability and feasibility.

1.2.1 The development of ICF Core Sets

To enhance the applicability of the ICF classification, ICF-based tools need to be tailored to the needs of the users, without forging the strengths of the ICF [40]. One approach to enhance the application of the ICF is the development of so-called ICF Core Sets for specific health conditions [33,41]. Within this approach functioning and disability are explicitly connected to a defined health condition. This accords with the biopsychosocial perspective and with the requirement of the joint use of the ICF together with the ICD, as intended by the WHO. The WHO has recognized that in everyday clinical practice, only a fraction out of the total number of the ICF categories will be needed [42].

Accordingly, ICF Core Sets are practical tools that represent a selection of categories out of the whole classification. ICF Core Sets for specific health conditions are short lists of such ICF categories that are relevant to most patients with the respective condition [40,41]. Scientifically based internationally agreed ICF Core Sets for 12 chronic health conditions have been developed in a collaborative project of the

Ludwig-Maximilian University, Munich with the Classification, Assessment, Surveys and Terminology Group (CAS) of the WHO, and together with partner organizations worldwide, for the following chronic health conditions [41]:

- Breast Cancer [43]
- Chronic Ischemic Heart Disease [44]
- Chronic Widespread Pain [45]
- Depression [46]
- Diabetes Mellitus [47]
- Low Back Pain [48]
- Obesity [49]
- Obstructive Pulmonary Diseases [50]
- Osteoarthritis [51]
- Osteoporosis [52]
- Rheumatoid Arthritis [53]
- Stroke [54]

The ICF Core Sets for patients with a determined health condition (‘condition-specific ICF Core Sets’) represent a selection of ICF categories out of the entire classification which can serve as standards for the reporting of functioning and health for clinical studies and clinical encounters or as standards for multiprofessional, comprehensive assessment under consideration of influential *Environmental Factors*. Since the condition-specific ICF Core Sets address aspects within all the components of the ICF (*Body Functions*, *Body Structures*, *Activities and Participation*, *Environmental Factors*) they present a broad, condition-specific perspective that may reflect the whole health experience of patients.

For each of these chronic health conditions listed above two types of ICF Core Sets have been developed. *Comprehensive ICF Core Sets* include the prototypical spectrum of problems in functioning in patients with a specific condition. They have been developed to guide multi-professional comprehensive assessment and to include as few as possible, but as many as necessary ICF categories to sufficiently describe patients’ functioning. The *Brief ICF Core Sets* can serve as minimum data sets to be reported in every clinical study and to be assessed at any clinical encounter involving patients with the specific health condition. They include the most important ICF categories in any situation, setting, country or culture [40,41]. Using the universal terminology of the ICF, condition-specific ICF Core Sets preserve all advantages and potentials of the classification, at the same time by their manageable size enhancing its feasibility for the application field of a particular health condition.

The development of ICF Core Sets for 12 chronic health conditions is conceived as an evidence-based scientific process and at the same time as a consensus process. Preparatory studies have been conducted to provide the evidence basis for selecting the relevant categories for the ICF Core Sets. The preparatory studies for each health condition included a Delphi exercise to represent the health professionals' perspective [55], a systematic review on outcomes used in randomized clinical trials (RCTs) to represent the researchers' perspective [56,57,58,59], and an empirical data collection based on the WHO's ICF Checklist [60] representing the perspective of patients undergoing inpatient or outpatient rehabilitation [61]. The ICF categories to be included in the first versions of the ICF Core Sets were identified in international consensus conferences by the means of a formal decision-making and consensus process integrating the evidence gathered from the preparatory studies [41].

1.2.2 ICF Core Sets for rheumatoid arthritis

In line with the general definition of ICF Core Sets, the *ICF Core Sets for rheumatoid arthritis (RA)* [53] are selections of salient ICF categories out of the whole ICF classification, which describe the typical spectrum of problems in RA patients' functioning based on the universal language of the ICF. Seventeen experts (7 physicians with at least a specialization in physical and rehabilitation medicine, 7 rheumatologists, 1 nurse, 1 occupational therapist, and 1 physical therapist) from 12 different countries attended the consensus conference for the *ICF Core Sets for RA* [53].

The total number of ICF categories in the *Comprehensive ICF Core Set for RA* is 96. These 96 ICF categories are made up of 25 (26%) categories from the component *Body Functions*, 18 (19%) from the component *Body Structures*, 32 (33%) from the component *Activities and Participation*, and 21 (22%) from the component *Environmental Factors.* Fifteen of the 25 ICF categories of the component *Body Functions* are at the 2nd, five at the 3rd and five at the 4th level of the ICF classification. The 15 ICF categories at the 2nd level represent 13 percent of the total number of categories at the 2nd level in this component. Most of the categories of the *Body Function*s belong to *chapter 7 'Neuromusculoskeletal and movement-related functions'* (8 categories). The ICF categories included in the *Comprehensive ICF Core Set for RA* are shown in Appendix 1.

With respect to the ICF categories at the 2nd level contained in the *Comprehensive ICF Core Set for RA* the *Brief ICF Core Set for RA* includes 8 (53%) categories from the component *Body Functions*, 7 (88%) from *Body Structures*, 14 (44%) from *Activities and Participation*, and 10 (48%) from *Environmental Factors*. The 8 ICF categories of the component *Body Functions* represent 7 percent, the 7 categories of the component *Body Structures* 13 percent, the 14 categories of the component *Activities and Participation* 12 percent , and the 10 categories of the component *Environmental Factors* 14 percent of the total number of ICF categories at the 2nd level in their respective components. Appendix 2 shows the ICF categories that have been selected for the *Brief ICF Core Set for RA*.

The *Comprehensive ICF Core Set for RA* is one of the largest ICF Core Sets developed for the 12 chronic health conditions. The fact that 96 ICF categories covering all components of the ICF classification and covering all 9 chapters of the component *Activities and Participation* were included in the *Comprehensive ICF Core Set for RA* reflects the multiple and important impairments, limitations and restrictions of *Activities and Participation* involved, as well as the numerous interactions with *Environmental Factors*.

Like all other 11 condition-specific ICF Core Sets, the *Comprehensive ICF Core Set for RA* is now undergoing worldwide testing and validation using a number of approaches including an international multicentre validation study and validation from the perspective of health professionals [62]. Another key aspect is the validation from the patient perspective. While the patient perspective was implicitly included in the development of ICF Core Sets [61], the patients now will be explicitly involved in the process of the validation of condition-specific ICF Core Sets. When measuring and assessing daily functioning in people with RA from a comprehensive perspective in rehabilitation, it is important to include the patient perspective because personal values for outcomes vary between and within patients and professionals [63,64]. As standards of functioning and health in research and clinical practice, the ICF Core Sets have to show that they address the perspective of those who experience the disease.

However, no methodology has been so far developed to validate the condition-specific ICF Core Sets from the patient perspective and most specifically, the ICF Core Sets for RA.

1.3 Qualitative methodology: exploring the patient perspective

Qualitative methodology has gained recognition in health science research in recent times and is now widely used and increasingly accepted in health research and health-related sciences [65,66,67], particularly in rehabilitation research [68]. To obtain a rich and comprehensive view on a specific research topic qualitative methods are often included in mixed-methodology-studies together with quantitative methods [69,70,71]. Qualitative methodology provides the possibility to explore the perspective of those who experience a health problem, i.e. the so-called patient perspective [72,73]. Unlike quantitative methods (e.g. survey research) qualitative methods allow the individuals to respond in their own words, using their own categorizations and perceived associations. However, they are not completely lacking in structure, because the researcher does raise questions to guide the data collection [74].

Two of the most broadly used methodologies in qualitative research are focus groups [75,76,77] and individual interviews [78,79]. Focus groups are "carefully planned series of discussions designed to obtain perceptions on a defined area of interest in a permissive, non-threatening environment" (p. 5) [80]. They are especially useful for studies that involve complex issues that entail many levels of feeling and experience [81]. "The basic goal in conducting focus groups is to hear from the participants about the topics of interest to the researcher" (p. 11) [82]. The idea behind this methodology is that group processes can help people to explore and clarify their views [83]. The non-directive nature of focus groups affords participants an opportunity to comment, explain, disagree and share experiences and attitudes [84]. Focus groups generate a rich understanding of people's experiences and beliefs [85]. Carey outlined the advantages of the focus group methodology, which is "especially well suited for problems in health research where complex clinical issues are often explored through a qualitative approach" (p. 227) [86]. Focus groups differ from individual interviews in that the interaction and group process can enrich the information generated within a group of individuals [74,75]. To attain the so-called triangulation of methodology sometimes both methods were used for data collection in one and the same study. Triangulation addresses the issue of internal validity by using more than one method of data collection to answer a research question [87,88]. The data proceeding from the two methods are usually reported together without any differentiation regarding their "origin". It is commonly assumed that focus groups revealed a larger number of ideas and statements in comparison to individual interviews [89,90,91]. Focus groups are, however, associated with more time and effort (e.g. more resources, participants, costs), and a greater tendency for logistic problems. In general, these assumptions were drawn without any evidence from the collected data.

Only a few studies compare focus groups and individual interviews in a structured way. Thomas and colleagues reported that certain concepts were more likely to occur in focus groups than in individual interviews [89]. However, no difference was found between the two methods in the depth of data generated. The authors also described logistic problems with focus groups and were able to conduct a far greater number of individual interviews. In marketing research, Fern systematically tested the effect of group size on response quantity and quality in focus groups and the effect of the number of individual interviews [92]. In contrast to Thomas and colleagues the author reported that individual interviews generated significantly more ideas and significantly higher quality of ideas than focus groups.

There seems to be out of question that focus groups and individual interviews are methodologies of first choice when exploring the patient perspective. However, no recommendations can be provided so far regarding which methodology should be used in which situation, especially when the patient perspective is explored within the context of the validation of the ICF Core Sets.

The comparison of results proceeding from both methodologies can be facilitated by using a common reference. It can be assume that the ICF can be successfully used for this purpose [93,94] when the information gathered from patients refers to functioning and disability.

2 Research objectives

The overall objective of this doctoral thesis is to identify the most appropriate method to validate condition-specific ICF Core Sets from the patient perspective.

The specific aims are 1) to compare the advantages and disadvantages of two qualitative methods when used to validate ICF Core Sets from the patient perspective, 2) to develop a protocol to validate ICF Core Sets from the patient perspective to be used for different health conditions and in different countries and 3) to examine the content validity of the *Comprehensive ICF Core Set for RA* applying the selected method.

With respect to these specific aims the doctoral thesis is subdivided into three parts. The first part presents an analysis of qualitative data obtained from two qualitative studies to establish the most appropriate method to validate condition-specific *Comprehensive ICF Core Sets*. The following part illustrates the development of a protocol regarding the validation of condition-specific ICF Core Sets from the patient perspective with respect to the results reported in the previous part. Finally, the last part presents the results of the validation of the *Comprehensive ICF Core Set for RA* from the patient perspective using the method that was considered most appropriate. Each of these parts contains a respective discussion section referring to the specific results.

3 Development of a method to validate ICF Core Sets from the patient perspective: Comparison of two qualitative methods

3.1 Objective

The general objective of this part of the doctoral thesis is to compare the advantages and disadvantages of two qualitative methods when used to validate ICF Core Sets from the patient perspective. To reach this objective two qualitative methods – focus groups and individual interviews – and two different approaches used in both methods – ‘open approach’ and ‘ICF-based approach’ – are examined to come forward with the most appropriate method to validate ICF Core Sets from the patient perspective.

3.2 Methods

3.2.1 Design

Two studies were conducted with RA patients using two qualitative methods, namely focus groups and individual interviews. To come forward with an appropriate method to validate *Comprehensive ICF Core Sets* from the patient perspective for each of the two methods two different approaches were used – the so-called ‘open approach’ and the ‘ICF-based approach’. The two methods with their respective approaches were compared with regard to (1) formal aspects (costs of the methods applied) and (2) the results obtained (content).

In both approaches open-ended questions asking the patients to name their problems in *Body Functions*, *Body Structures*, and *Activities and Participation* were used. Furthermore, the participants were asked about *Environmental Factors* (barriers and facilitators) influencing their everyday life (see Table 1). In the ICF-based approach, each of the titles of the ICF chapters from which categories are included in the *Comprehensive ICF Core Set for RA* were additionally presented to the participants to stimulate the naming of problems.

Both studies were approved by the institutional review boards of the Medical University of Vienna and the Ludwig-Maximilian University Munich.

3.2.2 Participants

Sampling of participants

In focus groups and individual interviews patients with RA diagnosed according to the revised ACR criteria [95] who were willing to participate gave written informed consent according to the Declaration of Helsinki 1996. Participants were selected by the maximum variation strategy [96] based on the criteria disease duration and age group.

Specifics in focus groups

All patients who had been treated in the day clinic of the Department of Physical Medicine and Rehabilitation of the Ludwig-Maximilian University in Munich at any time since 2001 were contacted by mail and asked whether they would like to participate in the study. Further participants were recruited from the German self-help service (‘Deutsche Rheuma-Liga e.V.’). The group size was set at a maximum of seven persons to represent different opinions and facilitate interactions.

Specifics in individual interviews

All patients who had appointments on five consecutive, randomly selected days in the outpatient department of the Rheumatology Outpatient Clinic of the

Vienna Medical University were asked whether they would like to participate in the study.

Sample size

The sample size was determined by saturation of data. Saturation refers to the point at which an investigator has obtained sufficient information from the field [80,96]. A detailed description of saturation is given in paragraph 3.2.4 *'Data analysis: saturation of data'*.

3.2.3 Data collection

Focus groups and individual interviews were conducted in a non-directive manner according to a guideline, including open-ended questions (see Table 1) and further instructions (e.g., procedure of the session, technical aspects). At the beginning of each focus group and individual interview, the procedure of the session was explained to the participants. Then one of the two different approaches was performed (open approach or ICF-based approach). In the ICF-based approach the model of the ICF was presented in layman terms to the participants. The open-ended questions (see Table 1) and the titles of the chapters (only ICF-based approach) were presented visually to the participants. At the end of each focus group and interview, a summary of the main results was given to the participants allowing them to verify and amend emergent issues. The two approaches were conducted alternately.

ICF components	Open-ended questions
b Body Functions	If you think about your body, what functional problems do you have?
s Body Structures	If you think about your body, where are your biggest problems?
d Activities & Participation	If you think about your daily life, what are your biggest problems?
e Environmental Factors	If you think about your environment, factors in your surroundings, and your living conditions, - what do you find helpful or supportive? - what do you find cumbersome?

Table 1 Open-ended questions of focus groups and individual interviews

Both the focus groups and the individual interviews were digitally recorded and transcribed verbatim. For each method and each approach applied the following variables were recorded:

- Characteristics of participants
- Time needed to conduct the studies, especially for the (a) recruitment of participants, (b) preparation of the sessions, (c) duration of the sessions (including a short break of 10 minutes in the focus groups), (d) transcription of the sessions, (e) data check of the transcripts, (f) analysis of the data, (g) peer review process, and (h) overall time needed to perform the studies
- Frequencies of concepts identified by the participants' statements (see 3.2.4 *'Data analysis: Qualitative analysis'*)
- Frequencies of ICF categories linked to the identified concepts (see 3.2.4 *'Data analysis: Linking to the ICF'*)
- Frequencies of ICF categories of the *Comprehensive ICF Core Set for RA* confirmed from the patient perspective using the methods and approaches applied (see 3.2.4 *'Data analysis: Confirmation of the Comprehensive ICF Core Set for RA'*)

Specifics in focus groups

The focus groups were conducted by the author of this doctoral thesis and one group assistant, who observed the group process and recorded the data. Additionally, the assistant filled in field notes according to a standardized coding schema. Field notes refer descriptive observations of the group interaction and of the topics of discussion. The open-ended questions and the titles of the chapters (only ICF-based approach) were presented visually to the participants by a PowerPoint presentation. After each focus group a debriefing with moderator and assistant took place to review the course of the respective focus group.

Specifics in individual interviews

The individual interviews were conducted by another investigator under the supervision of the autor of this doctoral thesis. The open-ended questions and the titles of the chapters (only ICF-based approach) were presented visually to the participants by a hardcopy.

3.2.4 Data analysis

Descriptive statistics

The number of patients participating in both methods and approaches, and descriptive statistics of the variables ‘gender’ (n), ‘age’, ‘disease duration’ (x, sd) and ‘time’ (x, sd, sum) were calculated. The Fisher’s Exact Test (gender) and the independent t-test (age, disease duration) were performed to compare participants’ characteristics regarding the two methods applied. A probability value of less than 0.05 was considered significant. The statistical analyses were performed by using SPSS for windows 14.0 (SPSS Inc., Chicago, Illinois, USA).

Qualitative analysis

The so-called ‘meaning condensation procedure’ [78] was used for the qualitative analysis of data. In the first step, the transcripts of the focus groups and individual interviews were read through to get an overview over the collected data. In the second step, the data were divided into units of meaning, and the theme that dominated a meaning unit was determined. A meaning unit was defined as a specific unit of text either a few words or a few sentences with a common theme [97]. Therefore, a meaning unit division did not follow linguistic grammatical rules. Rather, the text was divided where the researcher discerned a shift in meaning [78]. In the third step, the concepts contained in the meaning units were identified (see Table 2: first and second column). A meaning unit could contain more than one concept.

Linking to the ICF

Every concept of each meaning unit was linked to the most precise ICF category using the same linking rules which have been developed to link health-status measures to the ICF in a specific and precise manner [21,22]. The linking rules are guidelines, which enable concepts to be translated into the language of the ICF in a standardized manner. According to these linking rules, health professionals trained in the ICF are advised to link each concept identified in the qualitative analysis to the ICF category representing this concept most precisely (see Table 2: third column). If a meaning unit contains more than one concept, it was linked to more than one ICF category. An example is the meaning unit 'using a shopping device which I can pull behind me because I have problems with shopping' which contains the concepts 'shopping device' and 'problems with shopping'. The concept 'shopping device' was linked to the ICF category *e120 'Products and technology for personal indoor and outdoor mobility and transportation'.* The concept 'problems with shopping' was linked to the ICF category *d6200 'Shopping'*.

Concepts that cannot be linked to the ICF are documented in two ways. If a concept is not sufficiently specified to make a decision about which ICF category to use, the concept is coded 'nd' (not definable). For example, concepts such as 'physical disability' or 'health' are not sufficiently specified for precise linking. If a concept is not represented by the ICF, this concept is labeled 'nc' (not covered) [21].

However, two modifications beyond the linking rules were made for this linking of qualitative data, namely, if the content of a concept was not explicitly named in the corresponding ICF category, the 2nd level of the ICF classification was linked, rather than the 'other specified' option at the 3rd and 4th level of the ICF classification. The second modification was that, if a patient was more specific than the ICF, the specification of the patient was documented.

According to the purpose of 'multiple coding' [87,88], the identified concepts were linked to the ICF by two health professionals to ensure the rigour of the data analysis. Both health professionals conducted this procedure independently from each other, thus two independent linking versions were created, and then compared. Consensus between the two health professionals was used to decide which ICF category should be linked to each identified concept. In case of a disagreement, a third person trained in the linking rules was consulted. In a discussion led by the third person, the two health professionals that linked the concepts stated their pros and cons for the linking of the concept under question to a specific ICF category. Based on these statements, the third person made an informed decision.

Transcription →		**Meaning unit Concept** →	**ICF category**	
	Qualitative analysis		*Linking*	
Moderator:	*If you think about your body, what functional problems do you have?*			
Patient A:	I used to go to **sports** very often. Now I can´t anymore. I even had to **quit swimming**.	restriction of sports quit swimming	d9201 d4554	sports swimming
Patient B:	Exactly! I also had to **quit swimming**.			
Patient C:	**I can no longer cycle.** (…)	quit cycling	d4750	driving human-powered transportation
Moderator:	*If you think about your body, where are your biggest problems?*			
Patient C:	**Toes, ankle joints**, **knee joints**, **fingers**	toes ankle joints knee joints fingers	s7502 s75021 s75011 s7302	structure of ankle & foot ankle joint & joints of foot & toes knee joint structure of hand
Patient A:	What bothers me are my **wrists.** (…)	wrists	s73021	joints of hand & fingers

Table 2 Scheme of the qualitative data analysis and linking procedure

Saturation of data

In this study saturation of data retrieved from focus groups or individual interviews was defined as the point during data collection and analysis when the linking of the concepts of two consecutive focus groups or individual interviews reveals no additional 2nd level ICF categories of the *Comprehensive ICF Core Set for*

RA with respect to previous focus groups and individual interviews, respectively. Saturation was checked separately for the two approaches.

Confirmation of the Comprehensive ICF Core Set for RA

An ICF category of the *Comprehensive ICF Core Set for RA* was regarded as confirmed if the identical or a similar category emerged from the focus groups or individual interviews (e.g. *s299 'eye, ear and related structures, unspecified'* confirmed by *s230 'structures around eye'*). Since the ICF categories are arranged in a hierarchical code system, the 2nd level ICF categories of the *Comprehensive ICF Core Set for RA* were considered confirmed when the corresponding 3rd or 4th level ICF category of which they were a member had been named by the participants.

Accuracy of data analysis

To audit the accuracy of the analysis, 15 percent of the transcribed text of the focus groups and individual interviews were randomly selected, analysed according to the meaning condensation procedure, and linked to the ICF by two health professionals as a peer review. This process was performed in addition to the 'multiple coding' described in the paragraph *'Linking to the ICF'*. The degree of agreement between the two investigators regarding the linked concepts of this 15 percent of transcribed text was calculated by kappa statistic with 95%-bootstrapped confidence interval [98,99]. The values of the kappa coefficient generally range from 0 to 1, whereas 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance alone. The data analysis was performed with SAS for windows V9.1 [100].

3.3 Results

3.3.1 Descriptive statistics

Forty nine RA patients (open approach: n=25; ICF-based approach: n=24) and 21 patients (open approach: n=13; ICF-based approach: n=8) participated in the focus groups and individual interviews, respectively. Participants' characteristics are summarized in Table 3. The differences between the two methods and the two approaches regarding the characteristics of the participants were not statistically significant (see Table 4).

Characteristics		**Focus groups**		**Individual Interviews**	
		Open approach	**ICF-based approach**	**Open approach**	**ICF-based approach**
Age (years)	**M (SD)**	59,0 (±14,9)	54,3 (±12,9)	58,7 (±13,7)	57,0 (±15,6)
	Range	24-81	35-75	30 - 79	25 - 73
Gender		22 f, 3 m	20 f, 4 m	11 f, 2 m	7 f; 1 m
Duration of disease (years)	**M (SD)**	15,83 (±10,4)	14,62 (±12,5)	9,7 (±10,6)	11,7 (±8,8)

Table 3 Characteristics of the participants in focus groups and individual interviews

Characteristics			**Focus groups**	**Individual interviews**	**p**
Gender	**n (%)**	**female**	42 (85,7)	18 (85,7)	p≤1.000 *
	n (%)	**male**	7 (14,3)	3 (14,3)	
Age (years)	**M (SD)**		56,7 (±13,9)	57,7 (±1,8)	t= -,262 ** p≤.794
Duration of disease (years)	**M (SD)**		15,3 (±11,4)	10,3 (±9,5)	t= 1,711 ** p≤.092

Table 4 Comparison of the participants' characteristics

* Fisher's Exact Test
** Independent t-test

The time to perform the sessions in the open approach was, on average, in the focus groups 1:21 hours (± 0:09; Range: 0:52 h - 1:15 h) and in the individual interviews 0:26 hours (±0:06; Range: 0:19 h - 0:44 h). The time to perform the sessions with the ICF-based approach was, on average, in the focus groups 1:47 hours (±0:24; Range: 1:17 h - 2:06 h) and in the individual interviews 0:36 hours (±0:08; Range: 0:28 h - 0:54 h). Table 5 shows the mean time to perform the different aspects of the study in detail regarding the two methods and approaches applied. With an overall time of 183 hours, the ICF-based approach of the focus groups was the most time-consuming approach compared to the other approaches of focus groups and individual interviews.

Time-related aspects		Focus groups		Individual Interviews	
		Open approach	ICF-based approach	Open approach	ICF-based approach
Time for **- recruitment**	**M (SD)**	4:00h (±0:00)	4:00h (±0:00)	0:30h (±0:00)	0:30h (±0:00)
	Total	20:00h	20:00h	6:30h	4:00h
- preparation of sessions	**M (SD)**	2:00h (±0:00)	2:00h (±0:00)	0:05h (±0:00)	0:05h (±0:00)
	Total	10:00h	10:00h	1:05h	0:40h
Duration of sessions	**M (SD)**	1:21h (±0:09)	1:47h (±0:24)	0:26h (±0:06)	0:36h (±0:08)
	Total	6:48h	8:59h	5:46h	4:48h
Time for data analysis **- transcription**	**M (SD)**	6:48h (±1:26)	9:09h (±2:23)	2:29h (±0:38)	3:24h (±0:50)
	Total	34:00h	45:45h	32:17h	27:12h
- data check	**M (SD)**	3:44h (±0:35)	4:51h (±1:09)	0:49h (±0:12)	1:08h (±0:16)
	Total	18:00h	24:15h	10:45h	9:04h
- qualitative analysis	**M (SD)**	4:14h (±0:37)	5:45h (±1:40)	1:38h (±0:25)	2:16h (±0:33)
	Total	21:10h	28:45h	21:33h	18:09h
- linking	**M (SD)**	5:15h (±0:44)	7:10h (±2:07)	2:03h (±0:31)	2:49h (±0:42)
	Total	26:16h	35:50h	26:51h	22:38h
- peer review	**M (SD)**	1:25h (±0:12)	1:56h (±0:34)	0:33h (±0:08)	0:45h (±0:11)
	Total	7:06h	9:41h	7:15h	6:07h
Overall time	**M (SD)**	28:48h (±3:22)	36:39h (±8:09)	8:37h (±2:01)	11:34h (±2:43)
	Total	144:00h	183:15h	112:02h	92:38h

Table 5 Time to perform focus groups and individual interviews

3.3.2 Qualitative analysis: Identified concepts

In the focus groups 897 concepts (open approach) and 1003 concepts (ICF-based approach) were identified within the statements of the participants, respectively. In the individual interviews 522 concepts were identified in the open approach and 374 concepts in the ICF-based approach, respectively.

3.3.3 Linking to the ICF: Identified ICF categories

In the focus groups a total of 188 ICF categories in the open approach and 231 ICF categories in the ICF-based approach were considered as relevant by the participants. These categories could be assigned to 26 out of the 30 chapters (1st level ICF categories) of the entire ICF classification for both approaches. In the individual interviews a total of 102 ICF categories (open approach) and 110 ICF categories (ICF-based approach) were identified. These categories represent 16 chapters of the ICF classification in the open approach and 21 chapters in the ICF-based approach. The frequencies of the identified 2nd, 3rd, and 4th level ICF categories of the four ICF components are shown in Table 6 for both methods and approaches applied.

Level of ICF categories	**Focus groups**		**Individual interviews**	
	Open approach	**ICF-based approach**	**Open approach**	**ICF-based approach**
Body Functions				
2nd level ICF categories	26	39	6	9
3rd level ICF categories	14	32	11	14
4th level ICF categories	5	9	2	2
Body Structures				
2nd level ICF categories	8	9	2	5
3rd level ICF categories	11	12	5	8
4th level ICF categories	9	10	5	2
Activities and Participation				
2nd level ICF categories	18	24	18	14
3rd level ICF categories	46	48	26	29
Environmental Factors				
2nd level ICF categories	30	28	15	15
3rd level ICF categories	21	20	12	12
Total				
2nd level ICF categories	82	100	41	43
3rd level ICF categories	92	112	54	63
4th level ICF categories	14	19	7	4

Table 6 Identified ICF categories in focus groups and individual interviews

3.3.4 Saturation of data

Saturation of data was reached after conducting 5 focus groups and 13 individual interviews in the open approach and 5 focus groups and 8 individual interviews in the ICF-based approach, respectively (see Figure 2). After conducting two focus groups 83 percent (open approach) and 92 percent (ICF-based approach) of the overall identified ICF categories within the focus groups emerged, respectively. After five individual interviews using the open approach and four individual interviews using the ICF-based approach 87 percent (open approach) and 86 percent (ICF-based approach) of the overall identified ICF categories of the individual interviews emerged.

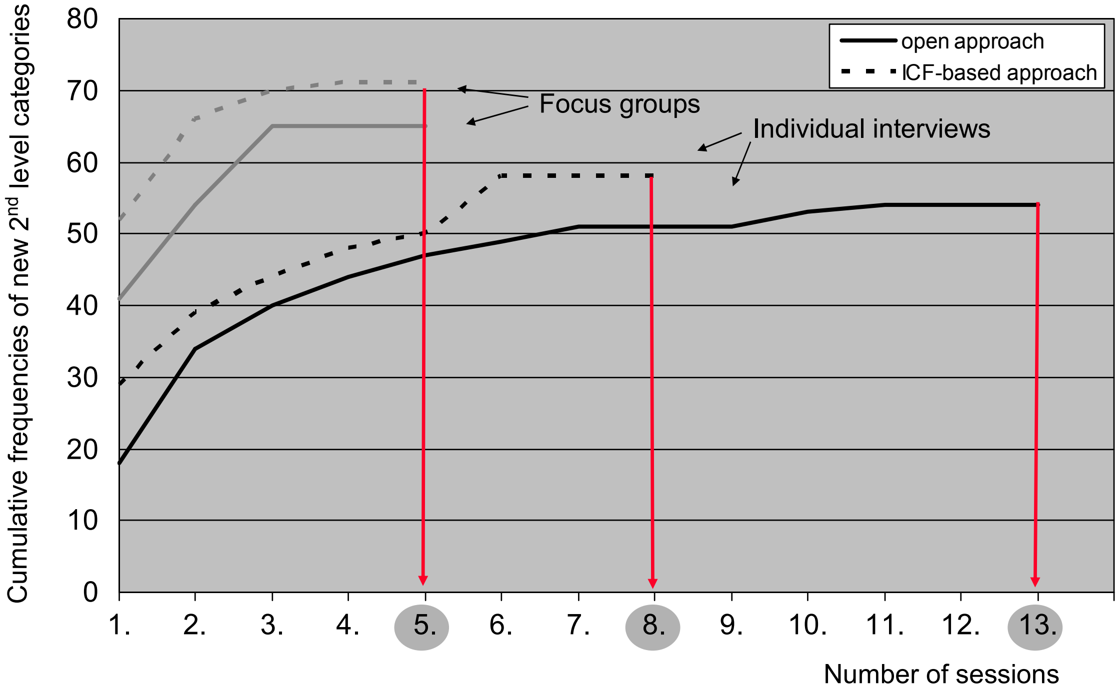

Figure 2 ***Saturation of data in focus groups and individual interviews***

3.3.5 Confirmation of the *Comprehensive ICF Core Set for RA*

For the further analysis, the ICF categories identified in both methods (focus groups and individual interviews) and in both approaches (open approach and ICF-based approach) are checked to what extent they confirm the *Comprehensive ICF Core Set for RA*.

In total, 74 categories (focus groups) and 65 categories (individual interviews) out of 76 2nd level ICF categories contained in the current version of the *Comprehensive ICF Core Set for RA* were reported by the participants based on both approaches, respectively. Table 7 illustrates the number of the confirmed ICF categories of the *Comprehensive ICF Core Set for RA* regarding the four components of the ICF classification and the two approaches. All 2nd level ICF categories of the components *Body Functions* (n=15) and *Body Structures* (n=8) which are included in the *Comprehensive ICF Core Set for RA* were reported by the participants of ICF-based focus groups. A detailed listing of the 76 ICF categories of the *Comprehensive ICF Core Set for RA* confirmed by both methods and approaches applied is shown in Appendix 3.

ICF components	**Focus groups**		**Individual interviews**	
	Open approach	**ICF-based approach**	**Open approach**	**ICF-based approach**
Body Functions (n=15)	12	15	9	9
Body Structures (n=8)	8	8	5	8
Activities and Participation (n=32)	26	30	25	26
Environmental Factors (n=21)	19	18	15	15
Total (N=76)	65	71	54	58

Table 7 Confirmed 2nd level ICF categories of the Comprehensive ICF Core Set for RA

3.3.6 Accuracy of data analysis

In the focus groups the kappa coefficient for the agreement between the linked ICF categories of the focus groups by the two health professionals (peer review) was .66. The 95%-bootstrapped confidence interval, which indicates the precision of the estimated kappa coefficient, was .61 to .73. The result of the kappa statistic for agreement between the two health professionals regarding the individual interviews was .62 with a 95%-bootstrapped confidence interval of .59 to .66.

3.4 Discussion

In this part of the doctoral thesis it could be demonstrated that the ICF classification can be a useful tool to compare the results of focus groups and individual interviews when the topic of interest is functioning and disability. Based on the ICF it could be shown that more ICF categories were identified in the focus groups than in the individual interviews. In addition, more ICF categories were revealed by the ICF-based approach in both methods (focus groups and individual interviews). Regarding the performance of focus groups, the ICF-based approach was more time-consuming compared to the individual interviews and the open approach. For the examination of the efficiency of the methods, the number of sessions to reach saturation of the data also had to be taken into account. To reach saturation more individual interviews than focus groups were conducted. The ICF-based approach appears to be more structured. This approach offers the participants of focus groups and individual interviews more prompts by naming the titles of the ICF chapters in the open-ended questions, which were used to initiate the data collection of both methods.

No significant differences between the two methods and approaches concerning the characteristics of the participants were found. The participants' characteristics (gender, age, disease duration) are comparable to participants in other German, Austrian [101,102], and international samples [28,103].

The focus groups were more time-consuming than the individual interviews. Some authors pointed out that focus groups are relatively inexpensive and less time-consuming than other qualitative approaches [91,104]. Others emphasize that one can hear several individuals within a single session and cover many topics in a relatively short time [105]. On the other hand, several authors argued that focus groups could not be considered as a 'quick method' because a great amount of time is needed for the recruitment of the groups, the transcription, and analysis of the collected data [85,106,107]. Additionally, the logistic aspects of focus groups which were necessary to bring together the several participants of one focus group at the same time and location were seen as very time-consuming [89]. The findings of this part of the doctoral thesis regarding the effort and time of the two methods supported these facts. Unfortunately, no empirical comparison in the literature regarding these assumptions was found.

In the qualitative analysis more concepts were identified in the focus groups compared to the individual interviews. Similar to this finding regarding the identified concepts of the qualitative analysis, more ICF categories within several levels of the classification (2nd to 4th level) in the focus groups than in the individual interviews were found. Thus, the precision of statements and ICF categories is higher in the data of the focus groups compared to the data of the individual interviews. In contrast to the results presented here, Thomas and colleagues did not find data with greater 'depth' in focus groups compared to individual interviews [89]. All concepts identified in their analysis were found in both methods. The result refering to the amount and precision of data could be due to the interaction process in the focus groups supporting the popular assumption that group processes can help people to explore and clarify their views [83]. The non-directive nature of focus groups allows participants to comment, explain, disagree, and share experiences and attitudes [84]. Several authors pointed out that in focus groups there would be greater synergy and spontaneity which optimizes the generation of (new) ideas [74,75,89]. Statements of participants in focus groups could be seen as stimuli for other participants to add similar experiences or problems to the discussion. In one of the focus groups a participant reported his/her experiences with hiking: “Hiking is a problem for me. Going uphill is OK, but going down – I can't do it anymore”. A second participant added to this statement: „Oh yes, walking down is very difficult for me, too. I walk backwards when there are only a few stairs. Going down backwards is much easier than going forwards“. Furthermore, in “individual interview[s] the interaction is limited to the interviewer and the respondent, while in [… focus groups] there is much more interaction between the [several participants]” ([105]; p 434)). Therefore a more relaxed atmosphere could be established in focus groups than in a one-to-one setting. The single participants of a focus group do not feel forced to answer every question [77]. Since they feel comfortable and free to speak in a safe forum, their self-disclosure is facilitated [85,108]. Additionally, this more relaxed atmosphere in focus groups could create a setting where sensitive topics can be discussed more frequently and openly than in other qualitative methods [86,105]. In contrast, Greenbaum pointed out that sensitive topics could be addressed more often in individual interviews avoiding the possible embarrassment of individuals in a focus group setting [109]. The differences regarding the sensitive topics in focus groups and individual interviews can not be confirmed in this doctoral thesis. The participants of the focus groups as well as the participants of the individual interviews named several sensitive topics (e.g. weight maintenance, urination functions, and intimate relationship). Some authors argued that potential differences regarding the amount of information revealed in focus groups and individual interviews and the willingness of individuals to self-disclosure depend on the research topic and the composition of the group [109,110]. Ezzy [111] summarized that the type of information revealed in focus groups is different to that obtained in individual interviews. The participants' statements revealed in focus groups – and in a next step the interpretations of these statements - are profoundly influenced by the group processes and the relationship between the participants, whereas statements in individual interviews are influenced by the relationship between the interviewer and the interviewee. With regard to the results presented in this part of the doctoral thesis, the difference regarding the type of information between the two qualitative methods applied can not be confirmed. Further methodological research is needed to clarify the differences between focus groups and individual interviews regarding the amount of ideas generated with these two qualitative methods.

Saturation of data was reached earlier in the focus groups than in the individual interviews. According to the conventions of qualitative data analysis the unit of data analysis - and in a next step the unit for applying saturation of data - is the focus group and not the single participants of the group [112,113]. Nevertheless more patients participated in the focus groups than in the individual interviews. It seems to be only one paper in the literature that systematically explored the occurrence of saturation of individual interviews [114].The results presented here are comparable to the findings of Guest and colleagues who reported that 73 percent and 92 percent of all identified themes of a total of 30 interviews was found after conducting the first 6 and first 12 individual interviews, respectively.

Comparing the two approaches (open approach versus ICF-based approach) the ICF-based approach provided more identified concepts and ICF categories in both methods (focus groups and individual interviews). The higher amount of concepts within the ICF-based approach could be associated with the naming of the ICF chapters in the open-ended questions of this approach. Because of the wording of these questions the participants could be encouraged to name experiences and problems in functioning, which they would not have come across spontaneously in the open approach. It is important to mention that some patient-sensitive issues were only reported in the ICF-based approach (e.g. sexual functions, toileting). Issues concerning mood, disease management and coping were reported in detail in the open approach.

There are also some limitations in this first part of the doctoral thesis that need to be mentioned. It is important to notice that the reported time is the working time to perform and analyze the sessions without consideration of the time needed for the development of the study audit, the development and specification of study materials and methods (e.g. topic guide, guidelines for data analysis), and the ongoing practical and methodological discussions during the study's progress. By interpreting the reported time frames, one has to take into account that the author of this thesis and the health professionals involved in the multiple coding and the peer review have expert knowledge and experiences in the performance and data analysis of qualitative studies, and the application of the ICF. Additionally, one has to consider potential 'hidden costs' occurring with the planning and performing of focus groups, which were not described in the results reported above. However, these hidden costs could extremely raise the amount of time needed to plan and perform a study. Finding an appropriate and convenient location could be more difficult in focus groups compared to individual interviews [85]. A focus groups' moderator has to fulfill more qualifications compared to the interviewee, because the one-to-one setting required in individual interviews is generally considered to be easier to handle than group discussions [106,109]. The recruitment strategy of participants (e.g. availability, accession) has to be carefully planned to assure an unproblematic sampling. Additionally, for the sampling of the focus groups' participants, an over-recruitment is reported as being beneficial [115] to compensate the cancellation of single participants. Depending on the willingness of the individuals to participate in a focus group, a higher number of potential participants has to be planned. The transcription of the focus groups' recordings should be done by a highly experienced person because it is especially labour-intensive and often challenging [112,116]. Distinguishing between participants talking at the same time, quietly spoken statements, and indifferent pronunciation of single participants could make the transcription problematic.

It is important to mention, that these hidden costs of the focus groups reported here were comparatively low. The author of this doctoral thesis could use the facilities and equipment of the medical department without having any time-consuming or logistic problems. The participants of the focus groups were closely bound in the day-clinic of rheumatology. The effort concerning the support and contact (e.g. additional telephone calls, letters, and information) to the participants prior to the focus group sessions was relatively small. Their willingness and trustworthiness were remarkable high. Therefore no over-recruitment regarding the sampling of the focus groups was needed. The experience of the person responsible for the transcription of the recordings has also to be considered. It should be noted that the importance and the degree of these hidden costs of focus groups could be diverse in other studies using focus groups.

Another limitation is associated with the qualitative data analysis and the linking of the identified concepts to ICF categories. One has to take into account that the individuals' way of telling their problems or views is very different. It can be assumed that some participants of the focus groups and individual interviews tend to tell extended and detailed stories. Others tend to generalize their experiences in a few words on a very global level. This has an effect on the qualitative analysis (phrasing of the concepts), the level of the linked ICF categories and the precision of the data. Linking concepts to ICF categories is a kind of generalisation and standardization of the data. Therefore some detailed statements of the participants and very specific concepts would be summarized on a higher level of abstraction by the application of the linking procedure. Several individual perspectives could thus be summarized under one ICF category. One example is the ICF category *d445 'hand and arm use'*; the following four concepts were documented from the patient perspective and assigned to this category: 'opening a milk package', 'using a coffee machine', 'using one's hand while sailing' and 'using hand and arm to lean on something'. The precision of the data could be underestimated as a consequence of this aggregation. On the other hand, the linking procedure offers the opportunity to compare the results of the two methods and approaches applied.

Saturation of data operationalized by the cumulative frequencies of 2nd level ICF categories included in the *Comprehensive ICF Core Set for RA* might be a questionable criterion to determine the amount of groups and number of participants in a study. Saturation is defined differently in the literature and an engaging operationalization is missing [114]. It might not ever be possible to have obtained sufficient information from the field, especially in the individual interviews because adding one individual participant after two interviews which did not reveal any new information could still add some more issues from the individual's perspective. Additionally, one has to note that the higher number of identified ICF categories revealed in the focus groups could also be related to the number of participants included. The inclusion of further participants in the individual interviews could probably increase the number of identified ICF categories, whereas the reported saturation of the interviews' data were contrary to this argument.

In conclusion, focus groups using the ICF-based approach are the recommended methodology to validate condition-specific ICF Core Sets from the patient perspective. However, it has still to be taken into account that the performance of focus groups, and especially the ICF-based approach were more time-consuming compared to the individual interviews and the open approach, respectively. Focus groups and the ICF-based approach raised more ICF categories.

This could be relevant if the perspective of patients should be explored as broadly and deeply as possible. Thus, the final recommended approach should not only be superior concerning the precision of data generated and the amount of concepts found, but also concerning the feasibility and economic aspects. Additionally, the decision about the favoured method should depend on the objective of the study, the attributes of the health condition and the participants involved in the study.

4 Validation of ICF Core Sets from the patient perspective: Development of a protocol

4.1 Objective

The objective of this part of the doctoral thesis is to develop a protocol to validate condition-specific ICF Core Sets from the patient perspective to be used for different health conditions and in different countries.

4.2 Method

According to the results of the comparison of the two qualitative methods and approaches reported in paragraph 3.3 of this doctoral thesis a protocol for the validation of condition-specific ICF Core Sets from the patient perspective was developed. The aim of this protocol is to provide interested researchers with detailed information on how to perform the validation of ICF Core Sets from the patient perspective using focus groups and the ICF-based approach. All materials were prepared in English avoiding the naming of a specific health condition, so that they can be easily adapted for the validation of ICF Core Sets for any other health condtition beside RA. Based on the author's experiences with the performance of focus groups and individual interviews with RA patients some modifications were taken into account when developing these study materials.

4.3 Results

4.3.1 Protocol

The standarized protocol can be found in Appendix 4 of this doctoral thesis. These are the contents of the standardized protocol:

- Protocol Synopsis: basic data of the study
- Responsibilities
- Background: information on the comprehensive biopsychosocial model of functioning and disability, the ICF, ICF Core Sets, qualitative methodology, patient perspective, and the ICF Core Sets' validation process
- Objective
- Methods: information on study design, study population (sampling, inclusion and exclusion criteria, sampling strategy), instruments (topic guide, questionnaires), data collection, data analysis (qualitative analysis, linking of concepts to ICF categories, comparison with the ICF categories of ICF Core Sets, saturation of data),
- Monitoring and accuracy of data: information on multiple coding and peer review
- Ethics
- Project management, coordination, and collaboration
- Time frame

4.3.2 Protocol attachement: Guideline for the performance and analysis of focus groups

The guideline provides the researcher with information on the performance and analysis of ICF-based focus groups to validate condition-specific ICF Core Sets from the patient perspective. The entire guideline can be found in the attachment of the protocol (see Appendix 4: pages 109-148).

These are the contents of the guideline:

- Background: information on ICF Core Sets, focus groups and individual interviews
- General considerations: information on requirements concerning the focus groups' moderator and participants of the study, information regarding the time needed to perform the sessions, the setting (room), technical equipment, and templates provided by the ICF Research Branch
- Preparatory work: recommendations on the recruitment of participants, information on sample size, patient information and agreement, description and instruction for the use of the Case Record Form (CRF), the topic guide (with the open-ended questions), and further study materials (research diary, seating plan, field notes)
- Procedure of focus group sessions: detailed information and instructions on the performance of focus groups (hints for warm up, initiating the group discussion between the participants, conversation techniques, closing words)
- Transcription: requirements and instructions on the transcription of the recorded data
- Procedure of data analysis: detailed information on the qualitative analysis, linking of concepts to ICF categories, comparison with the ICF categories of ICF Core Sets, saturation of data, accuracy of data analysis (multiple coding, peer review)
- Contact information

To ensure a standardized data analysis nine rules for the identification of concepts are included in this guideline (see Appendix 4: pages 140-143). Examples from the focus group study with RA patients illustrate the application of the respective rule. Additionally, one can find a version of the linking rules of Cieza and colleagues [21,22] in the guideline. These rules were originally developed for the linking of concepts identified in health status measures. Therefore some modifications and additions were nessecary for their use in the linking of patients' statements. Numerous examples from the focus group study with RA patients ensure a standardized application of these rules (see Appendix 4: pages 144-148).

4.3.3 Further materials

Open-ended questions

An English template of a PowerPoint presentation was developed that can be used to guide the focus group sessions ('Topic guide') (see Appendix 4; pages 122-126). It is recommended to translate the open-ended questions presented in Table 8 into the respective language of the country according to a standardized translation process with forward translation and back-translation into English. The translation process should be performed by at least two persons who should (1) compare their results of the translations and (2) build an agreed-on version of the translated questions.

ICF components	Open-ended questions*
Body functions	If you think about your body and mind, what does not work the way it is supposed to?
Body structures	If you think about your body, in which parts are your problems?
Activities & Participation	If you think about your daily life, what are your problems?
Environmental factors - facilitators	If you think about your environment and your living conditions, what do you find helpful or supportive?
Environmental factors - barriers	If you think about your environment and your living conditions, what barriers do you experience?

Table 8 Open-ended questions

* The open-ended questions are followed by the title of the chapters from which categories are included in the selected Comprehensive ICF Core Set

Further templates

To ensure a standardized data collection further templates were established which can be adapted to the needs and characteristics of the respective study site:

- Case Record Form (CRF): to collect patient and disease specific variables. The CRF contains the following parts: inclusion criteria, disease specific data, socio-demographic data, ratings on general health and functioning from the patient perspective, health conditions, diagnosis and comorbidities. A detailed description of the CRF is presented in Appendix 4 (see pages 119-121)
- Patient information and agreement (see Appendix 4: pages 116-118)
- Seating plan: to document the patients participating in the respective focus group sessions (see Appendix 4: page 127)
- Form to take field notes: During the focus group session, the group assistant records field notes. Field notes may provide the researcher with additional information useful for the data analysis. In the case of a break down of the recorder, the information recorded on this form will minimize the loss of data (see Appendix 4: pages 127-128).
- Transcription sheet: to ensure a standardized transcription of the recorded data (see Appendix 4: page 134)

4.4 Application of the protocol

In September 2006 an international workshop of interested researchers from different countries (Australia, Germany, Hungary, and Sweden) took place at the ICF Research Branch (Munich) to train the participants on the validation of ICF Core Sets for chronic conditions from the patient perspective according to the protocol mentioned above. The workshop was organized by the author of this doctoral thesis. In the meantime several researchers have started the process of validating ICF Core Sets for different health conditions using the provided materials (see Table 9). For the studies in foreign countries listed below the open-ended questions were successfully translated according to the recommended translation procedure.

Health condition	Country	Method	Status
Breast cancer			
Chronic widespread pain	Germany	focus group	in process
Ischemic heart disease			
Depression			
Diabetes mellitus	Germany	focus group	in process
Low back pain	Hungary	focus group	in process
	Germany	focus group	planned
Obesity			
Obstructive pulmonary diseases			
Osteoarthritis 1)	Singapore	focus group	completed [117]
Osteoporosis			
Rheumatoid arthritis	Germany	focus group	completed [93,118,119]
	Austria	individual interview	completed [94]
Stroke	Sweden	individual interview	in process
	Finland	individual interview	in process
	Germany	individual interview	in process
	Germany	focus group	planned

Table 9 Status of validation studies from the patient perspective

1) The validation of the *Comprehensive ICF Core Sets for osteoarthritis* was not performed according to the protocol which is presented in this doctoral thesis

4.5 Discussion

The protocol on the validation of condition-specific ICF Core Sets from the patient perspective ensures a standardized design and methodology to be used with different patient populations and in different countries. The protocol is being successfully implemented in Germany (chronic widespread pain, diabetes mellitus, and stroke) and in further countries (Hungary: low back pain; Sweden and Finland: stroke). The results of these ongoing studies will made their contribution to the validation of the respective ICF Core Set from the patient perspective.

The experiences with the ongoing validation studies and the successful implementation of the protocol in different health conditions and different countries indicate to the applicability and practicability of the design and the provided materials.

The network of researchers working on the validation of the ICF Core Sets for chronic conditions from the patient perspective is steadily growing. The work performed by all researchers of this framework will essentially contribute the final versions of the condition-specific ICF Core Sets helping to include one of the most important perspectives, namely, the perspective of those who suffer the disease – the patient perspective.

5 Content validity of the Comprehensive ICF Core Set for rheumatoid arthritis from the patient perspective using focus groups

5.1 Objective

The objective of this part of the doctoral thesis is to examine the content validity of the *Comprehensive ICF Core Set for RA* applying the selected method. The specific aim is to explore the aspects of functioning and health important to patients with RA using the ICF-based focus group methodology and to examine to what extent these aspects are represented by the current version of the *Comprehensive ICF Core Set for RA*.

5.2 Methods

The methods are described in detail in paragraph 3 *'Development of a method to validate ICF Core Sets from the patient perspective: comparison of two qualitative methods'* of this doctoral thesis. Thus, only a few methodological details which are specific for this focus group study using the ICF-based approach are presented below.

5.2.1 Design

A qualitative study with RA patients using the ICF-based focus group methodology was conducted. According to the results of the part of the doctoral thesis dealing with the comparison of the qualitative methods and approaches (see paragraph 3) the most appropriate method was used to validate the *Comprehensive ICF Core Set for RA* from the patient perspective, namely a focus group study using the ICF-based approach.

5.2.2 Participants

Patients with RA diagnosed according to the revised ACR criteria [95] were recruited form the day clinic of the Department of Physical Medicine and Rehabilitation of the Ludwig-Maximilian University in Munich and the German self-help service (‘Deutsche Rheuma-Liga e.V.’).

5.2.3 Data collection

The focus groups using the ICF-based approach were conducted according to the focus group guideline including open-ended questions and further instructions (e.g. introduction, procedure of the session, technical aspects).

5.2.4 Data analysis

The linked ICF categories of the focus group study using the ICF-based approach were compared with the current version of the *Comprehensive ICF Core Set of RA* with its selected 2nd level ICF categories (n=76) [53]. The following three outcomes are documented:

- **confirmed 2nd level ICF categories** of the *Comprehensive ICF Core Set for RA*: an ICF category of the *Comrephensive ICF Core Set for RA* is regarded as confirmed, if the identical or a similar ICF category emerged from the focus groups (e.g. *s299 ‘eye, ear and related structures, unspecified’* confirmed by *s230 ‘structures around eye’*). Since the ICF categories are arranged in a hierarchical code system, the 2nd level ICF categories of the *Comprehensive ICF Core Set for RA* are considered confirmed when the corresponding 3rd or 4th level ICF category of which they are a member had been named by the participants.

- **not confirmed 2nd level ICF categories** of the *Comprehensive ICF Core Set for RA:* an ICF category is regarded as not confirmed if it is contained in the current version of the *Comprehensive ICF Core Set for RA*, but was not named from the patient perspective
- **additional 2nd level ICF categories** of the *Comprehensive ICF Core Set for RA*: an ICF category is regarded as additional if it is not contained in the current version of the *Comprehensive ICF Core Set for RA*, but was named from the patient perspective.

5.3 Results

5.3.1 Description of the focus groups

Focus groups with a total of 24 participants were conducted. Participants' characteristics are summarized in Table 10. Saturation of data was reached after conducting five focus groups. The focus group sessions lasted from 1:17 hours to 2:06 hours with a mean of 1:47 hours.

Characteristics of participants	
Number of participants, n	24
Mean age, year (range)	54 (35-75)
Gender, % female	83
Mean disease duration, year (range)	15 (3-56)

Table 10 Characteristics of participants of the ICF-based focus groups

5.3.2 Confirmed ICF categories of the *Comprehensive ICF Core Set for RA*

In total 71 out of the 76 2nd level ICF categories included in the *Comprehensive ICF Core Set for RA* were confirmed by the participants of the focus groups using the ICF-based approach. All 2nd level categories of the components *Body Functions* (n=15) and *Body Structures* (n=8) which are included in the *Comprehensive ICF Core Set for RA* were reported by the participants (see Table 11 - Table 14; ICF categories in bold typeface).

5.3.3 Not confirmed ICF categories of the *Comprehensive ICF Core Set for RA*

Five ICF categories out of the 76 2nd level ICF categories included in the *Comprehensive ICF Core Set for RA* were not confirmed by the participants of the ICF-based focus groups. These ICF categories are allotted to the components *Activities and Participation* (n=2) and *Environmental Factors* (n=3) (see Table 11 - Table 14; grey shaded ICF categories in italic typeface).

5.3.4 Additional ICF categories

Fifty six 2nd level additional ICF categories which are not included in the current version of the *Comprehensive ICF Core Set for RA* were identified in the focus groups (see Table 11 - Table 14; ICF categories in grey font). Most of these additional categories derive from the component *Body Functions* (n=28) followed by *Environmental Factors* (n=16). Eight additional ICF categories were reported by the participants as related to the component *Activities and Participation*. Four additional ICF categories referred to the component *Body Structures*.

ICF categories	
ICF code	**ICF category title**
b126	Temperament and personality functions
b130	**Energy and drive functions**
b134	**Sleep functions**
b140	Attention functions
b147	Psychomotor functions
b152	**Emotional functions**
b160	Thought functions
b180	**Experience of self and time functions**
b210	Seeing functions
b220	Sensations associated with the eye and adjoining structures
b230	Hearing functions
b240	Sensations associated with hearing and vestibular function
b250	Taste function
b255	Smell function
b265	Touch function
b270	Sensory functions related to temperature and other stimuli
b280	**Sensation of pain**
b410	Heart functions
b430	**Haematological system functions**
b435	Immunological system functions
b455	**Exercise tolerance functions**
b460	Sensations associated with cardiovascular and respiratory functions
b510	**Ingestion functions**
b515	Digestive functions
b525	Defecation functions
b530	Weight maintenance functions
b535	Sensations associated with the digestive system
b540	General metabolic functions
b610	Urinary excretory functions
b620	Urination functions
b640	**Sexual functions**
b710	**Mobility of joint functions**
b715	**Stability of joint functions**
b730	**Muscle power functions**
b740	**Muscle endurance functions**
b760	Control of voluntary movement functions
b770	**Gait pattern functions**
b780	**Sensations related to muscles and movement functions**
b810	Protective functions of the skin
b820	Repair functions of the skin
b840	Sensation related to the skin
b850	Functions of hair
b860	Functions of nails

Table 11 ***Body Functions (b): Patients' reporting of ICF categories (2nd level)***
Confirmed ICF categories of the *Comprehensive ICF Core Set for RA* are shown in bold typeface
Additional ICF categories are shown in grey font

ICF categories ICF code	ICF category title
s299	**Eye, ear and related structures, unspecified** (s220)*
s320	Structure of mouth
s530	Structure of stomach
s540	Structure of intestine
s710	**Structure of head and neck region**
s720	**Structure of shoulder region**
s730	**Structure of upper extremity**
s750	**Structure of lower extremity**
s760	**Structure of trunk**
s770	**Additional musculoskeletal structures related to movement**
s810	**Structure of areas of skin**
s830	Structure of nails

Table 12 Body Structures (s): Patients' reporting of ICF categories (2nd level)

Confirmed ICF categories of the *Comprehensive ICF Core Set for RA* are shown in bold typeface
Additional ICF categories are shown in grey font
* confirmation according to similar ICF categories

ICF categories	
ICF code	**ICF category title**
d163	Thinking
d166	**Reading**
d170	**Writing**
d210	**Undertaking a single task**
d230	**Carrying out daily routine**
d240	**Handling stress and other psychological demands**
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** (d430/d445)*
d450	**Walking**
d455	**Moving around**
d460	**Moving around in different locations** (d455)*
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 one's health***
d610	**Acquiring a place to live**
d620	**Acquisition of goods and services**
d630	**Preparing meals**
d640	**Doing housework**
d650	**Caring for household objects**
d660	**Assisting others**
d720	**Complex interpersonal interactions**
d750	**Informal social relationships**
d760	**Family relationships**
d770	**Intimate relationships**
d850	**Remunerative employment**
d859	**Work and employment, other specified and unspecified** (d850)*
d910	**Community life**
d920	**Recreation and leisure**

Table 13 ***Activities and Participation*** **(d)**: ***Patients' reporting of ICF categories (2nd level)***

Confirmed ICF categories of the *Comprehensive ICF Core Set for RA* are shown in bold typeface
Not confirmed ICF categories are shown grey shaded and in italic typeface
Additional ICF categories are shown in grey font
* confirmation according to similar ICF categories

ICF categories ICF code	ICF category title
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**
e130	Products and technology for education
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**
e160	Products and technology of land development
e165	Assets
e210	Physical geography
e225	**Climate**
e310	**Immediate family**
e315	Extended family
e320	**Friends**
e325	Acquaintances, peers, colleagues, neighbours and community members
e340	**Personal care providers and personal assistants**
e345	Strangers
e350	Domesticated animals
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**
e430	Individual attitudes of people in positions of authority
e445	Individual attitudes of strangers
e450	**Individual attitudes of health professionals**
e460	**Societal attitudes**
e510	Services, systems and policies for the production of consumer goods
e540	***Transportation services, systems and policies***
e555	Associations and organizational services, systems and policies
e560	Media services, systems and policies
e565	Economic services, systems and policies
e570	**Social security services, systems and policies**
e575	General social support services, systems and policies
e580	**Health services, systems and policies**
e590	Labour and employment services, systems and policies

Table 14 Environmental Factors (e): Patients' reporting of ICF categories (2nd level)

Confirmed ICF categories of the *Comprehensive ICF Core Set for RA* are shown in bold typeface
Not confirmed ICF categories are shown grey shaded and in italic typeface
Additional ICF categories are shown in grey font

5.4 Discussion

The current version of the *Comprehensive ICF Core Set for RA* could be confirmed almost entirely from the patient perspective using focus groups with the ICF-based approach. A large number of patient-relevant aspects of functioning and health are included in the *Comprehensive ICF Core Set for RA* and confirmed by the participants of the focus groups. However, some issues emerged from the patient perspective which had not yet been covered by the *Comprehensive ICF Core Set for RA* or even by the ICF classification. Saturation of data was reached after conducting five focus groups with a total of 24 RA patients.

The ICF-based focus groups confirm relevant outcomes of treatment in RA from the patient perspective which have been found in other studies with RA patients (e.g. pain, stiffness, fatigue, mobility, muscle strength, getting social support) [73,103,120]. The ICF categories of the *Comprehensive ICF Core Set for RA* not reported by the participants were *d560 'drinking'*, *d570 'looking after one's health'*, *e135 'products and technology for employment'*, *e360 'other professionals (support and relationship)'*, and *e540 'transportation services and policies'*. The ICF category *d570 'looking after one's health'* refers among other things to the patients' compliance with medical advice or managing diet which are important issues from the perspective of health professionals. However, from the patient perspective, compliance represents behaviour that they may take for granted and, therefore, did not mention. In the same line, a lot of concepts referred to needs and side effects of medication, food, nutrition and diet linked to ICF categories of the component *Environmental Factors* were found. This points to the importance of the themes 'health' and 'health-related behaviours' from the patient perspective without reporting these themes on the basis of daily activities. The ICF category *e360 'other professionals'*, which means all service providers working outside the health system, like lawyers, teachers, architects, and designers, seems to have no relevance for the patients with RA in their daily living. Another explanation for this finding is that patients with RA have no experiences with this kind of support and relationships, because supporting structures exist exclusively within the health system.

Fifty six additional 2nd level ICF categories which are not covered in the current version of the *Comprehensive ICF Core Set for RA* were raised from the patient perspective. Most of these additional ICF categories belong to the component *Body Functions* (n=28) followed by the component *Environmental Factors* (n=16). Some of these additional ICF categories need special discussion.

It is important to emphasize that there were a number of ICF categories that were named by the participants of the focus groups at a higher level of specification than the 2nd level of the ICF classification. Some of these more specific ICF categories are included in the *Comprehensive ICF Core Set for RA*, and some are not [53]. One of these very specific categories not included in the *Comprehensive ICF Core Set for RA* at higher levels of specification are 'fatigue' and 'fatiguability'. 'Fatigue' and 'fatiguability' were linked to the 3rd level ICF categories *b1300 'energy level'* and *b4552 'fatiguability',* which belong to the 2nd level ICF categories *b130* '*energy and drive functions'* and *b455 'exercise tolerance functions'*, respectively. Fatigue was also identified as an area of particular importance to patients with RA at several OMERACT sessions [72,121,122,123,124,125], as patient-relevant outcome in RA [103,123,126], and as an adverse effect of medication [127,128]. It could, thus, be a suggestion from this doctoral thesis that the categories *b1300 'energy level'* and *b4552 'fatiguability'* should be specifically and explicitly included in the *Comprehensive ICF Core Set for RA*. This suggestion is strengthened by the findings of the ICF Core Set validation study deriving from individual interviews [94] and validation studies from the perspective of health professionals using the Delphi exercise [62].

Numerousness additional ICF categories were related to side effects of medication, which are an important issue for satisfaction with treatment from the patient perspective [73,103,129]. Some of these causal relationships can also be found in the literature as complications due to medication [130,131,132,133,134,135, 136,137,138] or as relevant problems from the patient perspective [139,140]. The participants of the ICF-based focus groups explicitly attributed some ICF categories from the components *Body Functions* and *Body Structures* to side effects of antirheumatic medication. Some of these causal relationships can also be found in the literature. The ICF categories *b515 'digestive functions'*, *b525 'defecation functions'*, *b535 'sensations associated with the digestive system'* and the ICF categories *s530 'structure of stomach'* and *s540 'structure of intestine'* could be related to gastrointestinal complications due to disease modifying anti-rheumatic drugs (DMARDs) [130,131] or non-steroidal anti-inflammatory drugs (NSAIDs) [132,133]. Other relevant side effects of medication reported by the patients were *b210 'seeing functions'*, *b220 'sensations associated with the eye and adjoining structures', b810 'protective functions of the skin', b820 'repair functions of the skin', b840 'sensations related to the skin', b850 'functions of hair', b860 'functions of nails',* and *s830 'structure of nails'*. Skin problems, such as skin thinning, rashes, and trouble with dry skin, are relevant problems from the patient perspective [139,140] and are reported as side effects of glucocorticoid treatment [134,135,136]. The question whether ICF categories concerning side effects of medication should be included in the *Comprehensive ICF Core Set for RA* has to be considered carefully. With the advent of new medications, new side effects may appear. On the one hand, one has to keep in mind that the ICF Core Sets establish the standards of 'what to measure' in patients with RA independent of the treatment (one could even say independent of 'fashionable treatment'). On the other hand, the intake of medication and the suffering of side effects belong to the reality of patients with RA. Perhaps one solution to this dilemma could be the development of treatment-specific ICF Core Sets.

Ten categories of the component *Activities and Participation* which are not included in the *Comprehensive ICF Core Set for RA* are relevant from the patient perspective. They probably reflect the individual perspective of some patients and the complexity and individuality of *Activities and Participation* which could be affected by RA. However, the ICF category *d240 'handling stress and other psychological demands'* was extensively reported by the participants in the focus groups. The inclusion of this ICF category was also discussed by the expert panel at the ICF Consensus Conference for the development of the *Comprehensive ICF Core Set for RA*. Taking into account the large number of ICF categories included in the

Comprehensive ICF Core Set for RA, the experts decided that the psychosocial factors influencing RA disability are sufficiently represented by the ICF category *b152 'emotional functions'* [53]. Nevertheless, and under the consideration of the results of this study, the inclusion of this ICF category could be reconsidered when the final version of the *Comprehensive ICF Core Set for RA* will be established.

Within the component *Environmental Factors* numerous ICF categories not included in the current version of the *Comprehensive ICF Core Set for RA* were reported by the participants of the focus groups. Grimby et al. [141] pointed out that there is a need for research into the effects of contextual (environmental) factors. Information about the relevance and the importance of specific *Environmental Factors* can primarily be given by patients. There is no doubt that social support is an important *Environmental Factor* for patients with RA [102]. Several studies pointed out the relationship and interaction between social support and disease activity, pain or disability [28,142,143]. The ICF category *e165 '(financial) assets'* which is not included in the current version of the *Comprehensive ICF Core Set for RA* was reported by the participants in the focus groups as a relevant *Environmental Factor*. Economic consequences in relation to income reduction or to loss of paid work due to physical disability were also found to be an important issue to patients with RA in the literature [4,28,29,144]. Within this context, it has to be taken into account, that patients with RA often have substantial RA-related out-of-pocket medical expenditures for copayments for prescribed drugs, over-the-counter drugs and costs to complementary and alternative medicine [145,146].

In qualitative research and studies with focus group methodology, sample sizes typically remain small because intensive data analysis is required [76,80]. A small sample size with a diverse range of participants (n=24) was used to obtain the required level of rich and meaningful data. According to Curtis et al. [147] the small samples in qualitative research are studied intensively and typically generate a large amount of information. By keeping the questions open-ended, the moderator can stimulate useful trains of thought in the participants that were not anticipated [148]. The focus groups were composed of four to seven participants. Groups with few participants were performed because of the complexity of the topic and the expertise of the participants according to the literature [107]. With a small group size, each participant has a greater opportunity to talk, which is reported as an important aspect for the group dynamics in groups with elderly and ill participants [76,67,149].

It is important to mention, that several strategies were used to improve and verify the trustworthiness of the qualitative data. *(1) Multiple coding* was performed to ensure the rigour of analysis. *(2) Continuous data analysis* was used according to Pope et al. [150] to check the saturation of data. *(3) Reflexivity* was assured by conducting a research diary for the documentation of memos concerning the design, data collection and analysis. *(4) Clear exposition* was used establishing guidelines for conducting the focus groups (including open-ended questions), verbatim transcription, and linking rules [21,22]. Thus, a clear account of methods of data collection and analysis was assured. *(5)* Finally, a *peer review* was performed to quantify the accuracy of analysis. The kappa coefficient of .66 (.61 - .73) for the accuracy of the peer review is comparable to other studies reporting kappa statistic concerning the linking of ICF categories [62,94] and can be regarded as ‘substantial agreement’ [151].

There are also some limitations that need special mention. The sample consists only of German participants. Studies using the same methodology should now be conducted in other countries to establish a cross-cultural perspective. Secondly, the linking process was performed by two health professionals according to established linking rules [21,22]. However, it remains unclear whether other health professionals would have decided differently. Finally, the strategy of saturation during data analysis with the criteria of two consecutive focus groups revealing no additional 2nd level ICF categories of the *Comprehensive ICF Core Set for RA* with respect to previous focus groups was followed. Participants in a sixth focus group still might report new themes and concepts not yet reported.

6 Conclusion

The doctoral thesis presented here, identified the ICF-based focus group methodology as the most appropriate method to validate condition-specific ICF Core Sets from the patient perspective. The comparison between the two methods (focus groups and individual interviews) and the two approaches applied (‘open approach’ and ‘ICF-based approach’) shows that more ICF categories were revealed by the focus groups and the ICF-based approach, respectively. However, the focus groups and the ICF-based approach are more time-consuming compared to the individual interviews and the open approach. Thus, the final recommended approach should not only be superior concerning the precision of data generated and the amount of concepts found, but also concerning the feasibility and economic aspects. Additionally, the decision about the favoured method should depend on the objective of the study, the attributes of the health condition and the participants involved in the study.

To come forward with the validation of condition-specific ICF Core Sets from the patient perspective a standardized protocol regarding the most appropriate method, namely the ICF-based focus group methodology was developed and is being successfully implemented in different countries and different health conditions. The experiences with the ongoing validation studies and the successful implementation of the protocol indicate to the applicability and practicability of the design and the standardized protocol.

Based on the ICF-based focus group methodology the *Comprehensive ICF Core Set for RA* was validated from the patient perspective. A large number of patient-relevant aspects of functioning and health are included in the *Comprehensive ICF Core Set for RA* and were confirmed by the participants of the focus groups. However, some issues emerged from the patient perspective which had not yet been covered by the *Comprehensive ICF Core Set for RA*. The results of the focus groups will be presented at an international WHO conference and will be taken into account for the decision on the final version of the *Comprehensive ICF Core Set for RA*.

7 Summary

Background

Rheumatoid arthritis (RA) is a chronic disabling disease that lead to impairments in body functions and structures, limitations of activities, and restrictions in participation under consideration of contextual factors (e.g. environmental and personal factors) and the health condition itself.

With the World Health Organization's *International Classification of Functioning, Disability and Health* (ICF) [31] a globally agreed-on language and classification is available to describe functioning and health of individuals by means of more than 1400 so-called ICF categories. To enhance the applicability of this comprehensive classification so-called *Comprehensive ICF Core Sets* for 12 chronic health conditions [41], amongst other for RA [53] were developed. The *Comprehensive ICF Core Set for RA* is a short list of ICF categories, which are relevant for most patients with RA and describe the typical spectrum of problems in functioning based on the universal language of the ICF. The condition-specific ICF Core Sets are now undergoing worldwide validation using a number of approaches. One key aspect is the validation from the patient perspective. Qualitative methods provide the possibility to explore the perspective of those who experience a health problem. However, no methodology has been so far developed to validate the ICF Core Sets from the patient perspective.

Objectives

The overall objective of this doctoral thesis is to identify the most appropriate method to validate condition-specific ICF Core Sets from the patient perspective. The specific aims are 1) to compare the advantages and disadvantages of two qualitative methods when used to validate ICF Core Sets from the patient perspective, 2) to develop a protocol to validate ICF Core Sets from the patient perspective to be used for different health conditions and in different countries, and 3) to examine the content validity of the *Comprehensive ICF Core Set for RA* applying the selected method.

With respect to these specific aims the doctoral thesis is subdivided into three parts. The first part presents an analysis of qualitative data obtained from two qualitative methods and two approaches to establish the most appropriate method to validate condition-specific *Comprehensive ICF Core Sets* from the patient perspective. The next part illustrates the development of a protocol regarding the validation of ICF Core Sets with respect to the results reported in the previous part. In the last part the results of the validation of the *Comprehensive ICF Core Set for RA* from the patient perspective using the most appropriate method are reported.

Development of a method to validate ICF Core Sets from the patient perspective: Comparison of two qualitative methods

The objective of this part of the doctoral thesis is to compare the advantages and disadvantages of two qualitative methods when used to validate ICF Core Sets from the patient perspective. Two qualitative methods – focus groups and individual interviews – and two different approaches used in both methods – open approach and ICF-based approach – are examined to come forward with the most appropriate method to validate condition-specific ICF Core Sets from the patient perspective. The two methods with their respective approaches were compared with regard to (1) formal aspects (time) and (2) the results obtained (content).

Patients diagnosed with RA were selected by the maximum variation strategy [78] to participate in focus groups and individuals interviews. Sample size was determined by saturation of data [96]. Focus groups and individual interviews were conducted in a non-directive manner by using open-ended questions according to a standardized guideline, were digitally recorded and transcribed verbatim. The meaning condensation procedure [78] was used for the qualitative analysis of data. The identified concepts of this qualitative analysis were linked to the most precise

ICF categories using standardized linking rules [21,22]. To audit the accuracy of the analysis a peer review was performed.

Forty nine patients and 21 patients participated in the focus groups and individual interviews, respectively. Saturation of data was reached after conducting 5 focus groups and 13 individual interviews in the open approach and 5 focus groups and 8 individual interviews in the ICF-based approach. It could be demonstrated that the ICF classification can be a useful tool to compare the results of focus groups and individual interviews when the topic of interest is functioning and disability. It was shown that more concepts and more ICF categories were identified in the focus groups than in the individual interviews. In addition, more concepts and more ICF categories were revealed by the ICF-based approach in both methods (focus groups and individual interviews). Regarding the performance of focus groups, the ICF-based approach was more time-consuming compared to the individual interviews and the open approach. The ICF-based focus group approach is the most appropriate method to validate condition-specific ICF Core Sets from the patient perspective.

Validation of ICF Core Sets from the patient perspective: Development of a protocol

The objective of this part of the doctoral thesis is to develop a protocol to validate condition-specific ICF Core Sets from the patient perspective to be used for different health conditions and in different countries.

Based on the most appropriate method to validate ICF Core Sets from the patient perspective, namely the ICF-based focus group methodology, a protocol was developed to provide interested researchers with detailed information on how to perform the validation of ICF Core Sets from the patient perspective in a standardized way. The protocol is being successfully implemented in Germany (chronic widespread pain, diabetes mellitus, and stroke) and in further countries (Hungary: low back pain; Sweden and Finland: stroke).

Content validity of the Comprehensive ICF Core Set for rheumatoid arthritis from the patient perspective using focus groups

The objective of this part of the doctoral thesis is to examine the content validity of the *Comprehensive ICF Core Set for RA* applying the selected method. The specific aim is to explore the aspects of functioning and health important to patients with RA using the ICF-based focus group methodology and to examine to what extent these aspects are represented by the current version of the *Comprehensive ICF Core Set for RA*.

A qualitative study with RA patients using focus groups and the ICF-based approach was conducted. The methods are described in detail above ('*Development of a method to validate ICF Core Sets from the patient perspective: Comparison of two qualitative methods*'). The linked ICF categories were compared with the current version of the *Comprehensive ICF Core Set for RA*. Five focus groups with a total of 24 patients were conducted. The current version of the *Comprehensive ICF Core Set for RA* was confirmed almost entirely from the participants. In total, 71 out of the 76 ICF categories (2nd level) of the *Comprehensive ICF Core Set for RA* were named by the patients. However, some issues emerged from the patient perspective which had not yet been covered by the *Comprehensive ICF Core Set for RA*. These issues are mostly related to *Body Functions* and *Environmental Factors* and many of them could be explained by side effects of medication.

Conlusion

The ICF-based focus group methodology is the most appropriate method to validate ICF Core Sets for chronic conditions from the patient perspective. However, the final recommended approach should not only be superior concerning the precision of data generated and the amount of concepts found, but also concerning the feasibility and economic aspects.

The standardized protocol for the validation of condition-specific ICF Core Sets from the patient perspective is been successfully implemented in different health conditions and in different countries. The experiences with the ongoing validation studies and the successful implementation of the protocol indicate to the applicability and practicability of the design and the standardized protocol.

Using the ICF-based focus group methodology the *Comprehensive ICF Core Set for RA* was validated from the patient perspective. A large number of patient-relevant aspects of functioning and health and ICF categories of the *Comprehensive ICF Core Set for RA* were named and confirmed by the participants of the focus groups, respectively. The results of the focus groups will be presented at an international WHO conference and will be taken into account for the decision on the final version of the *Comprehensive ICF Core Set for RA*.

8 Zusammenfassung

Hintergrund

Rheumatoide Arthritis (rA) ist eine chronische Erkrankung, die zu Schädigungen von Körperfunktionen und –strukturen sowie Beeinträchtigungen von Aktivitäten und Partizipation unter Berücksichtigung von Kontextfaktoren, wie Umwelt- oder personenbezogenen Faktoren, sowie der Krankheit selbst führt.

Mit der Internationalen Klassifikation der Funktionsfähigkeit, Gesundheit und Behinderung (ICF) [31] der Weltgesundheitsorganisation WHO steht eine global verbindliche Sprache und Klassifikation zur Verfügung, mit der Funktionsfähigkeit und Gesundheit von Individuen anhand von mehr als 1400 sogenannten ICF-Kategorien beschrieben werden kann. Um die Anwendbarkeit dieser umfangreichen Klassifikation zu erhöhen, wurden sogenannte *Comprehensive ICF Core Sets* für 12 chronische Erkrankungen [41], darunter auch rA [53] entwickelt. Das *Comprehensive ICF Core Set für rA* ist eine kurze Liste mit ICF-Kategorien, die für die meisten Patienten mit rA relevant sind und das typische Spektrum der Probleme im Bereich Funktionsfähigkeit auf der Basis der universellen Sprache der ICF beschreiben. Die ICF Core Sets werden nun einer weltweiten Validierung unter Verwendung zahlreicher Methoden unterzogen. Einen wichtigen Aspekt stellt dabei die Validierung aus der Patientenperspektive dar. Qualitative Methoden bieten die Möglichkeit, die Perspektive derjeniger zu explorieren, die die Gesundheitsstörung „erfahren“. Bisher wurde allerdings keine Methode entwickelt, um ICF Core Sets aus der Patientenperspektive zu validieren.

Ziele

Das allgemeine Ziel dieser Doktorarbeit ist es, die am besten geeignete Methode zu identifizieren, mit der krankheitsspezifische ICF Core Sets aus der Patientenperspektive validiert werden können. Die spezifischen Ziele sind 1) die Vor- und Nachteile von zwei qualitativen Methoden zu vergleichen, die zur Validierung von ICF Core Sets aus der Patientenperspektive eingesetzt werden, 2) ein Protokol zu entwickeln, mit dessen Hilfe, ICF Core Sets für verschiedene Gesundheitsstörungen und in verschiedenen Ländern aus der Patientenperspektive validiert werden können und 3) die Inhaltsvalidität des *Comprehensive ICF Core Set für rA* unter Anwendung der ausgewählten Methode zu überprüfen.

Unter Berücksichtigung dieser spezifischen Ziele gliedert sich die hier vorgelegte Doktorarbeit in drei Teile: Im ersten Teil wird eine Analyse von qualitativen Daten, die aus der Anwendung zweier verschiedener qualitativer Methoden stammen, dargestellt, um die am besten geeigneten Methode zur Validierung von Comprehensive ICF Core Sets aus der Patientenperspektive zu bestimmen. Im nächsten Teil der Doktorarbeit wird die Entwicklung eines Protokols zur Validierung von ICF Core Sets unter Einbeziehung der Ergebnisse aus dem vorangegangenen Teil geschildert. Im letzten Teil werden die Ergebnisse zur Validierung des *Comprehensive ICF Core Set für rA* aus der Patientenperspektive unter Anwendung der am besten geeigneten Methode präsentiert.

Die Entwicklung einer Methode zur Validierung von ICF Core Sets aus der Patientenperspektive: Ein Vergleich zweier qualitativer Methoden

Das Ziel dieses Teils der Doktorarbeit ist es, die Vor- und Nachteile zweier qualitativer Methoden zu vergleichen, die zur Validierung von krankheitsspezifischen ICF Core Sets aus der Patientenperspektive eingesetzt wurden. Zwei qualitative Methoden – Fokusgruppen und Einzelinterviews – sowie zwei Vorgehensweisen, die in beiden Methoden angewandt wurden – die ’offene’ Vorgehensweise und die ‘ICF-basierte’ Vorgehensweise – wurden überprüft, um die am besten geeignete Methode zur Validierung krankheitsspezifischer ICF Core Sets aus der Patientenperspektive zu bestimmen. Beide Methoden als auch die beiden Vorgehensweisen wurden hinsichtlich (1) formaler Aspekte (z.B. Zeit) und (2) der Ergebnisse (Inhalt) verglichen.

Patienten mit der Diagnose rA wurden nach der ‘maximum variation’ Strategie [78] zur Teilnahme an Fokusgruppen bzw. Einzelinterviews ausgewählt. Die Stichprobengröße wurde anhand der Sättigung der Daten bestimmt [96]. Fokusgruppen und Einzelinterviews wurden nondirektiv unter Verwendung offener Fragen nach einer standardisierten Guideline durchgeführt, digital aufgezeichnet und wörtlich transkribiert. Die Methode der ’meaning condensation’ [78] wurde für die qualitative Analyse der Daten verwendet. Die Konzepte, die in der qualitativen Analyse identifiziert wurden, wurden unter Anwendung von standardisierten Linking-Regeln [21,22] zu der jeweils präzistesten ICF-Kategorie ‚gelinkt’ (übersetzt). Um die Genauigkeit der Auswertung zu überprüfen, wurde ein peer review durchgeführt.

Neunundvierzig bzw. 21 Patienten nahmen an den Fokusgruppen bzw. Einzelinterviews teil. Die Sättigung der Daten wurde nach der Durchführung von 5 Fokusgruppen sowie 13 Einzelinterviews in der offenen Vorgehensweise und 5 Fokusgruppen sowie 8 Einzelinterviews in der ICF-basierten Vorgehensweise erreicht. Es konnte gezeigt werden, dass die ICF-Klassifikation ein nützliches Werkzeug darstellt, um die Ergebnisse von Fokusgruppen und Einzelinterviews zu vergleichen, wenn der Fokus der Untersuchung auf Funktionsfähigkeit und Behinderung liegt. Es wurde dargestellt, dass im Vergleich zu den Einzelinterviews in den Fokusgruppen mehr Konzepte und ICF-Kategorien identifiziert wurden. Zusätzlich wurden in beiden qualitativen Methoden – Fokusgruppen und Einzelinterviews - mehr Konzepte und ICF-Kategorien in der ICF-basierten Vorgehensweise gefunden. Hinsichtlich der Durchführung von Fokusgruppen wurde gezeigt, dass diese in der ICF-basierten Vorgehensweise am zeitaufwendigsten verglichen mit den Einzelinterviews bzw. der offenen Vorgehensweise sind. Die ICF-basierte Vorgehensweise der Fokusgruppen stellt die am besten geeignete Methode zur Validierung krankheitsspezifischer ICF Core Sets aus der Patientenperspektive dar.

Validierung von ICF Core Sets aus der Patientenperspektive: Entwicklung eines Protokolls

Das Ziel dieses Teils der Doktorarbeit ist es, ein Protokoll für die Validierung von krankheitsspezifischen ICF Core Sets aus der Patientenperspektive zu entwickeln, das für verschiedene Gesundheitsstörungen und in verschiedenen Ländern angewendet werden kann.

Auf der Grundlage der am besten geeigneten Methode zur Validierung von ICF Core Sets aus der Patientenperspektive, nämlich der Methode der ICF-basierten Fokusgruppen, wurde ein Protokoll in standardisierter Form entwickelt, das interessierten Forschern detaillierte Informationen zur Validierung von ICF Core Sets aus der Patientenperspektive anbietet. Das Protokoll konnte bereits erfolgreich in Deutschland (für chronischen Ganzkörperschmerz, Diabetes mellitus und Schlaganfall) sowie international (Ungarn: chronischer Rückenschmerz; Schweden und Finnland: Schlaganfall) implementiert werden.

Inhaltsvalidität des Comprehensive ICF Core Set für rheumatoide Arthritis aus der Patientenperspektive unter Anwendung von Fokusgruppen

Das Ziel dieses Teils der vorliegenden Doktorarbeit ist es, die Inhaltsvalidität des *Comprehensive ICF Core Set für rA* unter Anwendung der ausgewählten Methode zu untersuchen. Das spezifische Ziel ist, die Aspekte von Funktionsfähigkeit und Gesundheit, die für Patienten mit rA wichtig sind, anhand der Methode der ICF-basierten Fokusgruppen zu untersuchen. Zudem soll überprüft werden, in welchem Ausmaß diese Aspekte in der aktuellen Version des *Comprehensive ICF Core Set für rA* repräsentiert sind.

Es wurde eine qualitative Studie mit rA Patienten unter Anwendung der Methode der ICF-basierten Fokusgruppen durchgeführt. Die Methodik dieses Teils der Doktorarbeit wurde bereits oben dargestellt (siehe '*Entwicklung einer Methode zur Validierung von ICF Core Sets aus der Patientenperspektive: ein Vergleich zweier qualitativer Methoden*'). Die gelinkten ICF-Kategorien wurden mit der aktuellen Version des *Comprehensive ICF Core Set für rA* verglichen. Fünf

Fokusgruppen mit insgesamt 24 Teilnehmern wurden durchgeführt. Die aktuelle Version des *Comprehensive ICF Core Set für rA* wurde weitestgehend von den Teilnehmern der Fokusgruppen bestätigt. Insgesamt wurden 71 der 76 ICF-Kategorien (2. Ebene) des *Comprehensive ICF Core Set für rA* von den Teilnehmern benannt. Allerdings wurden auch zahlreiche zusätzliche Inhalte aus der Patientenperspektive gefunden, die nicht in dem *Comprehensive ICF Core Set für rA* enthalten sind. Diese Inhalte beziehen sich hauptsächlich auf *Körperfunktionen* und *Umweltfaktoren*; viele von ihnen können durch Nebenwirkungen von Medikamenten erklärt werden.

Schlussfolgerung

Die Methode der ICF-basierten Fokusgruppen ist die am besten geeignete Methode zur Validierung von krankheitsspezifischen ICF Core Sets aus der Patientenperspektive. Allerdings sollte die letzendlich zu empfehlende Vorgehensweise nicht nur die Präzision der erhaltenen Daten und die Anzahl der identifizierten Konzepte in den Mittelpunkt stellen, sondern auch die Machbarkeit und ökonomische Aspekte berücksichtigen.

Das standardisierte Protokoll für die Validierung von krankheitsspezifischen ICF Core Sets aus der Patientenperspektive konnte erfolgreich für weitere Gesundheitsstörungen und in anderen Ländern implementiert werden. Die Erfahrungen mit den derzeit durchgeführten Validierungsstudien und die erfolgreiche Implementierung des Protokolls sprechen für die Anwendbarkeit und Praktikabilität des Designs und des standardisierten Protokolls.

Unter Verwendung der Methode der ICF-basierten Fokusgruppen wurde das *Comprehensive ICF Core Set für rA* aus der Patientenperspektive validiert. Eine große Anzahl an patientenrelevanten Aspekten der Funktionsfähigkeit und Gesundheit und die Mehrzahl der ICF-Kategorien des *Comprehensive ICF Core Set für rA* wurden von den Teilnehmern der Fokusgruppen genannt bzw. bestätigt. Die Ergebnisse dieser Fokusgruppen werden auf einer internationalen WHO-Konferenz präsentiert und bei der Verabschiedung der endgültigen Version des *Comprehensive ICF Core Set für rA* berücksichtigt werden.

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10 Appendix

Appendix 1 Comprehensive ICF Core Set for rheumatoid arthritis

ICF code 2nd 3rd 4th level	ICF category title
Body Functions	
b130	Energy and drive functions
b134	Sleep functions
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 functions
b510	Ingestion functions
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	
s299	Eye, ear and related structures, unspecified
s710	Structure of head and neck region
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

ICF code 2nd 3rd 4th level	ICF category title
Activities and Participation	
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 one's 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	
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

ICF code 2nd 3rd 4th level	ICF category title
e410	Individual attitudes of immediate family members
e420	Individual attitudes of friends
e425	Individual attitudes of acquaintances, peers, colleagues, neighbors 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

Table 1 Comprehensive ICF Core Set for RA

Appendix 2 Brief ICF Core Set for rheumatoid arthritis

ICF code	ICF category title
Body Functions	
b134	Sleep functions
b280	Sensation of pain
b455	Exercise tolerance functions
b710	Mobility of joint functions
b730	Muscle power functions
b740	Muscle endurance functions
b770	Gait pattern functions
b780	Sensations related to muscles and movement functions
Body Structures	
s299	Eye, ear and related structures, unspecified
s710	Structure of head and neck region
s720	Structure of shoulder region
s730	Structure of upper extremity
s750	Structure of lower extremity
s760	Structure of trunk
s810	Structure of areas of skin
Activities and Participation	
d230	Carrying out daily routine
d410	Changing basic body position
d430	Lifting and carrying objects
d440	Fine hand use
d445	Hand and arm use
d450	Walking
d470	Using transportation
d510	Washing oneself
d540	Dressing
d550	Eating
d770	Intimate relationships
d850	Remunerative employment
d859	Work and employment, other specified and unspecified
d920	Recreation and leisure
Environmental Factors	
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
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
e310	Immediate family
e355	Health professionals
e540	Transportation services, systems and policies
e570	Social security services, systems and policies
e580	Health services, systems and policies

Table 2 Brief ICF Core Set for RA

Appendix 3 Confirmed ICF categories of the Comprehensive ICF Core Set for rheumatoid arthritis: comparison of focus groups and individual interviews

ICF categories		Open approach		ICF-based approach	
ICF code	ICF category title	FG	EI	FG	EI
b130	Energy and drive functions	◆	◆	◆	◆
b134	Sleep functions	◆	◆	◆	
b152	Emotional functions	◆	◆		◆
b180	Experience of self and time functions		◆	◆	
b280	Sensation of pain	◆	◆	◆	◆
b430	Haematological system functions	◆		◆	◆
b455	Exercise tolerance functions	◆	◆	◆	◆
b510	Ingestion functions	◆		◆	◆
b640	Sexual functions			◆	◆
b710	Mobility of joint functions	◆	◆	◆	◆
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	◆		◆	

*Table 3 **Body Functions (b): Confirmed ICF categories (2nd level) of the Comprehensive ICF Core Set for RA***

ICF categories		Open approach		ICF-based approach	
ICF code	ICF category title	FG	EI	FG	EI
s299	Eye, ear and related structures, unspecified (s220)*	◆		◆	◆
s710	Structure of head and neck region	◆		◆	◆
s720	Structure of shoulder region	◆	◆	◆	◆
s730	Structure of upper extremity	◆	◆	◆	◆
s750	Structure of lower extremity	◆	◆	◆	◆
s760	Structure of trunk	◆	◆	◆	◆
s770	Additional musculoskeletal structures related to movement	◆	◆	◆	◆
s810	Structure of areas of skin	◆		◆	◆

*Table 4 **Body Structures (s): Confirmed ICF categories (2nd level) of the Comprehensive ICF Core Set for RA***

ICF categories		**Open approach**		**ICF-based approach**	
ICF code	**ICF category title**	**FG**	**EI**	**FG**	**EI**
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 (d430/d445)*				
d450	Walking	◆	◆	◆	◆
d455	Moving around	◆	◆	◆	◆
d460	Moving around in different locations (d455)*		◆		◆
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 one’s 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 (d850)*				
d910	Community life			◆	
d920	Recreation and leisure	◆	◆	◆	◆

Table 5 ***Activities & Participation (d):*** ***Confirmed categories (2nd level) of the Comprehensive ICF Core Set for RA***

ICF categories		Open approach		ICF-based approach	
ICF code	**ICF category title**	**FG**	**EI**	**FG**	**EI**
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	◆	◆	◆	◆

Table 6 Environmental Factors (e): Confirmed categories (2nd level) of the Comprehensive ICFCore Set for RA

Appendix 4 Protocol for the validation of ICF Core Sets of chronic health conditions from the patient perspective

WHO Collaboration Project

Validation of the ICF Core Sets for [insert health condition] from the patient perspective

Protocol

Protocol Synopsis

Objective: The goal of this study is to explore the aspects of functioning and health important to patients with [insert health condition] and to examine to what extent these aspects are represented by the current version of the ICF Core Sets for [insert health condition].

Study Design: The study is qualitative using focus groups.

Frequency of data collection: once

Participants: Participants are patients diagnosed with [insert health condition], being treated in the [insert clinic] of the [insert department] in [insert town]. Up to 6 focus groups with patients with [insert health condition] will be included in the study before saturation will be reached.

Instruments:

- Topic guide for focus groups
- Case Record Form for Patients (CRF): The CRF is a self administered questionnaire including sociodemographic and disease related variables
- Comorbidity Questionnaire (SCQ)
- [insert further disease-specific questionnaires]

Outcome: Validation of the ICF Core Sets for [insert health condition] by obtaining aspects of functioning and health important to patients with [insert health condition].

Time Frame:

Start: [insert month/year]
Finish: [insert month/year]

Responsibilities

Project Director: [insert name]
[insert department]

[insert address]

Project Coordinator: [insert name]
[insert department]

[insert address]

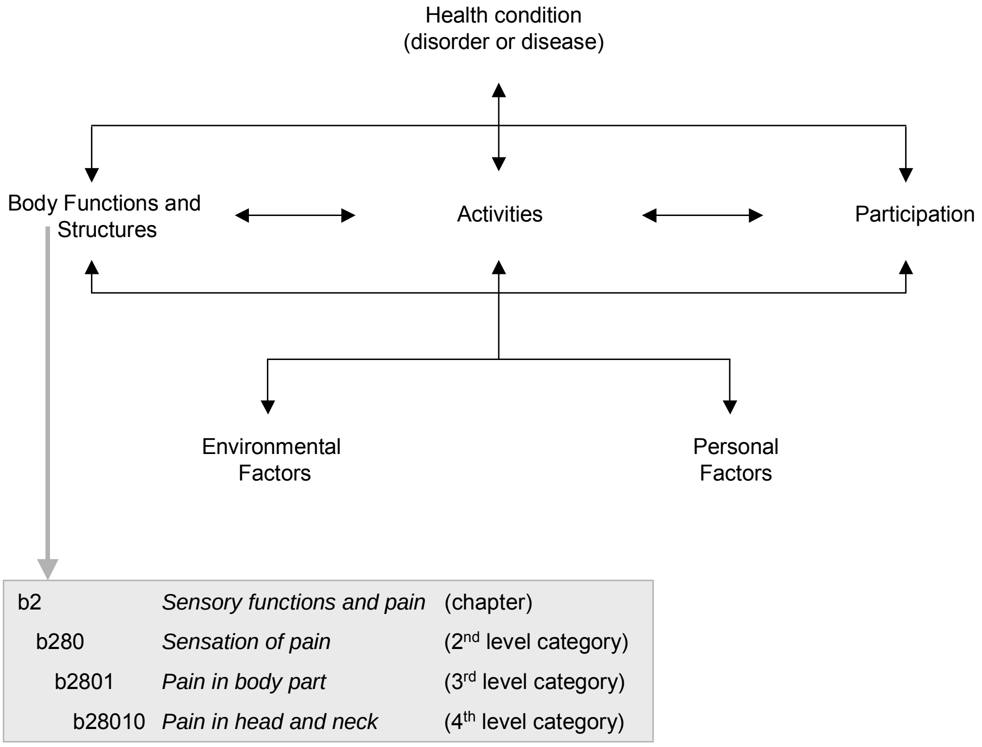
Background

The International Classification of Functioning, Disability and Health, known as ICF, is a multipurpose classification which belongs to the WHO family of international classifications and is designed to record and organize a wide range of information about health and health-related states [1]. The ICF was approved by the World Health Assembly in May 2001.

The specific aims of the ICF according to WHO 2000 are: (1) to provide a scientific basis for understanding and studying health and health-related states, outcomes and determinants, (2) to establish a common language for describing health and health-related states to improve communication among health professionals, researchers, patients and other stakeholders in the health-care system, (3) to permit the comparison of data across countries, health-care disciplines, services and time, and (4) to provide a systematic coding scheme for health-information systems.

The development of the ICF was based on the so called bio-psycho-social model. The domains contained in the bio-psycho-social model are described from the perspective of the body, the individual and the society (see figure 1). This model groups different domains for a person in a given health condition. As a term, functioning encompasses all body functions, body structures, activities and participation; similarly, disability serves as a term for impairments of body functions and body structures, activity limitations and participation restrictions. The bio-psycho-social model also contains environmental and personal factors that interact with functioning and disability. This bio-psycho-social approach establishes the basis for a more appropriated description of the whole health experience of patients suffering from disease.

According to the bio-psycho-social model the ICF classification contains the four components Body functions, Body Structures, Activities and Participation, and Environmental Factors. The component Personal Factors has not yet been classified. Each component consists of several chapters, and within each chapter, of categories which are the units of the classification. Within the hierarchical code system of the ICF classification, the letters b, s, d, and e, which refer to the component of the classification, are followed by a numeric code that starts with the chapter number (single digit) followed by the 2nd-level (two digits) and the 3rd- and 4th-level (one digit each) (see figure 1). In this way, it enables the user to record useful profiles of individuals’ functioning, disability and health in various settings [1].



b2	*Sensory functions and pain*	(chapter)
b280	*Sensation of pain*	(2^{nd} level category)
b2801	*Pain in body part*	(3^{rd} level category)
b28010	*Pain in head and neck*	(4^{th} level category)

Figure 1: ***The current framework of functioning and disability – the WHO International Classification of Functioning, Disability and Health (ICF)***

Since the ICF has been developed in a worldwide comprehensive consensus process over the last years, it is likely to become the generally-accepted framework to describe persons' functioning and health in rehabilitation [2, 3, 4]. Since the endorsement of the ICF by the WHO the application in clinical practice was addressed by several research projects [5]. Considering that it may take hours to fully classify an individual patient in its current form (even after intensive training), the practicability of the ICF remains an important issue.

To facilitate the use of the ICF classification in rehabilitative medicine, e.g. for planning of rehabilitative interventions, disease-specific ICF Core Sets have been developed by the ICF Research Branch located at the Department of Physical Medicine and Rehabilitation at the Ludwig-Maximilian University in Munich. The condition-specific ICF Core Sets include as few domains as possible to be practical and as many as necessary to be comprehensive enough to cover the prototypical spectrum of limitations in functioning and health encountered in a specific health condition. ICF Core Sets for 12 health conditions (rheumatoid arthritis, stroke, osteoarthritis, osteoporosis, low back pain, chronic generalized pain, depression, obesity, breast cancer, diabetes mellitus, obstructive pulmonary disease, chronic ischemic heart disease) have been developed in a multi-phase research project including systematic literature review, expert surveys using Delphi-technique, empiric data collection and consensus conference [6, 7, 8, 9].

As a result of this project two *ICF Core Sets for [insert health condition]* are available: The *Comprehensive ICF Core Set* to guide multidisciplinary assessments in patients with [insert health condition] and the *Brief ICF Core Set* to be rated in all patients included in a clinical study with [insert health condition] [10]. The total number of categories in the *Comprehensive ICF Core Set for [insert health condition]* is [insert number of categories included in the respective Core Set], and the total number of categories in the *Brief ICF Core Set for [insert health condition]* is [insert number of categories included in the respective Core Set] [insert reference]. The Comprehensive ICF Core Set for a multidisciplinary assessment in [insert health condition] may be used in future to facilitate clinicians and researchers efforts to incorporate a patient oriented, multilevel and comprehensive view in their everyday practice.

Before using the ICF Core Sets in clinical routine an extensive validation process will be conducted. This process will follow three approaches:

- Validation with empirical data from cross-sectional studies (ICF Core Sets multi-centre international validation study)
- Validation from the perspective of health professionals
- Validation from the patient perspective

The first validation approach analyses patient data of international cross-sectional studies. Psychometric properties of the ICF Core Sets will be tested using different statistical techniques. The aim of the second approach is to validate ICF Core Sets from the perspective of health professionals involved in the health care of patients suffering from a specific disease using the Delphi-technique. The third approach in the validation process is the validation from the patient perspective using a qualitative methodology. While the patient perspective has been included implicitly in the development of the ICF (e.g. limitations of activities, restriction of participation, personal factors) the patients now will be involved explicitly in the process of the validation of ICF Core Sets. As standards of functioning and health in research and clinical practice, the ICF Core Sets should address the perspective of those who experience the disease. Qualitative methodology provides the possibility to explore the perspective of those who experience the health problem, i.e. the so-called patient perspective. One possible approach to identify the prototypical spectrum of functioning and health of individuals afflicted with [insert health condition] is to interview patients in small groups. These so-called focus groups [11, 12] differ from individual interviews concerning the interaction and group process that can enrich the information generated within a group of patients. Although no difference was found in the depth of data generated [13], more concepts are likely to occur in focus groups compared to individual interviews [14]. In a previous study concerning the validation of the ICF Core Sets for rheumatoid arthritis from the patient perspective a focus group methodology – the so-called ICF based approach - was developed and found to be an effective method to validate ICF Core Sets from the patient perspective [14]. The validation from the patient perspective aims at checking whether the individual problems in functioning and health noticed by the patients themselves are represented by the ICF categories selected for the ICF Core Sets for e.g. [insert health condition].

[insert aspects of epidemiology and etiology, diagnostic criteria of the health condition] [insert relevant aspects of the health condition: body functions, body structures, limitations of activities, restrictions of participation, environmental factors]. Therefore [insert health condition] may be seen as a complex bio-psycho-social disorder. A bio-psycho-social approach can be useful in describing the whole health experience of patients with [insert health condition] and is in accordance with the general concept of the ICF.

Objective

The objective of the study is to validate the current version of the *Comprehensive ICF Core Set* for *[insert health condition]* from the perspective of patients with [insert health condition]. Using a focus group approach, the goals of this study are:

- to explore aspects of functioning and health important to patients with [insert health condition]
- to examine to what extent these aspects are represented by the current version of the *Comprehensive ICF Core Set for [insert health condition]*

Methods

Study design

The study design is a qualitative study with individuals with [insert health condition] using the focus group methodology with the so called ICF-based approach [15].

Study population

Recruitment of the patients

Participants of the study are patients diagnosed with [insert health condition], being treated in the [insert study center of collaborating center]. The patients will be offered to participate in the study on a voluntary basis. The patients will be informed both verbally and in written form with a letter of background information and a description of the objectives of the study. Those not willing to participate will have no disadvantages regarding the quality of the treatment in [insert study center of collaborating center] and will receive the same therapy as those participating in the study. All individuals who agree to participate in patient focus groups and who fulfil the inclusion and exclusion criteria will be included regarding the sampling strategy.

[Insert specific recruitment strategies of the study center.]

Inclusion Criteria

Persons participating in the study must fulfill the following criteria:

- age ≥ 18 years
- diagnosis of [insert health condition] (according to the criteria [insert source, year])
- willing to participate in a focus group
- sufficient linguistic skills of the [insert language] language

Exclusion Criteria

The following persons are excluded from the study:

- patients who have had surgery briefly before participation in the study (not completed wound healing)
- patients with psychiatric disorders (e.g. acute major depression, personality disorders)

Sampling strategy

The sampling of patients will follow the maximum variation strategy [16, 17] based on the criteria: [insert criteria e.g. “disease” duration and age group]. Patients will be included in the study until the point of saturation of data is reached. Saturation refers to the point at which the investigator has obtained sufficient information from the field [18]. In this study, saturation is defined as the point in which further focus groups reveal no additional information (see 0). In accordance with the validation study in patients with rheumatoid arthritis, approximately five to six focus groups will be carried out before saturation is reached [15].

The focus group process explicitly aims at the interaction between patients. Therefore the group size will be set at a maximum of six persons to accommodate different individuals but to allow for easy interactions [19, 20]. According to a previous validation study with rheumatoid arthritis patients the optimum size of the focus groups has been found to be six patients per group [14]. This small group size with a diverse range of participants allows for the obtainment of rich and meaningful data.

Instruments

Topic guide for focus group

In the focus groups qualitative data will be collected. Focus groups are “carefully planned series of discussions designed to obtain perceptions on a defined area of interest in a permissive, non-threatening environment” [19; p.5). They are especially useful for studies that involve complex issues that entail many levels of feeling and experience. “The basic goal in conducting focus groups is to hear from the participants about the topics of interest to the researcher” [21; p.11]. The idea behind this methodology is that group processes can help people to explore and clarify their views. The non-directive nature of focus groups affords participants an opportunity to comment, explain, disagree and share experiences and attitudes.

In this study an established focus group methodology – the so called ICF-based focus group approach [15] - will be conducted according to a topic guide with open-ended questions and focus group guidelines with further instructions. In the ICF-based approach, each title of the ICF chapters from which categories are included in the *Comprehensive ICF Core Set for [insert health condition]* will be presented to the patients. For each of the presented chapters, open-ended questions on possible problems in each of the life areas that the ICF chapters represent will be used (see table 1). Finally, the patients will be asked if they think anything is missing in the *Comprehensive ICF Core Set for [insert health condition]*.

ICF component	
Body functions	If you think about your body and mind, what does not work the way it is supposed to?
Body structures	If you think about your body, in which parts are your problems?
Activities & Participation	If you think about your daily life, what are your problems?
Environmental factors facilitators	If you think about your environment and your living conditions, what do you find helpful or supportive?
Environmental factors barriers	If you think about your environment and your living conditions, what barriers do you experience?

Table 1: Open-ended questions of the focus groups

To facilitate the planning and conduction of the focus groups focus group guidelines with specific instructions for the following aspects will be developed:

- setting
- technical equipment
- wording of the introduction to the topic
- introductory questions for group discussion (exact wording)
- sequential order of the open-ended questions
- instructions for handling of requests
- instructions for closure of the focus group

Questionnaires

The following instruments (quantitative data) for the documentation of the patients will be used:

Case Record Form

For the description of the study population data are documented by the Case Record Form for patients containing the following parts:

- **Socio-demographic data:** date of birth, gender, years of formal education, marital status, living situation, current occupation

- **Patients' general health from the patients perspective:** Patients are requested to evaluate their own health as well as the extent of their own problems in functioning using a rating scale ranging from 1 (poor/complete problem) to 10 (excellent/no problem), respectively.

The Case Record Form is a self administered questionnaire including sociodemografic and disease related variables.

Comorbidity Questionnaire (SCQ) [22]

The Self-administered Comorbidity Questionnaire (SCQ) is an instrument to assess comorbidity for clinical and health services research. The patients are firstly asked "Do you have any of the following problems?" for the following health conditions: (1) heart disease, (2) high blood pressure, (3) lung disease, (4) cancer, (5) depression, (6) arthritis and (7) back pain. Additionally, patients have the option to add three additional conditions in an open-ended fashion. For each problem, the patients are asked "Do you receive treatment for it?" as a proxy for disease severity. To capture the burden of disease to the individual, the question "Does the problem limit your activities?" for each medical condition is intended.

[insert other disease specific questionnaires]

[insert description of other disease specific questionnaires].

Data collection

Data collection of focus groups

All focus groups will be conducted in a non-directive manner by the same moderator ([insert name]) and an assistant ([insert name]) according to focus group guidelines and the topic guide (see 0). At the beginning of each focus group, the procedure of the session will be explained, and the concept of the ICF will be presented in lay terms to all participants. The titles of the chapters will be presented visually to the participants by a Power-Point presentation. At the end of each focus group, a summary of the main results will be given back to the group to enable the participants to verify and amend emergent issues. According to a previous study with rheumatoid arthritis patients [15] the length of time for one focus group will be approximately 120 minutes. The order of the open-ended questions used in the focus groups should be randomized. That means that the first focus group session might be started with the question focusing on Body Functions. In contrast, the second focus group session might be started with the question focusing on barriers in the environment.

Each focus group will be digitally recorded and transcribed verbatim with the [digital transcription system; e.g. Olympus DSS-system]. The assistant will observe the process within the focus group and fill in field notes according to a standardized coding schema. After each focus group a debriefing with moderator and assistant will take place to review the course of the focus group.

Data collection of questionnaires

The patients' questionnaires will be filled out prior to the focus groups.

Data analysis

Data analysis of focus groups

The data analysis of the focus groups' transcripts consists of the following three parts (see figure 2):

- Part 1: Qualitative analysis (containing 3 steps)
- Part 2: Linking to the ICF
- Part 3: Comparison with the ICF

Part 1: Qualitative analysis

The qualitative data analysis will follow the 'meaning condensation procedure' [23] in a three-step process. In the first step, the transcripts of the focus groups will be read through to get an overview over the collected data. In the second step, the data will be divided into meaning units and the theme that dominates a meaning unit will be determined. A meaning unit will be defined as a specific unit of text either a few words or a few sentences with a common theme [24]. Therefore, a meaning unit division does not follow linguistic grammatical rules. Rather, the text is divided where the researcher discerned a shift in meaning [23]. In the third step, the concepts contained in the meaning units will be identified. A meaning unit can contain more than one concept.

Part 2: Linking to the ICF

The identified concepts will be linked to the ICF according to the linking rules of Cieza et al. [6, 7]. According to these linking rules, health professionals trained in the ICF are advised to link each concept to the ICF category representing this concept most precisely. One concept could be linked to one or more ICF categories, depending on the number of themes contained in the concept.

Part 3: Comparison with the ICF

The linked ICF categories will be compared with the existing version of the *Comprehensive ICF Core Set for [insert health condition].* The following three outcomes will be documented:

- confirmed ICF categories of the *Comprehensive ICF Core Set for [insert health condition]:*

  An ICF category of the *Comprehensive ICF Core Set for [insert health condition]* is regarded as confirmed, if the identical or a similar category emerged from the focus groups. Since the ICF categories are arranged in a hierarchical code system, the 2nd-level categories of the *Comprehensive ICF Core Set for [insert health condition]* are considered confirmed when the corresponding 3rd- or 4th-level category of which they are a member had been named by the patients.
- not confirmed ICF categories of the *Comprehensive ICF Core Set for [insert health condition]*
- additional ICF categories not contained in the existing version of the *Comprehensive ICF Core Set for [insert health condition]*

The data collection and analysis is completed when the saturation of data is reached. Saturation refers to the point at which an investigator has obtained sufficient information from the field [17]. In this study saturation is defined as the point during data collection and analysis when the linking of the concepts of two consecutive focus groups reveals no additional ICF 2nd-level categories of the *Comprehensive ICF Core Set for [insert health condition]* with respect to previous focus groups. According to a study in patients with rheumatoid arthritis, approximately six focus groups will be carried out at each site before saturation will be reached [15].

Data analysis of questionnaires

The entry and analysis of quantitative data of the Case Record Form and the disease specific questionnaires (SCQ, [insert disease specific quesionnaires]) will be conducted with the Data Editor Software package SPSS 14.0 for Windows. Data analysis will be descriptive. Data checks and plausibility checks will be conducted on a regular basis.

Monitoring and accuracy of data

Several strategies will be used to improve and verify the trustworthiness of the qualitative data:

- *Continuous data analysis* [25]: The data analysis starts during data collection, since the data that had already been gathered were analysed to verify the saturation of the qualitative data.

- *Reflexivity* was assured by the following strategies: A *research diary* will be kept the entire duration of the study. *Field notes* will be filled out by the assistant for the documentation of the focus groups according to a specific coding schema. After each focus group, a reflective *debriefing* of the moderator and the assistant should take place. The researcher should reflect on the course of the discussion in the focus group, what her or his own experiences were, why some topics were addressed by the participant while others were not addressed, what could be improved in the next focus group (learning experience) and what was good in the discussion.

- *Clear exposition* was used establishing guidelines for conducting the focus groups, verbatim transcription, and established procedures of data analysis. Thus, a clear account of methods of data collection and analysis was assured.

- *Multiple coding:* To ensure the comprehensiveness of data and the *investigator triangulation* [26, 27] the first focus group will be separately analysed by two health professionals who are experts in the ICF and in the application of the linkage rules to achieve agreement concerning the implementation of the linking rules in patients with [insert health condition]. Agreements, specifications and special cases of the linking rules occurred when applying the rules for the identification of concepts and the linking process will be documented. The data analysis of the two health professionals and the comparison of their data analysis follow a specific procedure containing 4 steps (see figure 2).

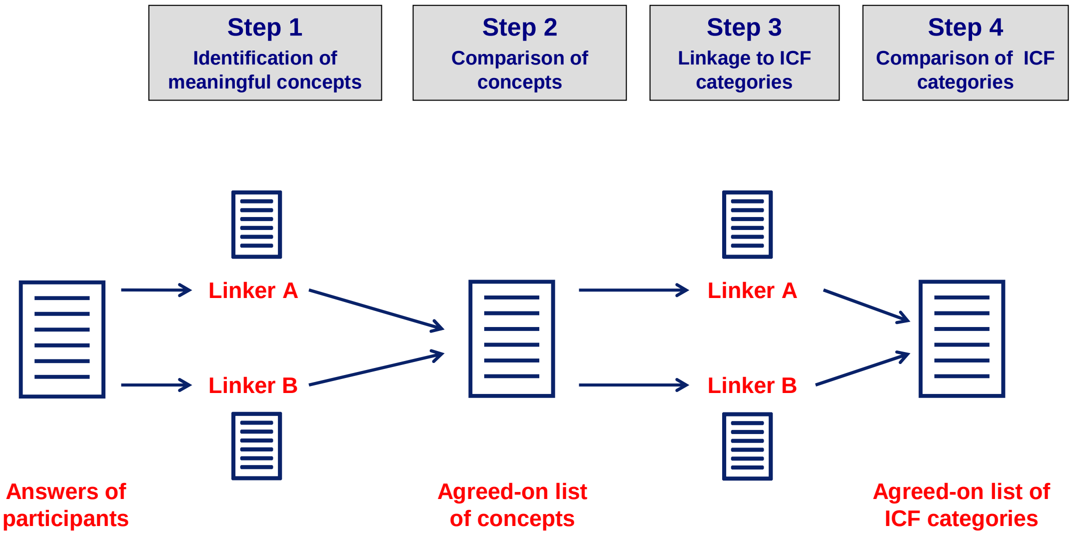


Figure 2: ***Investigator triangulation: multiple coding***

After the identification of concepts (Step 1) and linking to the ICF (Step 3) both experts will compare their results respectively (Step 2, Step 4). Initial disagreement will be solved after structured discussion between the two experts. If there is disagreement after all of this a third person will be consulted. Agreements and specifications of the linking rules will be documented. Data analysis and linking of further focus groups will be preformed by one researcher.

- *Peer review:* After the exclusion of data of the first focus group (with multiple coding) a random sample of 15% of the transcribed text and 15% of the identified concepts (of the first researcher) will be analyzed and linked additionally by the second researcher as a peer review, respectively. The degree of agreement between the two investigators regarding the identification of concepts and the linked concepts will be calculated by kappa statistic with 95%-bootstrapped confidence intervals [28, 29], respectively. The values of the kappa coefficient generally range from 0 to 1, whereas 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance alone.

Ethics Committee

The study will be conducted according to the ethical principles of the Declaration of Helsinki 1996. All documents will be presented to the Commission of Ethics [insert institution].

Training

The moderator of the focus groups and the assistant will be trained in the ICF, the focus group methodology and in the handling of the data analysis procedures by members of the ICF Research Branch of the Ludwig-Maximilian University, Munich.

Project Management, Coordination and Collaboration

[insert project responsibilities and collaborating institutions]

Time Frame

The time frame for the study is estimated at [insert time frame], beginning [insert month year], ending [insert month year].

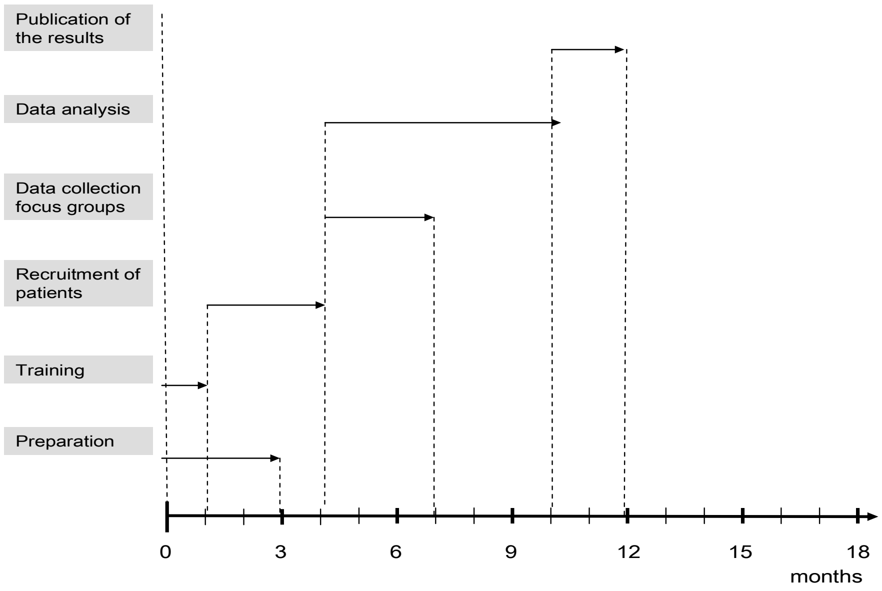


Figure 3: ***Time table of the study***

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Attachment

WHO Collaboration Project

ICF Core Set validation – patient perspective

Guideline to perform and analyse focus groups and individual interviews

Table of content

Figures

1 Background

An important basis for the optimal acute and long-term management of [insert health condition] is an in-depth understanding, systematic consideration and sound measurement of the impact of [insert health condition] on health and health-related domains. The International Classification of Functioning, Disability and Health (ICF) offers a framework for such a comprehensive understanding of the components of health. The ICF framework is based on the bio-psycho-social model covering functioning and disability with its components Body Structures, Body Functions, Activities and Participation as well as Personal and Environmental Factors. Since its classification with more than 1400 categories can serve as a reference but is not applicable in clinical practice, tools such as ICF Core Sets are needed to make the ICF useful for medicine.

The ICF Core Sets for [insert health condition] were defined at an international ICF Core Set Consensus Conference which has integrated evidence from preliminary studies. Within the validation process all relevant perspectives should be addressed adequately. The patient perspective is addressed in a qualitative way using focus groups and individual interviews. The clinician perspective is addressed by the multicenter empirical study. Finally, the expert opinion involving health professionals from the different backgrounds is addressed with a Delphi exercise.

Focus groups are “carefully planned series of discussions designed to obtain perceptions on a defined area of interest in a permissive, non threatening environment”. The non-directive nature of focus groups affords participants an opportunity to comment, to explain, to disagree and to share experiences and attitudes. Individual interviews differ from focus groups because an individual face-to-face interaction between the researcher and each participant takes place.

Individual interviews are an option for individuals who cannot participate in a focus group setting due to the severity of their health condition.

The objective of this user's guide is to provide researchers with a feasible methodological guideline to perform the data collection within the scope of the qualitative study using focus group and individual interview technique to validate the ICF Core Sets from the patient perspective.

2 General considerations

2.1 Requirements of a moderator/interviewer

The conduction of a focus group or an individual interview, respectively, requires special skills, e.g. sufficient linguistic skills of the language used in the focus group/individual interview, to ask appropriate questions and to feel empathy with the participants. A moderator of a focus group should be experienced in facilitating group processes. Moreover the researcher should be familiar with the typical problems with which people with [insert health condition] may be faced and the ICF.

When performing a focus group, please make sure that at least one group assistant will join your session to take field notes and to look after the recorders. All focus groups and individual interviews performed at one study site should be conducted by the same moderator/interviewer to ensure the continuity of data collection and data analysis.

2.2 Participant’s requirements

Participants of focus groups are selected according to the following inclusion criteria:

- Individual with [insert health condition] according to [insert criteria]
- Age>= 18
- Individual has been informed of the purpose and reason of the study, and both have been understood
- The individual has signed the “patient consent form”
- Individual without mental disorders prior to [insert health condition]
- [insert other inclusion criteria]

In case that an individual cannot join a focus group session due to the severity of the health condition, an individual interview would be an option.

2.3 Time

A time frame of up to 30 minutes has to be considered for an individual interview. Up to two hours should be considered for a focus group inclusive a break. Please make sure that the participants have no other appointments or examinations at the same time.

The appropriate time for a focus group/individual interview session should be discussed with each participant in order to prevent visitors or scheduled interventions from interrupting.

2.4 Setting

Focus groups/individual interviews should take place in a quiet room in order to ensure privacy and to prevent possible interruptions or noise which could damage the data on the tape.

2.5 Technical requirements

Following technical equipment is <u>necessary</u> to perform focus groups/individual interviews:

- at least two (digital) voice recorders
- omni-directional microphone
- extra battery/power supply
- notebook/PC
- transcription software for PCs[1]

Following technical equipment is <u>optional</u> to perform focus groups/individual interviews:

- video projector (only for focus groups)
- projection screen (only for focus groups)

Note:
Recorders should be tried out before use!
Be sure that the microphone is appropriate to record a discussion involving several individuals (<u>omni-directional</u> microphone)!
Please check the number of available sockets in the room where the focus groups will be performed; you may need additional multiple sockets and/or extension cords.

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[1] Available as free software e.g.: http://www.audiotranskription.de/english/f4.htm; http://www.nch.com.au/scribe/

2.6 Templates of study materials provided by the ICF Research Branch Munich

- Study protocol
- Topic guide
- Paper version of the Case Record Form
- Patient consent form and Patient information sheet
- Documentation sheet

3 Preparatory work

3.1 Recruitment of participants

The sampling of participants in focus groups/individual interviews follows the maximum variation strategy based on following criteria:

- Sex
- Age
- [insert other criteria; e.g. duration of disease; severity of disease]

Example to retrieve a study sample for focus groups

Step 1: on every first of the month you ask for an up-dated list of inpatients

Step 2: identify all eligible patients according to the inclusion criteria

Step 3: select up to seven patients with respect to the criteria ensuring the maximum variation within your focus group

Step 4: ask all selected patients personally whether they are interested to take part in the focus group. In case that a patient cannot join a focus group session due to the severity of the health condition, please ask whether s/he would agree to participate in an individual interview.

Step 5: include all patients who agree to participate

Repeat step 1 to 5 until saturation is reached (see 6.4). Saturation refers to the point at which you have obtained sufficient information from the field. According to a study in patients with rheumatoid arthritis, up to six focus groups were performed before saturation is reached.

3.2 Sample size of a focus group

It is recommended to include at least four but not more than seven participants in each focus group to accommodate different perspectives but to allow for easy interactions.

Example to retrieve a study sample for individual interviews

Step 1: Determine the beginning of the data collection at your study site

Step 2: Identify all eligible patients according to the inclusion criteria. Patients participating in individual interviews have to meet all inclusion criteria required for the participation in the focus groups. In addition, the patient's health condition does not allow her/his participation in a focus group.

Step 3: Since this point of time you will ask each patient selected with respect to the criteria ensuring the maximum variation whether s/he is interested to take part in the individual interview

Step 4: include all patients who agree to participate

Repeat step 1 to 4 until saturation is reached. Saturation refers to the point at which you have obtained sufficient information from the field see. According to a study in patients with rheumatoid arthritis, up to 12 individual interviews were performed before saturation is reached.

When asking the patients to participate, please hand over an information letter about the study. Please make sure prior to the focus group/individual interview session that all patients who agree to participate in a focus group/individual interview fulfil the inclusion criteria.

As the number of participants depends on the saturation criteria, you decide after each data analysis of a focus group or individual interview, respectively, whether further participant(s) should be recruited.

3.3 Patient information and agreement

Please inform the patient about nature and course of the study. To inform the patient use the information sheet specific for this study. Please give the patient sufficient time for his/her decision! It is important to emphasize that all personal data will be treated in strict confidence.

Consent to participate in the study must be given in writing. Therefore, please ask the patient or, if a patient is unable to sign the patient's carer, to sign his/her agreement in the form provided.

In the following you will find an example for an information dialogue with the patient. Of course you will not apply the dialogue verbatim. However, the content of following paragraphs has to be included in your information dialogue.

1. Introduction

Hello (individual's name), my name is (...). I'm (your profession) at the (name of your rehabilitation center). We are carrying out a study in cooperation with the World Health Organization (WHO). The objective of this study is to describe functioning and health of individuals with [insert health condition]. We would like to ask you, if you agree to participate in this study.

2. Voluntariness

Of course your participation in this study is voluntary. If you refuse to participate in the study, it will effect your treatment in no way.

3. Anonymity

The privacy of your data is ensured. All information will be recorded anonymously by using a coding number. This procedure enables to save and analyse data without using your name. Additionally, the research team is bounded to discretion.

4. Objective of the study

The objective of this study is to describe functioning and health of individuals with [insert health condition]. The study will identify relevant problems in the areas of body functions, body structures, and activities and participation. Furthermore, this study will identify positive and negative effects of the environment. In total up to fifty individuals with [insert health condition] treated in your rehabilitation hospital will be asked to participate in this worldwide study.

Procedure

The interview will be tape-recorded and transcribed. All data which could characterize you will be changed before reporting the data. The data collection will take you up to one and a half hours.

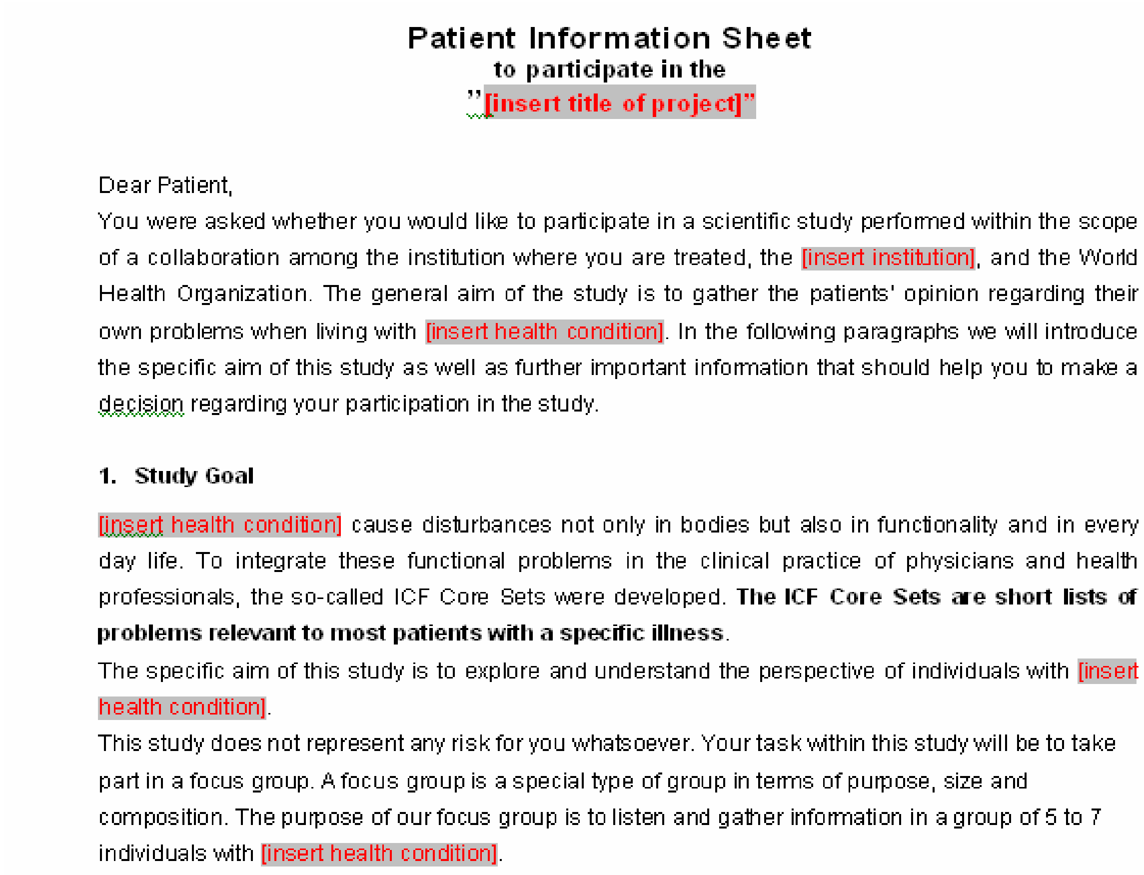
5. *Patient's consent*

Would you like to agree to participate in the study and would you allow that the information in your clinical documentation can be used? Do you have any further questions regarding the study procedure?

6. *Ending*

Please read this information sheet. If you agree to participate in this study, please sign the consent form. I will see you tomorrow and if you have any further questions, don't hesitate to ask me. You can call me under (your phone number). Thank you very much!

Template of the patient information sheet:



Patient Information Sheet
to participate in the
"[insert title of project]"

Dear Patient,
You were asked whether you would like to participate in a scientific study performed within the scope of a collaboration among the institution where you are treated, the [insert institution], and the World Health Organization. The general aim of the study is to gather the patients' opinion regarding their own problems when living with [insert health condition]. In the following paragraphs we will introduce the specific aim of this study as well as further important information that should help you to make a decision regarding your participation in the study.

1. Study Goal

[insert health condition] cause disturbances not only in bodies but also in functionality and in every day life. To integrate these functional problems in the clinical practice of physicians and health professionals, the so-called ICF Core Sets were developed. **The ICF Core Sets are short lists of problems relevant to most patients with a specific illness**.
The specific aim of this study is to explore and understand the perspective of individuals with [insert health condition].
This study does not represent any risk for you whatsoever. Your task within this study will be to take part in a focus group. A focus group is a special type of group in terms of purpose, size and composition. The purpose of our focus group is to listen and gather information in a group of 5 to 7 individuals with [insert health condition].

3.4 Process, if an individual refuses the participation in the study

During the information dialogue about nature and course of the study, you have to point out, that the patient has the possibility to refuse the participation in the study without any consequences at any time of the interview.

If the patient draws back her/his consent during the focus group/individual interview, please ask, whether the data, which will have been collected to that time point, can be used for the analysis. Please delete the audio data of the patient prior to transcription, if the patient does not agree to the use of her/his data. Please note in the documentation sheet that the patient refused the participation in the study.

3.5 Case Record Form

The Case Record Form (CRF) is necessary to document the verification of the inclusion criteria and the criteria that define the maximum variation in your sample. You assign an identification number to each participant prior to the data collection.

If required enter the CRF in the electronic database provided by the ICF Research Branch.

Note:

Please document the identification number with the respective name of the participant on a document sheet. This documentation sheet should be stored separately from the study material und must be eliminated after the study. In focus groups you also use these patient's identification numbers for the standardized coding scheme and the seating plan.

The CRF consists of following parts:

- Front page
- General instructions for filling in the CRF
- Inclusion criteria
- Disease specific data
- Socio-demographic data
- General health and functioning from the patient's perspective

- Health conditions, diagnosis & comorbidities
- Reasons for denial: only in case of denial

Front page

Please enter the date of the focus groups/interview and document the patient's identification number.

General instructions for filling in the CRF

Please read the instructions on page two of the case record form before starting to fill in.

Inclusion criteria

Please check whether the patient meets ALL inclusion criteria listed on this page.

Disease specific data

Date of diagnosis:

This variable specifies the date the health condition is diagnosed.

[insert other items]

Socio-demographic data

Date of birth:

This variable documents the patient's date of birth.

Gender:

This variable specifies the patient's gender.

Years of formal education:

This variable documents the total number of years of formal education (elementary/primary school, high/secondary school, apprenticeship, university).

Current marital status:

This variable documents the current marital status of the patient. Please check only one that is most applicable.

Living situation:

This variable documents the living situation of the patient (living alone, living with others).

Current occupation:

This variable documents the current occupational status. In patients, who are admitted to inpatient rehabilitation, the occupational status before the rehabilitation is documented.

General health and functioning from the patients' perspective

Please ask the patients to evaluate their own health as well as the extent of their own problems in functioning using a rating scale ranging from poor/complete problem to excellent/no problem, respectively, prior to the start of the focus group/individual interview session.

Health conditions, diagnosis & comorbidities

In the CRF a number of health condition groups are listed. For each health condition you can check one of two alternatives:

- Please mark the **first small box** with a cross, if an existing health condition can be assigned to this diagnosis group **but is no comorbidity**!
- Please mark the **second small box** with a cross, if an existing health condition can be assigned to this diagnosis group **but is a comorbidity**!

Note:

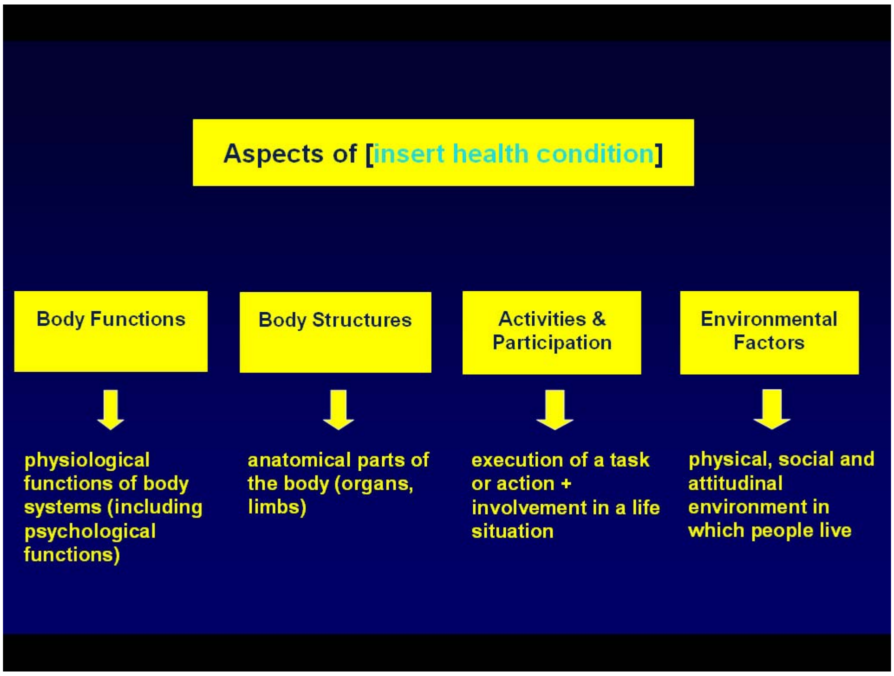
Comorbidity is defined as the presence of coexisting health conditions with reference to the main health condition for which the ICF Core Set validation is performed.

3.6 Topic guide

The same interview structure based on a list of open-ended questions including the four ICF Components *Body Structures, Body Functions, Activities and Participation,* and *Environmental Factors* is used for focus groups and individual interviews. This so-called topic guide is like an outline of issues to be pursued in the study (Figure 1 – 11).

While a hard copy of the topic guide will be sufficient in an individual interview session, the following Power Point presentation of the topic guide is adequate for a focus group session.

At the beginning of each focus group, the procedure of the session will be explained, and the concept of the ICF will be presented in lay terms to all participants.



Aspects of [insert health condition]

Body Functions

physiological functions of body systems (including psychological functions)

Body Structures

anatomical parts of the body (organs, limbs)

Activities & Participation

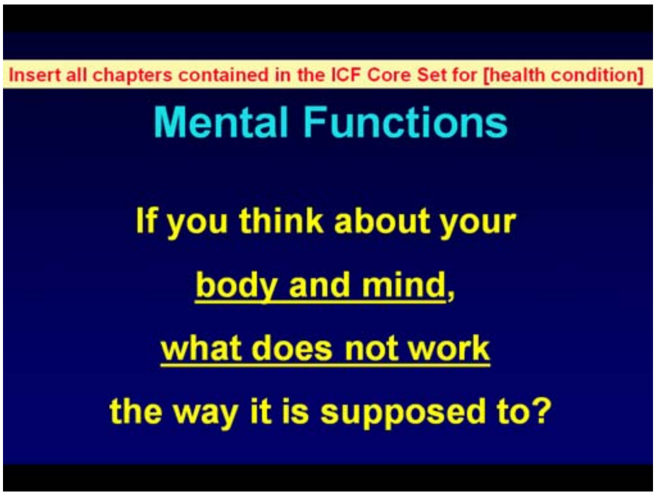
execution of a task or action + involvement in a life situation

Environmental Factors

physical, social and attitudinal environment in which people live

Figure 3: Explanation of the concept of the ICF

In the so-called ICF-based approach, each title of the ICF chapters from which categories are included in the Comprehensive ICF Core Set for [insert health condition] will be presented to the patients. For each of the presented chapters, open-ended questions on possible problems in each of the life areas that the ICF chapters represent will be used. Finally, the patients will be asked if they think anything is missing in *Body functions, Body structures, Activities & Participation or Environmental Factors*, respectively.

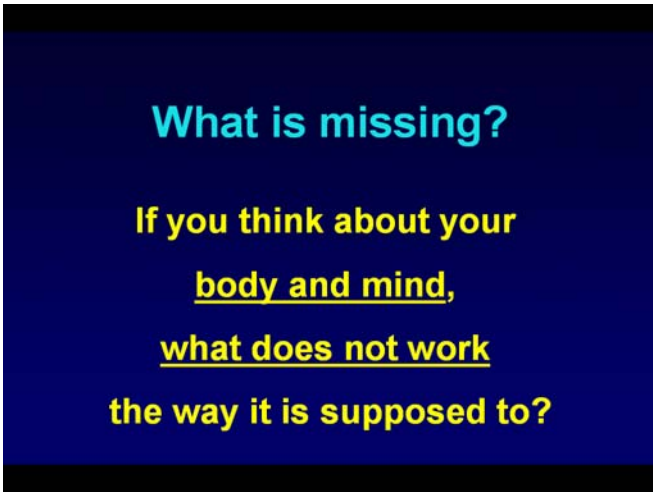


Insert all chapters contained in the ICF Core Set for [health condition]

Mental Functions

If you think about your
body and mind,
what does not work
the way it is supposed to?

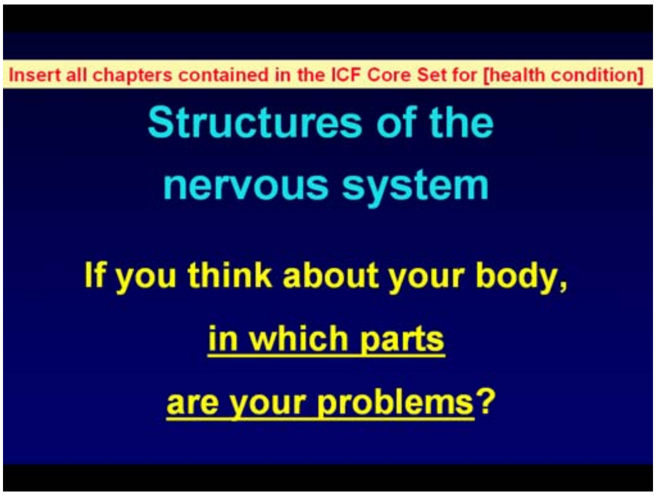
Figure 4: Question for Body Functions



What is missing?

If you think about your
body and mind,
what does not work
the way it is supposed to?

Figure 5: Question about missing aspects for Body Functions

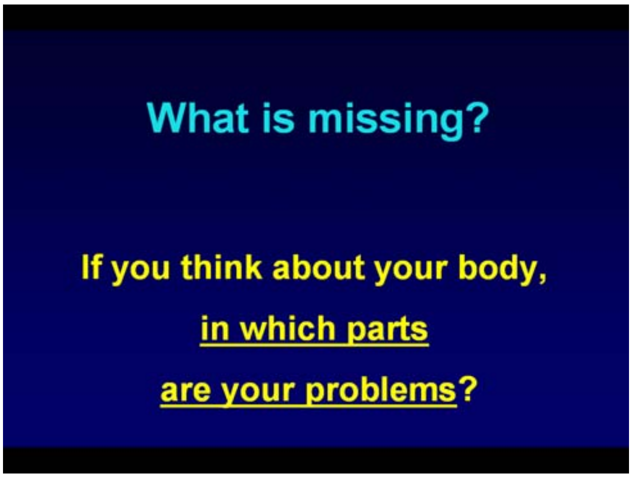


Insert all chapters contained in the ICF Core Set for [health condition]

Structures of the
nervous system

If you think about your body,
in which parts
are your problems?

Figure 6: Question for Body Structures



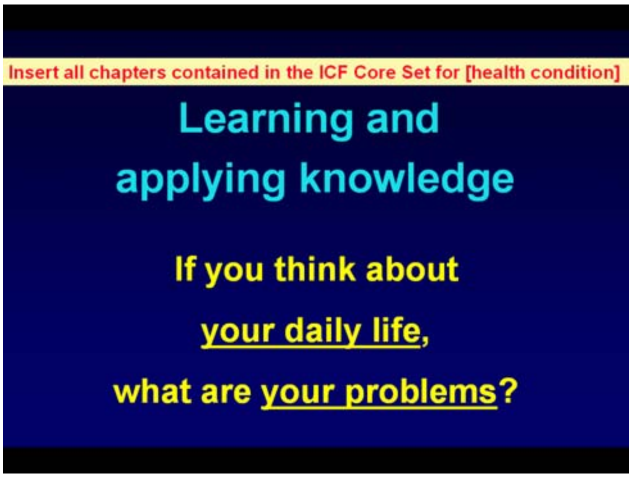
What is missing?

If you think about your body,

in which parts

are your problems?

Figure 7: *Question about missing aspects for Body Structures*



Insert all chapters contained in the ICF Core Set for [health condition]

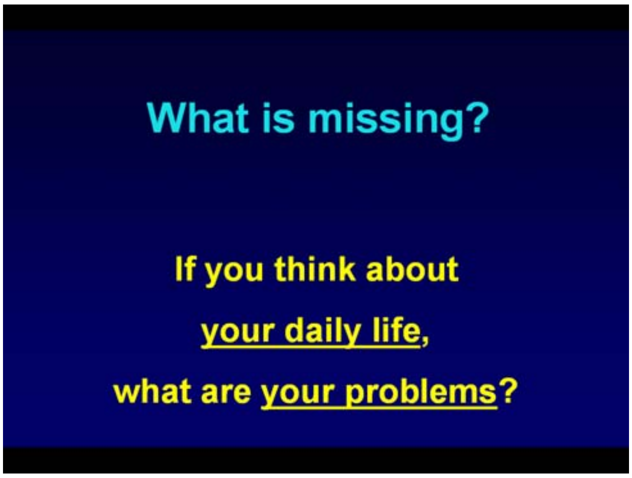
Learning and applying knowledge

If you think about

your daily life,

what are your problems?

Figure 8: *Question for Activities and Participation*



What is missing?

If you think about

your daily life,

what are your problems?

Figure 9: *Question about missing aspects for Activities and Participation*

Insert all chapters contained in the ICF Core Set for [health condition]

Products and technology

If you think about your environment and your living conditions,

what do you find helpful or supportive?

Figure 10: Question for Environmental Factors – facilitators

What is missing?

If you think about your environment and your living conditions,

what do you find helpful or supportive?

Figure 11: Question about missing aspects for Environmental Factors – facilitators

Insert all chapters contained in the ICF Core Set for [health condition]

Products and technology

If you think about your environment and your living conditions,

what barriers do you experience?

Figure 12: Question for Environmental Factors – barriers

What is missing?

If you think about your environment and your living conditions,

what barriers do you experience?

Figure 13: Question about missing aspects for Environmental Factors – barriers

At the end of each focus group, a summary of the main results will be given back to the group to enable the participants to verify and amend emergent issues.

3.7 Further study material

Please make sure that the following study material is available before you start with a focus group/an individual interview session.

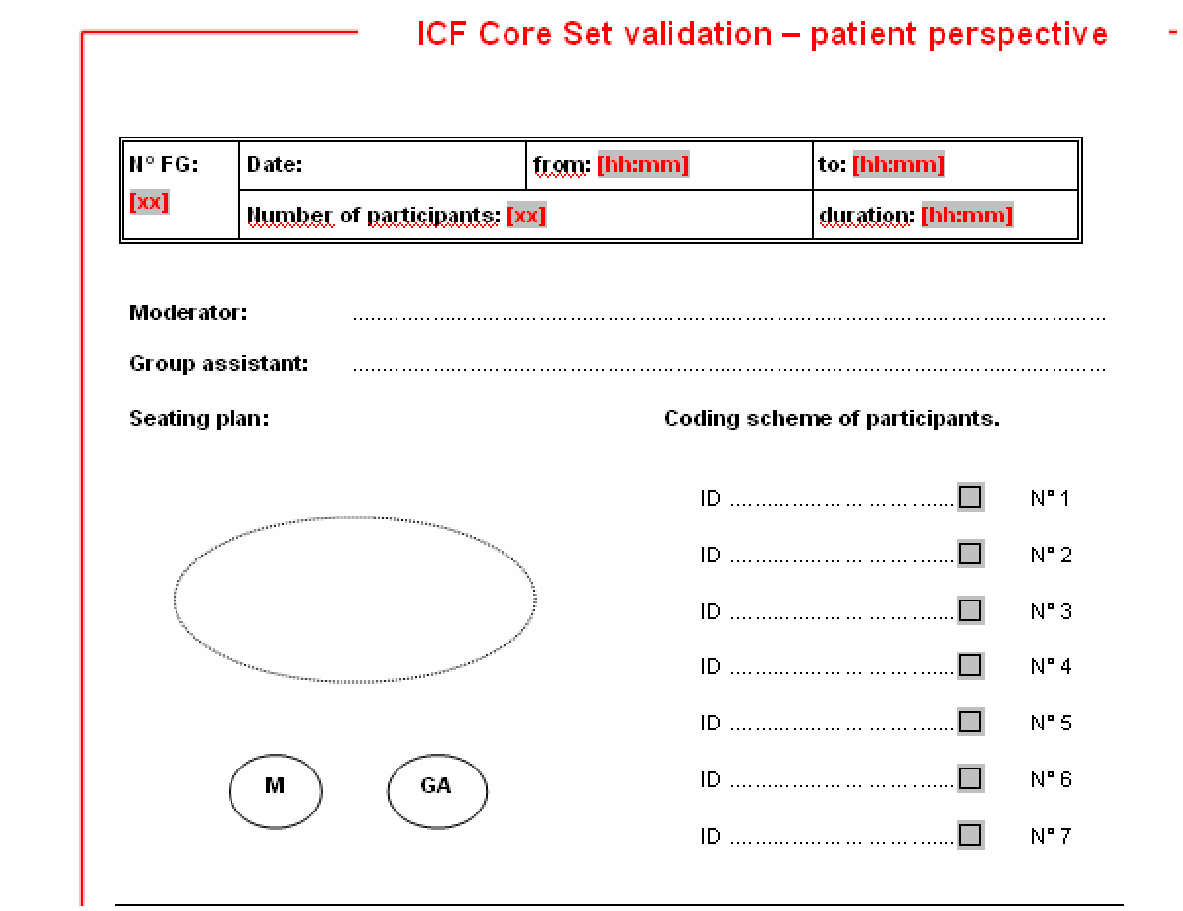
Research diary

Please use a research diary for both focus groups and individual interviews for following reasons:

- to record an audit trail of the data collection and analysis to increase the credibility and trustworthiness of the qualitative study
- to reflect the discussion e.g., why some topics were addressed by the participants while others were not addressed, what would you improve in the next discussion.

Seating plan for focus groups

A seating plan should be filled in prior to a focus group session.



ICF Core Set validation – patient perspective

N° FG: [xx]	**Date:**	**from:** [hh:mm]	**to:** [hh:mm]
	Number of participants: [xx]		**duration:** [hh:mm]

Moderator: ....

Group assistant: ....

Seating plan:

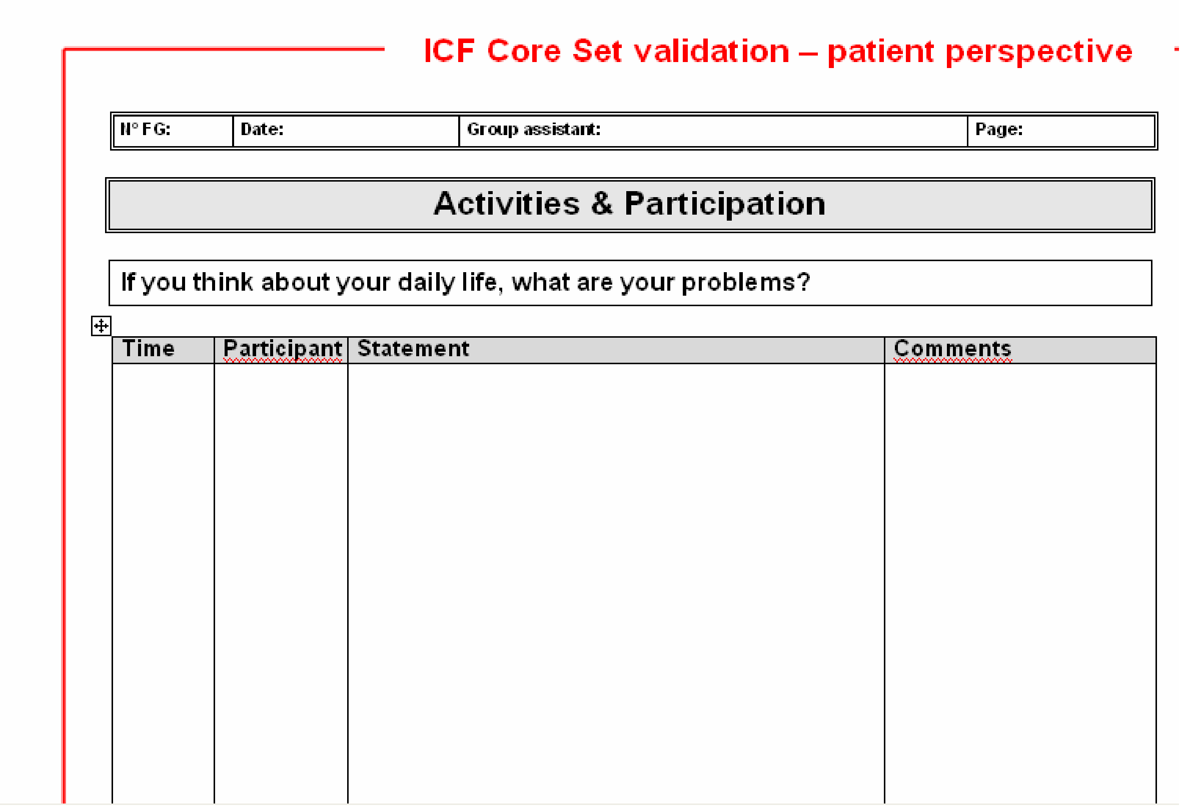
Coding scheme of participants.

ID	☐	N° 1
ID	☐	N° 2
ID	☐	N° 3
ID	☐	N° 4
ID	☐	N° 5
ID	☐	N° 6
ID	☐	N° 7

Form to take field notes

During the focus group session, group assistant(s) should record field notes (see template). Field notes may provide you with additional information useful for the data analysis. In the case of a break down of the recorder, the information recorded on the coding scheme will minimize your loss of data.

Template of the form to take field notes:



ICF Core Set validation – patient perspective

N° FG:	Date:	Group assistant:	Page:

Activities & Participation

If you think about your daily life, what are your problems?

Time	Participant	Statement	Comments

3.8 Room arrangement

Please take care for the room arrangement at least one day prior to the performance of the focus group and consider following aspects:

- From which place of the room will you moderate the focus group?
- Where should the projector screen be placed?
- Make sure that the video projector is not placed nearby the microphone. The noise produced by the video projector reduces the data quality significantly.
- The chairs should be placed in a semi-circle around the table
- The seating-accommodation should be fitted to the specific needs of the participants, e.g. for wheelchair users you have to remove the chairs prior to the focus group.
- The microphone should be placed in the centre of the table
- The group assisstants should be seated without attacting attention.
- The positioning of the voice recorders should allow group assistants to check the recording during the performance of the focus group.
- It is recommended to provide refreshments.

4 Procedures

4.1 Procedure of a focus group session

Introduction

In a first step, you introduce yourself and the group assistant(s). All participants introduce each other afterwards. Afterwards you explain the procedure of the session and the objective of the study:

> *On behalf of my colleagues I would like to welcome you to today's group discussion involving the study* [insert title of project]. *First, some information concerning the procedure: As mentioned in the letter, we will be recording the group discussion and for technical reasons we will be using two recorders. During the recording, my colleagues will be taking notes.*
>
> *You have agreed to have the group discussion be recorded by signing the declaration of consent. I would like to emphasize that for the transcription your name will be replaced by a code number. To protect your identity the tapes will be destroyed after the evaluation of the data. Do you have any questions so far?* (obtain nonverbal and verbal feedback) *OK! We will now start the recording.*

Turn on both recorders.

> *The group discussion will take approximately 120 minutes. About half way through, we will take a small break.*
>
> *Now, to the project itself: Receiving the diagnosis* [insert health condition] *has changed many things in your life. We are interested in obtaining information regarding changes in your functional health after receiving the diagnosis. Only you can give information regarding everyday problems or troubles having to do with* [insert health condition]. *But what are the problems and troubles that are especially relevant for those with* [insert health condition]*? To explore this question, we would like to consult you, since you have first-hand experience. You know best which obstacles and problems you have to face in your everyday life.*
>
> *I would like to begin with a short introduction of all participants. My name is…I am a….and work at the.... clinic. I will conduct and moderate the study* [insert title of the study]. *Please briefly introduce yourself* (introduction clockwise)*. Thank you for introducing yourselves. Now we can begin with the group discussion.*

Initiating the discussion

You initiate the discussion about problems associated with the respective health condition using the open-ended questions of the topic guide.

> *I will now ask you several questions concerning your health. Altogether, we will be discussing questions in the group. First, I will give you an overview of all aspects of the health condition so that you can see which topics we will be discussing. Here are the aspects.*

Read and explain all aspects (body functions, body structures, activities & participation, environmental factors) out loud.

> *Regarding the single aspects, I am interested in all factors concerning your health condition which are especially relevant for you. We will discuss each aspect one by one. We are interested in all of your personal experiences with your illness. It is important for you to know that there are no correct or incorrect opinions or views. Each of you should feel free to share the problems or troubles you experience. It is also important that within the group, you discuss your views and exchange opinions.*
>
> *Please respect the following rules of discussion:*
>
> - *Each opinion is important and of interest!*
> - *Please don‘t interrupt your partners!*
> - *Please don’t talk at the same time!*
> - *Please deal with the current subject!*
> - *Please talk about your own experiences!*
>
> *Let´s begin with the first question:*
>
> ***If you think about your body and mind, what does not work the way it is supposed to?***
>
> *Here we are interested in all factors regarding your health condition which you regard as being especially relevant.*
>
> *You have mentioned several factors regarding the question of what doesn’t function on the bodily level. For example….Is there anything you would like to add regarding this question? Now to the next question: …..*

Closing

Finally, you thank all participants for their engagement in the study.

> *I would like to take this opportunity to thank you for your participation in the group discussion. We were able to collect and discuss several interesting aspects which are relevant to you as a patient with a health condition. Thank you!*

Debriefing

After each focus group a debriefing with your group assistants should take place to review the focus group process.

Procedure of an individual interview session

Introduction

In a first step, you introduce yourself to the patient and explain the procedure of the interview session and the objective of the study.

Initiating the discussion

The individual interview is performed based on the printed version of the topic guide. A hard copy of the topic guide supports you during the interview session.

Closing

Finally, you thank her/him for her/his participation in the study.

Self-reflection

After each individual interview you should review the course of the individual interview by yourself and take notes in your research diary.

5 Transcription of audiodata

Each individual interview/focus group is digitally recorded and transcribed verbatim. In this case “verbatim” is meant literally. For example, the order of the phrases or single words within a phrase should not be changed. Nonverbal sounds should be documented by codes which are defined prior to the transcription. For example, babble of voices is documented by “(babel)” or laughter by “(laughing”).

Make sure that the names of the participants are replaced by the patient’s identification numbers.

Please use a heard break '¶ only at the end and not within a paragraph.
The moderator performed the focus group/individual interview should do the quality check of the transcription, i.e. s/he read through the text while listening to the audio data.

You can download professional audio player software designed to assist the transcription of audio recordings cost-free from the web such as “Express Scribe” or “f4” (www.nch.com.au/scribe). These computer transcriber applications feature variable speed wave playback, foot pedal operation, file management and more.

Express Scribe Transcription Playback Software

Transcription Audio Player Software

Express Scribe is professional audio player software designed to assist the transcription of audio recordings. It is installed on the typist's computer and controlled using the keyboard (with 'hot' keys) and / or can be used with a transcription pedal. This computer transcriber application features variable speed wave playback, foot pedal operation, file management and more. This program is free.

The full features list of Express Scribe transcription playback software follows but a quick way to test its suitability is to simply download and install it. You don't need to purchase anything and it only takes a couple of minutes to complete downloading and installation. (Click here to install Express Scribe for Windows).

Express Scribe is now free in the hope that because you will like it you will recommend our dictation recorder applications including *Express Dictate* Professional Dictation Recorder, *FastFox* Typing Expander Utility, *TexTally* Word, Line and Character Counter, *DialDictate* Phone Dictation Server, *Pocket Dictate* Dictation Recorder for Pocket PC or *Palm Dictate* Recorder for Palm OS. For all full list of all our dictation related software please visit our Dictation Software page.

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- Introduction
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- System Requirements
- Screenshots
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  - - exe file
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- Foot Pedal Controls
- Manual
- Introduction Tutorial
- Brochure
- Developers SDK
- Questions (FAQs)
- Technical Support
- Discussion Forum

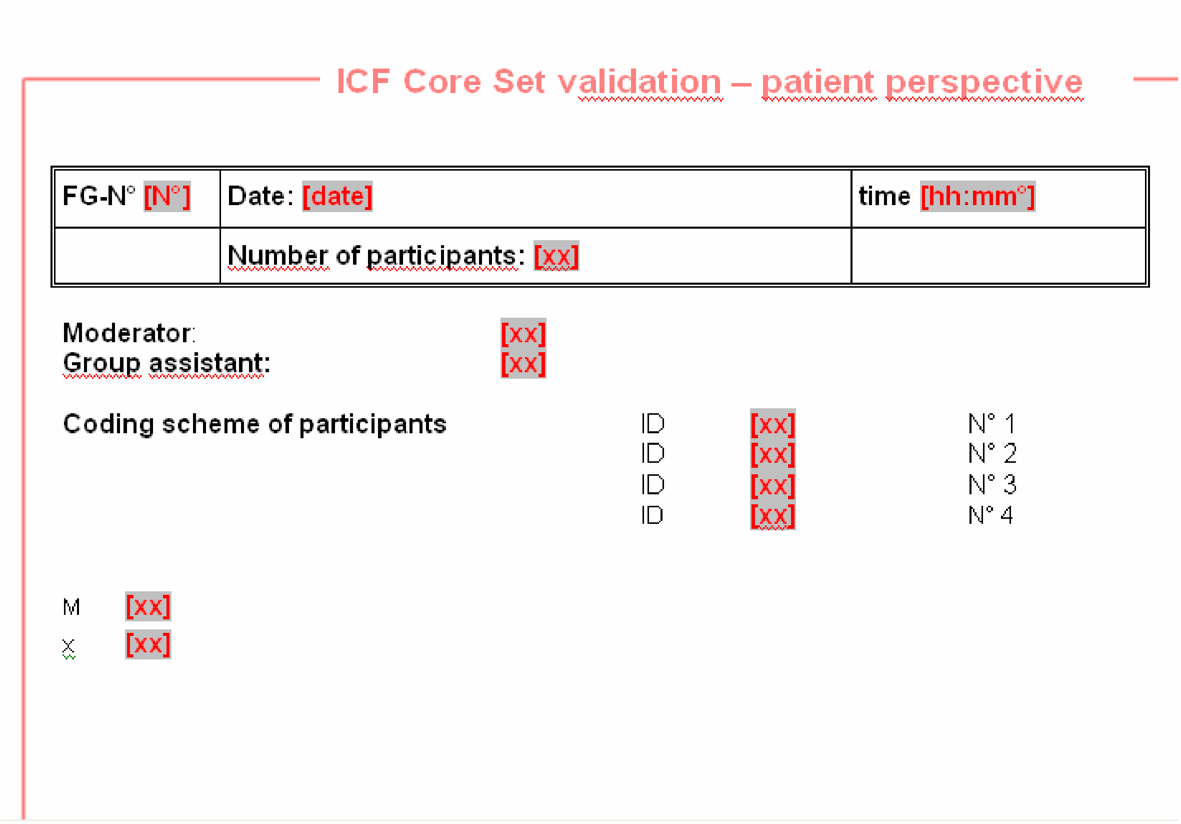
Languages
- en Español
- auf Deutsch
- 简体中文

Related Software
- Express Dictate
- Web Dictate

Features

- Ability to play most audio file formats (including encrypted dictation files).
- Variable speed (constant pitch) playback.
- Supports many professional foot pedals which connect to the game, serial or USB port to control playback. More info...
- Uses system wide 'hot' keys so you can control playback when using other software (eg. Microsoft Word).
- Ability to dock portable recorders (both analog and digital portables) to load recordings.
- Works with Microsoft Word and all major word-processor applications.
- Automatically receives and loads files by internet (FTP), email or over a local computer

Template of the transcription sheet:



ICF Core Set validation – patient perspective

FG-N° [N°]	Date: [date]	time [hh:mm°]
	Number of participants: [xx]	

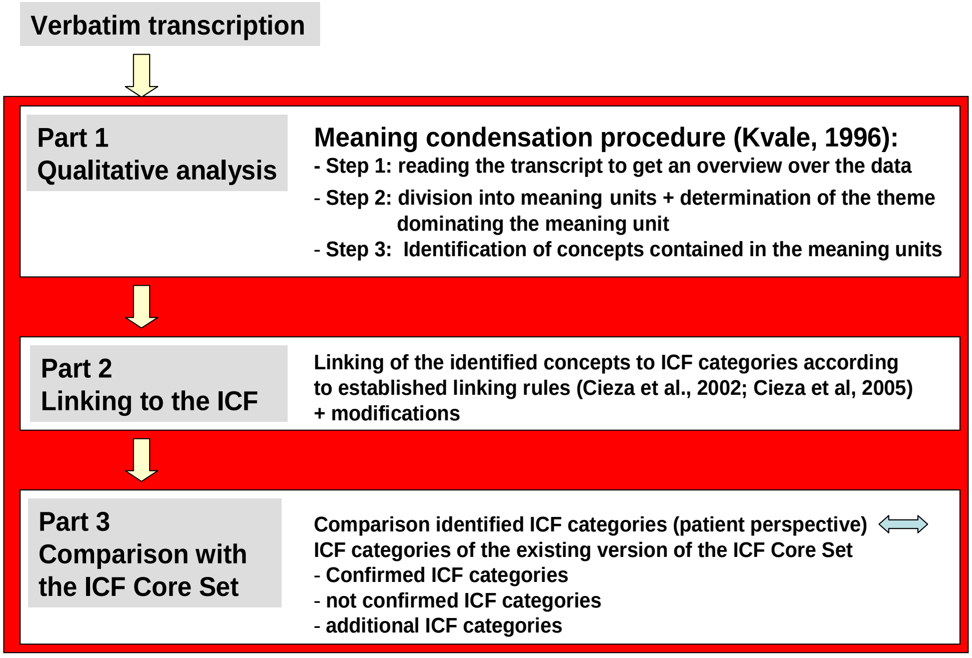
Moderator: [xx]
Group assistant: [xx]

Coding scheme of participants	ID	[xx]	N° 1
	ID	[xx]	N° 2
	ID	[xx]	N° 3
	ID	[xx]	N° 4

M [xx]
x [xx]

6 Procedure of the data analysis

The data analysis of the transcripts of the focus groups/ individual interviews consists of the following parts (see Figure 15):



Meaning condensation procedure (Kvale, 1996):
- Step 1: reading the transcript to get an overview over the data
- Step 2: division into meaning units + determination of the theme dominating the meaning unit
- Step 3: Identification of concepts contained in the meaning units

Linking of the identified concepts to ICF categories according to established linking rules (Cieza et al., 2002; Cieza et al, 2005) + modifications

Comparison identified ICF categories (patient perspective) ⟺ ICF categories of the existing version of the ICF Core Set
- Confirmed ICF categories
- not confirmed ICF categories
- additional ICF categories

Figure 15: Data analysis for the validation of ICF Core Sets

6.1 Qualitative data analysis to identify meaningful concepts

The qualitative data analysis will follow the ‘meaning condensation procedure’ in a three-step process according to specifications listed in the *Rules for the identification of meaningful concepts*.

Step 1 The transcripts of the focus groups/interviews will be read through to get an overview over the collected data.

Step 2 The data will be divided into meaning units and the theme that dominates a meaning unit will be determined. A meaning unit will be defined as a specific unit of text either a few words or a few sentences with a common theme. Therefore, a meaning unit division does not follow linguistic grammatical rules. Rather, the text is divided where the researcher discerned a shift in meaning.

Step 3 The concepts contained in the meaning units will be identified. A meaning unit can contain more than one concept.

6.2 Linking the identified concepts to the ICF

The identified meaningful concepts will be linked to the ICF according to the linking rules of Cieza and colleagues and the specifications listed in the *Rules for the linking of identified meaningful concepts to the ICF*. According to the linking rules, health professionals trained in the ICF are advised to link each concept to the ICF category representing this concept most precisely. One concept could be linked to one or more ICF categories, depending on the number of themes contained in the concept.

6.3 Comparison with the Comprehensive ICF Core Set

The linked ICF categories will be compared with the existing version of the Comprehensive ICF Core Set of the specific health condition. The comparison will be done with the ICF categories of the 2nd level. The following three outcomes will be documented:

- confirmed ICF categories (2nd level) of the Comprehensive ICF Core Set:
  An ICF category of the Comprehensive ICF Core Set is regarded as confirmed, if the identical or a similar category emerged from the focus groups/interviews. Since the ICF categories are arranged in a hierarchical code system, the 2nd-level categories of the Comprehensive ICF Core Set are considered confirmed when the corresponding 3rd- or 4th-level category of which they are a member had been named by the patients.
- not confirmed ICF categories of the Comprehensive ICF Core Set
- additional ICF categories not contained in the existing version of the Comprehensive ICF Core Set

6.4 Identification of saturation

After each focus group and individual interview, respectively, the linked ICF categories which are nominated for the first time are added to a list of all ICF categories nominated until to this point in time. Saturation is defined as the point during data collection and analysis when the linking of the concepts of two consecutive focus groups reveals no additional ICF 2nd-level categories of the Comprehensive ICF Core Set for [insert health condition] with respect to previous focus groups/individual interviews. According to a study in patients with rheumatoid arthritis, approximately six focus groups and 12 individual interviews will be carried out at each site before saturation will be reached, respectively.

Note:

ICF categories are presented at the 2nd-level. If a concept has been linked to a 3rd- or 4th-level ICF category, the corresponding 2nd-level category is reported. This is appropriate, because the lower-level categories share the attributes of the higher-level category.

6.5 Accuracy and rigour of data analysis

To ensure the accuracy and rigour of data analysis the following two strategies will be conducted:

Multiple coding

According to the purpose of multiple coding the *Qualitative analysis* (Part 1) and the *Linking to the ICF* (Part 2) of the first focus group/the first and second individual interview will be done by two health professionals who are experts in the ICF and in the application of the linking rules to achieve agreement concerning the implementation of the linking rules in a specific health condition. Agreements, specifications and special cases of the linking rules occurred when applying the rules for the identification of concepts and the linking process will be documented. The data analysis of the two health professionals and the comparison of their data analysis follow a specific procedure containing 4 steps:

Step 1 **Identification of all meaningful concepts** (= Part 1: *Qualitative analysis*) within each statement of the patients by two health professionals independently. If a single statement encompasses different meaningful concepts, all concepts should be documented.

Step 2 **Comparison** of the two versions **of the identified meaningful concepts**. Disagreement will be resolved by structured discussion and informed decision of a third expert to create a final agreed-on version of the meaningful concepts.

Step 3 **Linking** of the final agreed-on version of meaningful concepts (= Part 2: *Linking to the ICF*) to the most specific ICF categories by the two health professionals independently according to the linking rules of Cieza and colleagues.

Step 4 **Comparison** of the two versions of the **linking**. Disagreement will be resolved by structured discussion and informed decision of a third expert to create a final agreed-on version of the linked ICF categories.

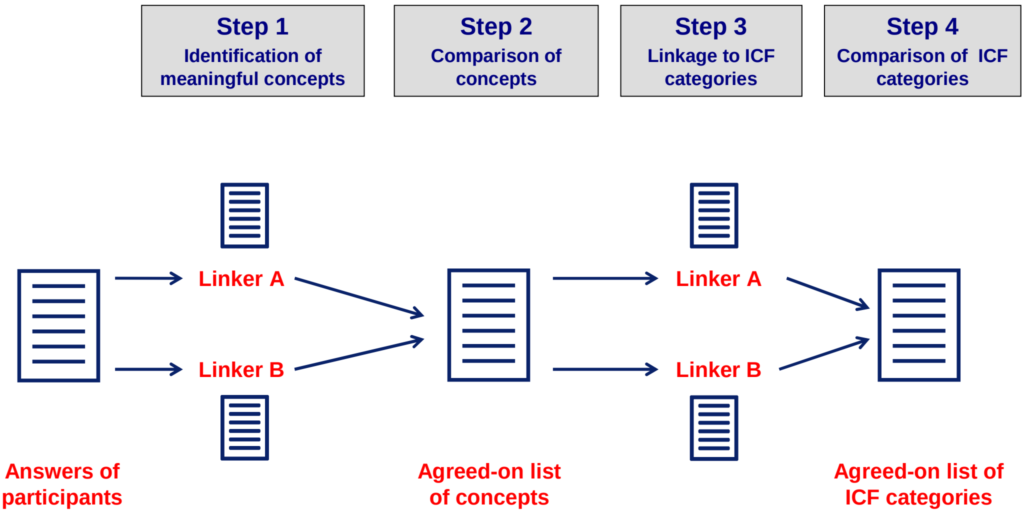


Figure 14: ***Data analysis: multiple coding***

Peer review

Further qualitative data analysis and linking (after completing the multiple coding of the first focus group) will be performed by one health professional. To ensure the accuracy (after the exclusion of data of the first focus group) random samples of 15% of the transcribed text and 15% of the identified concepts (of the first health professional) will be analyzed and linked additionally by the second health professional as a peer review, without creating any consensus between the two researchers.

The degree of agreement between the two health professionals regarding the identification of concepts and the linked ICF categories will be calculated by kappa statistic with 95%-bootstrapped confidence intervals, respectively. The values of the kappa coefficient generally range from 0 to 1, whereas 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance alone.

Contact

For further information regarding the performance of focus groups and individual interviews please do not hesitate to contact:

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Rules for the identification of meaningful concepts

Rule 1 A meaningful concept is a specific unit of text – either a few words or a few sentences – with a common theme. Therefore, a concept division does not follow linguistic grammatical rules. The text is divided where the researcher discerned a shift in meaning. **The basic principle for identifying concepts is to understand the meaning of the text.** To ensure clarity, further elucidations of the concepts will be given in brackets after the identified concept.

Example

transcription		identified concepts
1	*I used to go to sports very often. Now I can't anymore. I even had to quit swimming.*	- restriction in sports - to quit swimming
2	*Exactly! I also had to quit swimming.*	

Rule 2 **The interval of time** to which the text refers is not considered as a meaningful concept on its own.

Example

transcription		identified concepts
1	*The pain lasts over two hours*	pain ~~pain lasts over two hours~~

Rule 3 Details regarding the **extent of a determined problem is** to be considered as **part of the meaningful concept.**

Example

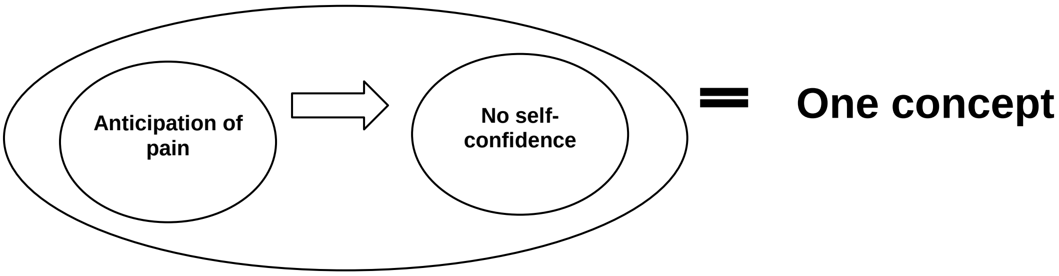
transcription		identified concepts
5	*I have severe pain in my knees*	pain in knees

Rule 4 All different single experienced **problems listed** by an individual are to be considered as **independent meaningful concepts**.

Example

transcription		identified concepts
1	*I have serious difficulties getting dressed, putting on my shoes and grooming myself.*	- difficulties getting dressed - difficulties putting on one’s shoes - difficulties grooming oneself ~~serious difficulties getting dressed, putting on shoes and grooming oneself~~

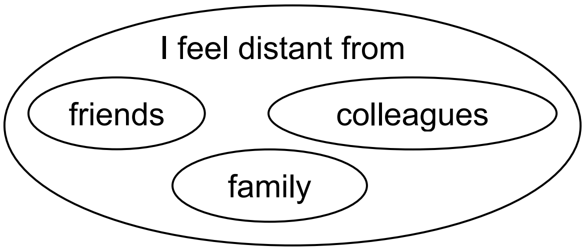
Rule 5 When the statement of a participant contains a **cause-effect relationship one concept is identified** containing the cause and the effect. The identified concept is usually linked **to two categories** (representing the cause and the effect, respectively):



Example

transcription		identified concepts
2	*I have no self confidence because I anticipate the pain*	having no self-confidence because of the anticipation of pain ~~- having no self-confidence~~ ~~- anticipation of pain~~

Rule 6 **Specifications** within a concept **will not be** considered as **independent concepts.**



= **One concept**
because the specifications are interchangeable

Example

transcription		identified concepts
3	*I distant from my friends and colleagues*	- I feel distant from my friends - I feel distant from my colleagues ~~- to feel distant~~ ~~- friends~~ ~~- colleagues~~

Rule 7 **Statements** of participants about problems or environmental factors, which are **not based on own experiences**, are **not identified as concepts**.

Example

transcription		identified concepts
1	*There is a device for putting on socks, but I don't need it yet. So far, I haven't had any problems putting on my shoes*	∅ ~~- device for putting on socks~~ ~~- problems putting on shoes~~
2	*There is a woman in my self-help group who complains about pain in her ankles.*	∅ ~~- self-help group~~ ~~- pain in ankle~~
1	*I once read in a magazine that there is a relation between rheumatism and sclerodermia. There the connective tissue is affected.*	∅ ~~- relation between rheumatism and sclerodermia~~ ~~- connective tissue affected~~

Rule 8 **The absence of a problem is not identified as a meaningful concept.**

Example

transcription		identified concepts
1	*[Do you also have ankle pain?]*	∅
2	*No, I've never had it.*	~~- pain in the ankles~~

Rule 9 Statements related to **problems associated to health conditions other than the index health condition will not be identified as concepts**.

Example

transcription		identified concepts
4	*I also have diabetes and so I have problems with my eyes.*	diabetes ~~- diabetes~~ ~~- problems with eyes~~

Rules for the linking of identified concepts to the ICF

Rule 1 Before you link meaningful concepts to the ICF categories, you should have acquired **good knowledge of the conceptual and taxonomical fundaments of the ICF**, as well as of the chapters, domains, and categories of the detailed classification, including definitions.

Rule 2 Each meaningful concepts of an answer is linked to the **most precise ICF category**.

Example

transcription		identified concepts	ICF categories	comment
3	…	problems when walking longer than two kilometers	d4501 Walking long distances ~~d450 Walking~~	
1	…	pain in knees	b28016 pain in joints ~~- b280 pain~~ ~~- s75011 knee joint~~	
2	…	fatigue[2]	- b1300 energy level - b4552 fatiguability	

Special case for rule 2

If a meaningful concept refers to an **Environmental Factor**, the additional information whether the linked Environmental Factor represents **a facilitator (+) or a barrier (-) is documented** in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
1	…	support from parents	e310 immediate family	+

---

[2] If aspects of fatigue are reported, the meaningful concept is linked to *exercise tolerance functions* (fatiguability: b4552) and *energy and drive functions* (energy level: b1300), respectively. If participants have named explicitly physical aspects of fatigue the category b4552 (fatiguability) is linked.

Rule 3 **Do not use** the so-called **“other specified”** ICF categories, which are uniquely identified by the final code 8. If the content of a meaningful concept is not explicitly named in the corresponding ICF category, the additional information not explicitly named in the ICF is documented in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
1	…	problems walking down stairs	d4551 climbing ~~d4558 moving around, other specified~~	walking down stairs

Rule 4 **Do not use** the so-called **“unspecified”** ICF categories, which are uniquely identified by the final code 9, but use the lower level category which is less specific.

Example

transcription		identified concepts	ICF categories	comment
1	…	problems in relationship with others	d7 Interpersonal interact. & relationships ~~d799 Interpersonal interac. & relationships, unspecified~~	

Rule 5 If the information provided by the meaningful concept is **not sufficient** for making a decision about the most precise ICF category it should be linked to, the meaningful concept is assigned **not definable (nd)**. The meaningful concept is documented in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
4	…	having strange feelings when being alone	nd	strange feelings when being alone

Special cases for rule 5

a) Meaningful concepts referring to health, physical health or mental (emotional) health in general, are assigned **nd-gh** (not definable-general health)**, nd-ph** (not definable-physical health) **or nd-mh** (not definable-mental health), respectively. The meaningful concept is documented in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
1	…	Worsening of health	nd - gh	Worsening of health

b) Meaningful concepts referring to quality of life in general are assigned **not definable-quality of life (nd-qol)**. The meaningful concept is documented in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
3	…	Worsening of quality of life	nd - qol	Worsening of qol

Rule 6 If the meaningful concept is not contained in the ICF, but is clearly a personal factor as defined in the ICF, the meaningful concept will be assigned to **personal factor (pf).** The additional information whether the linked Personal Factor **influences functioning in a positive (+) or negative (-) way is documented** in the column “comment”. The wording of the personal factor is documented in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
3	…	cheerful person	pf	cheerful person

Definition of Personal factors:

Personal factors are the factors which define the person as a unique individual and are not part of her/his condition. To decide whether a determined meaningful concept is a personal factor or not, it is helpful to be aware that from the perspective of the ICF personal factors cannot be impaired, limited or restricted. They can, however, have a positive or negative impact on disability and functioning, i.e. on (impaired) body functions and structures, on (limited) activities, and (restricted) participation. Therefore, if you are not sure whether a meaningful concept is a personal factor or not, ask the following question: Can the [*meaningful concept*] be impaired, restricted or limited? If the answer is no, the meaningful concept is probably a personal factor.

Rule 7 If the meaningful concept is not contained in the ICF and is clearly not a personal factor, this meaningful concept is assigned **concept not covered by the ICF (nc)**. The meaningful concept is documented in the column "comment".

Example

transcription		identified concepts	ICF categories	comment
3	…	loss of leisure time due to the consultations	nc	loss of leisure time due to consultations
5	…	catheterizing to stimulate [3]	nc	catheterizing
2	…	specific intervention for bladder management [3]	nc	intervention for bladder management
5	…	to need more time for activities	nc	to need more time for activities

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[3] Interventions are not covered by the ICF and linked to nc.

Rule 8 If the **meaningful concept** refers to a **diagnosis or a health condition**, the meaningful concept will be assigned **hc** (health condition). The diagnosis or health condition is documented in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
3	…	diabetes	hc	diabetes

Rule 9 If the meaningful concept refers to **satisfaction with a health area or circumstance**, this meaningful concept is assigned to the corresponding ICF category. The **additional information “s” (satisfaction) is documented** in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
3	…	satisfaction with work situation	d850 Remunerative employment	s

Rule 10 If the meaningful concept refers to the **side effects of the medication**, the meaningful concept will be assigned to **side effect (se)**. The additional information “se” is documented in the column “comment”.

Example

transcription		identified concepts	ICF categories	comment
3	…	digestive problems due to medication	- b515 digestive funct. - e1101 drugs	se -

Curriculum Vitae

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