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Validation of the ICF Core Set for Obstructive Pulmonary Diseases from the Perspective of Physicians: An International Delphi Survey

#### Dissertation

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### 1 German abstract (Deutsche Zusammenfassung)

Das "Umfassende ICF Core Set für obstruktive Lungenerkrankungen (OPD)" wurde für die klinische Anwendung der Internationalen Klassifikation von Funktionsfähigkeit, Behinderung und Gesundheit (ICF) entwickelt und beinhaltet das typische Spektrum von Problemen der Funktionsfähigkeit bei Patienten mit obstruktiver Lungenerkrankung.

Ziel dieser Studie war es, das "Umfassende Core Set für obstruktive Lungenerkrankungen" aus der Perspektive von Ärzten zu validieren.

Erfahrene Ärzte wurden zu Problemen, Ressourcen und Umweltfaktoren befragt, welche bei der ärztlichen Behandlung von Patienten mit obstruktiven Lungenerkrankungen eine Rolle spielen. Die Befragung wurde in drei Runden per elektronischer Post (E-Mail) durchgeführt. Dabei wurde die sogenannte Delphi-Methode angewandt.

Die Antworten wurden nach festgelegten Regeln von zwei darin erfahrenen und unabhängig voneinander arbeitenden Mitarbeiterinnen in ICF-Begriffe übertragen. Der Grad der Übereinstimmung dieser Ergebnisse wurde durch Berechnung des Kappa-Koeffizienten überprüft.

Insgesamt 76 Ärzte aus 44 Ländern nannten eine Gesamtzahl von 1330 Antworten, die dann 148 verschiedenen ICF-Kategorien zugeordnet wurden. 40 dieser Antworten wurden der noch nicht in der ICF enthaltenen Komponente der Personenbezogenen Faktoren zugeordnet oder als sogenannte Gesundheitszustände eingeordnet, 17 Antworten waren nicht durch ICF-Kategorien abgedeckt. Im Gesamten waren 66% der ICF-Kategorien, denen die Antworten der Teilnehmer zugeordnet worden waren, im ICF Core Set für obstruktive Lungenerkrankungen enthalten.

Einige Antworten, die der Komponente Körperfunktionen zugeordnet wurden, und noch nicht im ICF Core Set für obstruktive Lungenerkrankungen enthalten sind, müssen noch weiter untersucht werden.

#### 2 Abstract

The "Comprehensive ICF Core Set for Obstructive Pulmonary Diseases (OPD)" is an application of the International Classification of Functioning, Disability and Health (ICF) and represents the typical spectrum of problems in functioning of patients with OPD. The objective of this study was to validate this ICF Core Set from the perspective of physicians.

Physicians experienced in OPD treatment were asked about the patients' problems treated by physicians in patients with OPD in a three-round survey using the Delphi technique. Responses were linked to the ICF.

76 physicians in 44 countries gave a total of 1330 responses that were linked to 148 different ICF categories. 40 responses were linked to the not yet developed ICF component Personal Factors or were assigned health conditions and 17 were not covered by ICF. Overall, 66% of the ICF categories linked to the responses of the physicians were represented by the Comprehensive ICF Core Set for OPD.

Several responses assigned to the component Body Functions were identified which are not included and need to be investigated further.

#### 3 Introduction

#### 3.1 Clinical relevance and treatment of obstructive pulmonary diseases

Obstructive pulmonary diseases (OPD), in particular chronic OPD (COPD) and asthma, are characterized by obstructive airflow limitation and inflammatory alterations of the respiratory tract (Guerra, 2005; Global Initiative for Asthma, 2006).

#### 3.1.1 COPD

Chronic obstructive pulmonary disease (COPD) is considered to be a decisive reason for chronic morbidity worldwide, and a future increase of COPD in developed countries as well as in the developing world is expected (Murray et Lopez 1997; Pauwels et al., 2001). Since there have been different and vague definitions of COPD in the past, it is difficult to obtain data concerning the worldwide prevalence of COPD. Also, it is assumed that there is a significant underreporting of COPD because of

underdiagnosis and underrecognition (Global Initiative for Chronic Obstructive Lung Disease (GOLD), Updated 2008).

According to the Global Burden of Disease Study (Murray et Lopez, 1997), the prevalence of COPD in 1990 was calculated to be 9.34/1000 in men and 7.33/1000 in women. In general, COPD prevalence is directly connected to the prevalence of tobacco smoking (GOLD, Updated 2008). Based on data from prevalence surveys conducted in several countries, it is estimated that, according to GOLD, up to approximately 25% of adults at the age of 40 years and above may come under COPD Stage I: Mild COPD and higher (for COPD stages, see explanation stated below). There is also evidence that the prevalence of COPD is considerably higher in smokers and ex-smokers, adults over 40 years and men than in nonsmokers, adults under 40 and women (Halbert et al., 2006; Fukuchi et al., 2004).

Characteristic features of chronic OPD are slowly progressive symptoms, namely chronic cough, sputum production and dyspnea, especially on exertion. Also, patients often have been exposed to risk factors like tobacco smoke, occupational dusts or chemicals or smoke from cooking and heating at home. The airflow limitation of patients with chronic OPD remains irreversible to a large extent (Pauwels et al., 2001). The spirometric classification of severity according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD, Updated 2008) comprehends four stages of COPD depending on post-bronchodilator FEV<sub>1</sub>:

Stage I (Mild):  $FEV_1 / FVC < 0.70$ 

FEV<sub>1</sub> ≥ 80% predicted

Stage II (Moderate):  $FEV_1 / FVC < 0.70$ 

 $50\% \le FEV_1 < 80\%$  predicted

Stage III (Severe):  $FEV_1 / FVC < 0.70$ 

 $30\% \le FEV_1 < 50\%$  predicted

Stage IV (Very Severe):  $FEV_1 / FVC < 0.70$ 

FEV<sub>1</sub> <30% predicted or

FEV<sub>1</sub> <50% predicted plus chronic

respiratory failure

FEV<sub>1</sub>: forced expiratory volume in one second; FVC: forced vital capacity.

At Stage I (mild COPD), which is characterized by mild airflow limitiation (FEV<sub>1</sub> / FVC < 0.70; FEV<sub>1</sub>  $\geq$  80% predicted), the typical symptoms of chronic cough and production of sputum may occur, but are not necessarily present.

At Stage II (moderate COPD), the airflow limitation is proceeding (FEV<sub>1</sub> / FVC < 0.70;  $50\% \le \text{FEV}_1 < 80\%$  predicted). Dyspnea may occur, especially on exertion, as well as cough and sputum production.

The stage of severe COPD (Stage III) is characterized by continuing aggravation of airflow limitation (FEV<sub>1</sub> / FVC < 0.70;  $30\% \le \text{FEV}_1 < 50\%$  predicted). Dyspnea, reduced exercise capacity, tiredness and recurring exacerbations appear at that stage.

At Stage IV (very severe COPD), the airflow is severely limited (FEV $_1$  / FVC < 0.70; FEV $_1$  <30% predicted or FEV $_1$  <50% predicted plus chronic respiratory failure). Complications like right heart failure (cor pulmonale) may occur as a consequence of respiratory failure, and exacerbations may be perilous. Patients with a Stage IV COPD are afflicted with a constricted quality of life (GOLD, Updated 2008).

For the management of COPD, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) has developed a four components plan (GOLD, Updated 2008):

- Assess and Monitor Disease
- Reduce Risk Factors
- Manage Stable COPD
- Manage Exacerbations

An early identification of COPD patients is important. Any patient with symptoms of chronic and / or productive cough, shortness of breath, and / or exposure to risk factors should be considered as potential COPD patient. Therefore, access to spirometry, which is the gold standard for COPD diagnosis and assessment, is needed (GOLD, Updated 2008). Since COPD is a progressive disease, consequent monitoring is important.

The reduction of risk factors, especially smoking cessation, is a major part of COPD management. Since smoking cessation is "the single most effective (...) intervention in most people to reduce the risk of developing COPD and stop its progression" (GOLD, Updated 2008), helping patients to quit smoking should be an essential effort of health care. Moreover, risk factors like occupational dusts or other substances in the workplace as

well as indoor and outdoor air pollution should be considered in COPD management (GOLD, Updated 2008).

For the management of stable COPD, pharmacotherapy is used to control and reduce symptoms. The long-term decrease of lung function, however, can not be limited by medication (Anthonisen et al., 1994). Bronchodilators - mainly ß2-agonists, anticholinergics and methylxanthines - play a central in COPD management. According to GOLD, bronchodilators are prescribed on an as-needed basis for all COPD Stages. For Stages II-IV, a regular treatment with one or more long-acting bronchodilators should be added to prevent or reduce symptoms. For symptomatic patients at COPD Stages III and IV and patients with repeated exacerbations. regular treatment with inhaled glucocorticosteroids in addition to bronchodilator treatment recommended. At COPD Stage IV, a long term oxygen therapy for patients with chronic respiratory failure should be amended. Furthermore, surgical treatments like bullectomy, lung volume reduction surgery and lung transplantation are to be considered at the Stage of Very Severe COPD (GOLD, Updated 2008).

Further recommended options for the management of stable COPD are influenza vaccination for patients at all stages of COPD (Menon, Gurnani et Aggarwal, 2008; Wongsurakiat et al., 2004) and pneumococcal polysaccharide vaccines for patients 65 years and older and patients younger than age 65 with an  $FEV_1 < 40\%$  to prevent acute respiratory illness (Alfageme et al., 2006). Physical exercise also provides a benefit for all patients with COPD (Berry et al., 1999).

Patients' education about risk factors, smoking cessation and coping strategies is another very important issue in COPD management.

Exacerbations of COPD are defined by an aggravation of COPD symptoms beyond usual day-to-day variations, requiring a change in regular medication (Rodriguez-Roisin, 2000). COPD exacerbations are effectively treated by inhaled bronchodilators and oral glucocorticosteroids. Some patients may also benefit from antibiotics when there are clinical signs of airway infection (GOLD, Updated 2008). Moreover, it has been provided evidence by several studies that noninvasive intermittent mechanical ventilation (NIV) improves respiratory acidosis and decreases respiratory rate, intubation rate, dyspnea severity, length of hospital stay and mortality (Brochard et al., 1995; Plant, Owen et Elliott, 2000) in patients with exacerbations of COPD.

#### 3.1.2 Asthma

Asthma is considered as one of the most common chronic diseases worldwide. The estimated number of persons concerned amounts to 300 million, and a further increase of another 100 million individuals suffering from asthma is expected by 2025. The global prevalence of asthma varies from 1% to 18% of the population in different countries (Masoli et al., 2004).

Asthma symptoms, such as breathlessness, cough, wheeze and tightness of chest (Levy et al., 2005) typically show an early onset in life, change from one day to another and are mainly present at night or early morning. There is often found an association with allergies, allergic rhinitis, eczema or asthma in family history. Airway obstruction in asthma patients is mostly reversible, but in cases of severe asthma and in combination with late onset of the disease, airway hyperresponsiveness, sputum eosinophilia and exposition to tobacco smoke or other noxious substances, patients may develop some state of fixed airflow limitation (Global Initiative for Asthma (GINA), Updated 2008; ten Brinke et al., 2001).

The classification of asthma severity according to the Global Initiative for Asthma comprises four levels depending on the clinical picture before treatment (GINA, Updated 2008):

Intermittent asthma is characterized by symptoms occurring less than once a week, brief exacerbations and night-time symptoms not more than twice a month. Forced expiratory volume in one second (FEV1) or peak expiratory flow (PEF) values are above 80% predicted, with PEF or FEV1 variability less than 20%.

Mild persistent asthma shows symptoms occurring more than once a week but less than daily. Exacerbations may impair activity and sleep, and symptoms at night occur more than twice a month. FEV1 or PEF values are above 80% predicted, PEF or FEV1 variability is less than 20-30%.

Moderate persistent asthma is assigned to patients with daily symptoms and exacerbations that may affect activity and sleep. Nocturnal symptoms occur more than once a week, and the patient needs to use a short-acting ß2-agonist daily. FEV1 or PEF values are between 60% and 80% predicted, PEF or FEV1 variability is above 30%.

Severe persistent asthma is characterized by daily occurring symptoms, frequent exacerbations and frequent asthma symptoms at night. Physical activity of asthma patients at this level is impaired. FEV1 or PEF values

are equal or less than 60% predicted, PEF or FEV1 variability is above 30% (GINA, Updated 2008).

The treatment of asthma in adult patients provides medications for long-term clinical control which must be taken daily (controllers) and quickly acting medications to be used as acute medication in case of bronchoconstriction (relievers) on an as-needed basis (GINA, Updated 2008). As for controllers, inhaled glucocorticosteroids are the most effective medications available, while rapid-acting inhaled \(\mathbb{G}2\)-agonists are the medications of choice for relieving bronchospasm as well as for the pretreatment of bronchoconstriction induced by exercise (GINA, Updated 2008).

A five step treatment scheme adapted to the patients' level of asthma control has been established so that treatment can be stepped up until control is achieved, or stepped down when control can be held for three months or longer. This treatment scheme comprises rapid-acting bronchodilators for as-needed reliever medication at each treatment step and different controller medications and combinations of controllers for Steps 2 through 5, including inhaled glucocorticosteroids, long-acting \(\mathcal{B}^2\)-agonists, leukotriene modifiers, theophylline and oral glucocorticosteroids (GINA, Updated 2008).

Education of patients and their families, instructions for self-management, reduction of risk factors and regular monitoring and adaption of therapy are further important components of asthma management (GINA, Updated 2008).

#### 3.2 Pulmonary rehabilitation

Although asthma and COPD show significant differences in risk factors, onset, clinical appearance, progress and therapy, their impact on patients' functioning can assume similar proportions, especially regarding patients with advanced severity of asthma and permanent airflow obstruction.

Obstructive pulmonary diseases lead to limitations in physical activities and restrictions in daily life and societal participation including paid work (Álvarez-Gutiérrez et al., 2007; Juniper et al., 1999). Furthermore, psychological problems like anxiety and depression are more common among patients with chronic breathing disorders (Kunik et al., 2005).

Pulmonary rehabilitation is an important approach in the treatment of obstructive pulmonary diseases which addresses the wide range of functional impairments associated with both COPD and asthma. Evidentially,

pulmonary rehabilitation is an effective method to improve patients' quality of life, including the reduction of dyspnea, the reduction of days in hospital, as well as psychosocial benefits (Pesut, Ciobanu et Nagorni-Obradovic, 2008). For this purpose, an interdisciplinary team of health professionals is needed.

#### 3.3 International Classification of Functioning, Disability and Health (ICF)

The comprehensive management of obstructive pulmonary diseases involves different health professions. Therefore, a common framework and classification of patients' typical problems in functioning is necessary to optimize interventions aimed at maintaining functioning and minimizing disability (Stucki, Ewert et Cieza, 2003; Stucki et al., 2004). In 2001, the World Health Organization (WHO) published The International Classification of Functioning, Disability and Health (ICF), which was approved by all WHO member states at the Fifty-Fourth World Health Assembly on 22 May 2001 as the international standard for the description and measurement of health and disability (http://www.who.int/classification/icf). This classification system, based on the earlier International Classification of Impairments, Disabilities and Handicaps (ICIDH), offers a useful and globally accepted framework for classifying the components of health and consequences of a disease. It aims at providing a unified language for the description of health conditions in rehabilitation and a common framework for all health professions (WHO, 2001).

According to the ICF, the consequences of a disease may concern body functions and structures, the performance of activities and participation in life situations. Health states and the development of disability are modified by contextual factors such as environmental and personal factors (WHO, 2001; Figure 1).

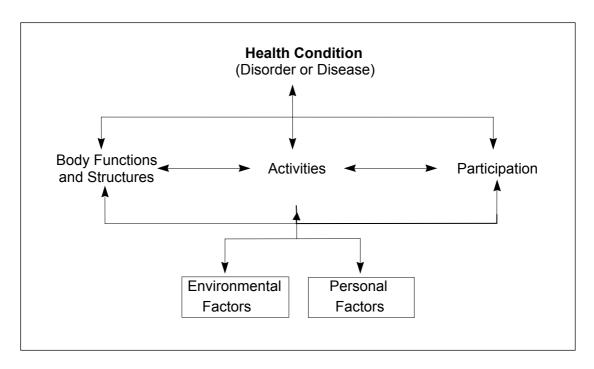


Figure 1 Components of the International Classification of Functioning, Disability and Health

The ICF is structured into two parts – Functioning and Disability (Part 1) and Contextual Factors (Part 2), each of them with two components (see Figure 2). The Functioning and Disability part includes the components *Body Functions* (b), namely the physiological functions of body systems, *Body Structures* (s) as anatomical parts of the body, and *Activities and Participation* (d), specifically tasks and actions an individual can perform and the involvement of an individual in situations of life. The component *Activities and Participation* covers categories of functioning from both an individual and societal perspective.

In contrast to other disability models, the ICF classifies contextual factors that may either facilitate or hinder functioning and therefore affect the development of disability. These contextual factors (Part 2) consist of two components. The component *Environmental Factors* (e) encompasses categories of the physical, social or attitudinal world, which are factors that build the environment people live in. The second component is *Personal Factors* (pf), which represent the particular background of an individual's life and living, such as gender, age, habits, lifestyle, coping style, etc. *Personal Factors* are not yet contained in the current ICF version because of the large social and cultural variety associated with *Personal Factors*. Within the three components *Body Functions* and *Structures*, *Activities and Participation* and

Environmental Factors, all items in the classification are arranged hierarchically (Figure 2). The magnitude of the level of health (e.g. severity of the problem) is denoted for each category by a qualifier according to a five level scale ranging from "no problem" to "severe problem".

The units of the ICF classification are its categories. They are arranged in a stem-branch-leaf scheme, so that a lower-level category shares the attributes of the higher level of which it is a member. Figure 2 shows the overall structure of the ICF.

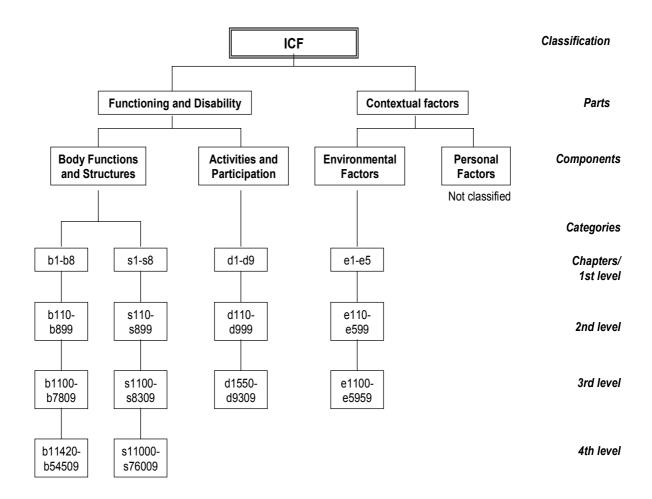


Figure 2 Structure of the International Classification of Functioning, Disability and Health

Despite its supposed value, the ICF classification as a whole - including more than 1400 categories - is not feasible for use in clinical practice. In order to facilitate the implementation of the ICF into clinical practice, ICF Core Sets for a number of health conditions including OPD (Stucki et al., 2004), have been developed by the ICF Research Branch of WHO Collaboration Center of the Family of International Classifications (DIMDI) at the Department of Physical Medicine and Rehabilitation of the Ludwig-Maximilians-University in Munich (http:\\www.ICF-Research-Branch.org) in cooperation with the Classification, Assessment and Surveys (CAS) team at the WHO and several partner organizations (Stucki et Grimby, 2004; Ustün, Chatterji et Kostanjsek, 2004; Cieza et al., 2004).

The Comprehensive ICF Core Set for OPD includes a set of categories out of the whole ICF classification which covers the typical spectrum of problems in functioning in patients with OPD, including asthma and COPD (Stucki et Grimby, 2004; Ustün, Chatterji et Kostanjsek, 2004; Cieza et al., 2004). It was developed in a formal decision-making and consensus process integrating evidence gathered from preliminary studies and expert knowledge: Stucki et Grimby, 2004; Wolff et al., 2004; Ewert et al., 2004. These preceding studies included a Delphi exercise representing the expert opinion, a systematic review to represent the view of researchers, and an empirical data collection. In a Delphi Exercise, 21 experts identified 34 ICF categories as most typical and relevant categories for patients with OPD (Weigl et al., 2004). In order to identify and compare the concepts contained in outcome measures of clinical trials on OPD and identify the corresponding ICF categories, a systematic review analyzed 253 trials on OPD between 1999 and 2003 (Wolff et al., 2004). Moreover, a multi-center cross-sectional study was conducted collecting empirical data of 89 patients with OPD to identify the most common problems using the ICF checklist (Ewert et al., 2004).

Based on the results from these preliminary studies, at the 3<sup>rd</sup> ICF Consensus Conference in 2003, 17 experts (11 physicians with different subspecializations, four physical therapists, one psychologist and one nurse) from 8 different countries decided to include 71 ICF categories altogether in the Comprehensive ICF Core Set for OPD in a formal consensus process (Stucki et al., 2004; Attachment 10.1).

By means of the Comprehensive ICF Core Set for OPD, the impairments, limitations in activities, restrictions in participation and the influential environmental factors of a determined patient can be described. A functioning profile can be created and used as a reference for follow-up.

Patients with chronic conditions, including OPD, benefit from a comprehensive therapeutic approach providing multidisciplinary care (Wagner, 2000). The multi-professional treatment of patients with OPD involves different health care professions, such as primary care physicians, pulmonologists, nurses, physical therapists, social workers and diet specialists, aiming at the provision of high quality health care (Kuzma et al., 2008). The exchange of information between the health care team members and the matching of each specializations' interventions demand a common language and framework for successful interdisciplinary care (Steiner et al., 2002). The Comprehensive ICF Core Set for OPD provides a very useful starting point in this concern.

#### 3.4 Objective

The Comprehensive ICF Core Set for OPD is now undergoing worldwide testing and validation using a number of approaches including international multi-centre field studies and validation from the patients' perspective. One key aspect is the validation from the users' perspective. Since ICF Core Sets should serve as a standard for multi-professional assessment and assessment in clinical trials, it is most important to ensure that the categories included in the Comprehensive ICF Core Sets cover the patients' problems addressed by the specific interventions of health professionals.

Therefore, the objective of this study was to validate the Comprehensive ICF Core Set for OPD from the perspective of physicians. The specific aims were firstly, to identify the patients' problems, resources and aspects of environment treated by physicians in patients with OPD and secondly, to examine how these aspects are represented by the current version of the Comprehensive ICF Core Sets for OPD.

#### 4 Methods

#### 4.1 The Delphi method

The authors conducted a three-round electronic-mail survey of physicians using the Delphi technique (Duffield, 1993; Goodman, 1987; Linstone et Turoff, 1975). The Delphi method is a systematic multi-stage survey designed to structure a group communication process. It aims at gaining consensus from a panel of individuals, commonly titled 'experts', who have knowledge of the topic being investigated (Mc Kenna, 1994). Conducting a Delphi exercise starts with the development of a questionnaire which is sent to the experts. After the questionnaire is returned, the results are summarized and a new questionnaire based upon the results of the first round is developed. This procedure can be repeated multiple times so that every participant is given the opportunity to reevaluate his or her original answers based upon examination of the group response. Thus, the Delphi technique facilitates communication and decision-making among a panel of experts. It is feasible among geographically dispersed respondents and it is effective in respect of time and costs (Linstone et Turoff, 1975; Adler et Ziglio, 1996). The technique is characterized by its anonymity, thus avoiding group dominance, iteration which allows panel members to change their opinions in subsequent rounds and controlled feedback showing the distribution of the group's response as well as the individual previous response (Jones et Hunter, 1995).

In health care, the Delphi method is frequently applied in consensus- and decision-making processes (Hasson et al., 2000).

#### 4.2 Recruitment of participants

In the preparatory phase of the study, 25 associations for respiratory medicine found by internet search were contacted by e-mail. In addition, literature search and personal recommendations were used to identify experts. Accessorily, a register of members of a German pulmonary specialist association (Deutsche Gesellschaft für Pneumologie und Beatmungsmedizin e.V.) was used to get in contact with German experts. The sample was selected using a purposive sampling approach. Purposive sampling is based on the assumption that a researcher's knowledge about the population can be used to handpick the cases to be included in the sample (Polit et Hungler, 1997).

To assure that the participants of the study are 'informed individuals' concerning OPD treatment, the initial letter notes that participants should be "physicians experienced in the treatment of OPD".

The first contact included an invitation to cooperate and a detailed description of the projects targets, the Delphi process and the timeline. Only persons who agreed to participate were included into the expert sample and received the questionnaire of the first Delphi round (see Attachment 10.2).

#### 4.3 Delphi Process

The process and verbatim questions of the electronic-mail survey using the Delphi technique are displayed in Figure 3. The participants were given 3 weeks to mail their responses for each round. Reminders were sent one week and 2 days before deadline.

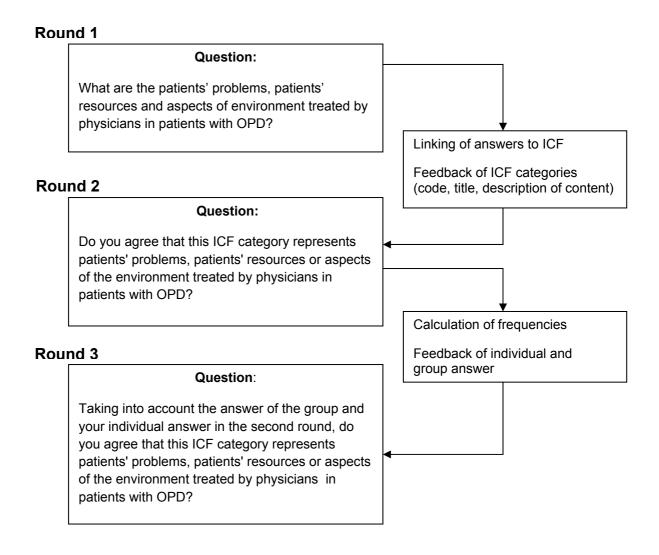


Figure 3 Description of the Delphi exercise

In round 1 of the Delphi exercise an information letter including instructions and an Excel file containing an open-ended questionnaire was sent to all experts. Participants were requested to list all the patients' problems, patients' resources and aspects of environment treated by physicians in patients with OPD.

Additionally, the participants were asked to complete questions on demographic characteristics and professional experience (see Attachment 10.2). Responses were collected and linked to the ICF.

In the second Delphi round, the participants received a list of the ICF categories linked to the responses of the first round (see Attachment 10.3). The categories were arranged according the structure of the ICF. The responses that could not be linked to an existing ICF category were categorized by the research team and listed. The participants were requested to agree or disagree whether the respective ICF category represents patients' problems, patients' resources or aspects of environment treated by physicians in patients with OPD.

In the third Delphi round the participants received a list of the ICF categories including the proportion and the identification numbers of the participants who did agree that the categories represent patients' problems, patients' resources or aspects of environment treated by physicians in patients with OPD (see Attachment 10.4). The participants were requested to answer the same question taking into account the responses of the group as well as their own previous opinion.

#### 4.4 Linking

An ICF category is coded by a component letter referring to one of the components *Body Functions* (b), *Body Structures* (s), *Activities and Participation* (d) and *Environmental Factors* (e) (Figure 2). This letter is followed by a one digit number indicating the chapter, the code for the second level (two digits) and the third and fourth levels (one digit each). A higher-level (more detailed) category shares the lower-level categories of which it is the member, i.e. the use of a higher-level category implies that the lower-level category is applicable, but not vice versa.

To demonstrate the use of letters and digit numbers, an example is shown below:

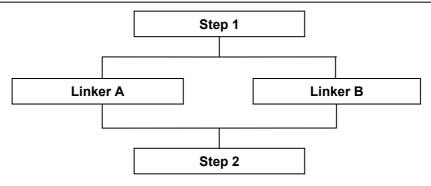
b	Body Functions	
b4	Functions of the cardiovascular, haematological, immunological and respiratory systems	Chapter 4 / 1 <sup>st</sup> level
b435	Immunological system functions	2 <sup>nd</sup> level
b4350	Immune response	3 <sup>rd</sup> level
b43500	Specific immune response	4 <sup>th</sup> level
b43501	Non-specific immune response	4 <sup>th</sup> level

Each of the participants' responses of the first Delphi round was linked to the most precise ICF category. The linkage was performed separately by a trained psychologist and a medical student on the basis of ten linking rules, established in former studies (Cieza et al., 2002; 2005).

If a response contained more than one concept, several ICF categories could be linked. Consensus between the health professionals was used to decide which ICF category should be linked to each response. In case of disagreements between the two health professionals, the suggested categories were discussed by a team consisting of the two health professionals and a third trained psychologist. Based on this discussion, a joint decision was made. The whole linking procedure is explained in Figure 4.

Answers of participating experts						
Example:						
Answer of participant						
establish long-term relationship with general practitioner						

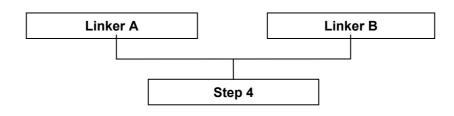
Identification of meaningful concepts								
Example:								
Answer of participant	Identified concept	Identified concept						
	Linker A	Linker B						
establish long-term relationship with general practitioner	long-term relationship with general practitioner	relationship with general practitioner						



Agreement on the concepts identified by Linker A and Linker B										
Example:										
Identified concept	Identified concept	Agreed-on concept								
Linker A	Linker B									
long-term relationship with general practitioner	relationship with general	relationship with general								
	practitioner	practitioner								

Step	3
- CUP	•

Linkage of the agreed-on concepts to the ICF								
Example:								
Agreed-on concept	ICF Linkage	ICF Linkage						
	Linker A	Linker B						
relationship with general practitioner	d740 Formal relationships	e355 Health professionals						



Agreement on ICF categories								
Example:								
ICF Linkage	ICF Linkage	Agreed-on						
Linker A	Linker B	ICF category						
d740 Formal relationships	e355 Health professionals	d740 Formal relationships						

Figure 4: Linking procedure in a four step process

#### 4.5 Statistical methods

Statistical analysis was performed using SAS for windows Version 8. Descriptive statistics were used to characterize the sample and frequencies of responses. To analyse group differences, Chi<sup>2</sup>-test or Fishers exact test were applied for nominal variables, Mann-Whitney-U-Test for ordinal variables. The level of significance was set to 0.05. Kappa statistics with bootstrapped confidence intervals were used to describe the agreement between the two persons who performed the linking (Cohen, 1969; Vierkant, 2004).

#### 5 Results

#### 5.1 Recruitment and participants

Fifty-five of 337 physicians found by internet search participated in the first Delphi round. Of the German Association for Pneumology and Respiratory Medicine, 109 members were invited to participate: 15 members agreed to participate and 8 of them actually participated in the first round of the study. Twelve additional experts who were contacted by literature search participated in the study. On the basis of personal recommendations of other participants ("snowball system"), 14 persons were contacted. Two of them participated in the first round of the Delphi process.

Seventy-six of 99 physicians (76.8%) who agreed to participate in the study filled in the first round questionnaire. The demographic and professional characteristics of the experts are shown in Table 1. Thirty-five participants (46.1%) were from Europe. The European participants did not significantly differ from the other participants with respect to demographic and professional characteristics. No significant changes of demographic sample characteristics due to attrition of participants between the three Delphi rounds could be found.

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

WHO-Region	Round 1 (n)	Round 2 (n)	Round 3	Female (%)	Age Median (Min-Max)	Professional Experience [years] Median (Min-Max)	OPD experience [years] Median (Min-Max)	Self-rating OPD Expertise <sup>#</sup> Median (Min-Max)	Mainly treating patients in acute situation (n)	Mainly treating patients in early-postacute chronic situation (n)	Mainly treating patients in chronic situation (n)
African Region	3	3	3	0.0	53.0 (49-59)	20.0 (18-29)	18.0 (7-24)	4 (1-4)	0	0	3
Region of the Americas	16	14	13	25.0	49.5 (36-65)	20.5 (5-42)	20.5 (5-31)	5 (3-5)	9	11	16
South-East Asia Region	3	3	2	0.0	52.0 (48-56)	30.0 (20-36)	26.0 (20-36)	4 (4-5)	2	2	3
European Region	35	28	27	11.4	48.0 (37-63)	20.0 (10-37)	18.0* (8-35)	4.5 (3-5)	24	16	25
Eastern Mediterran. Region	6	5	5	33.3	53.0 (42-59)	26.5 (15-33)	18.0 (4-33)	4.5 (3-5)	5	5	6
Western Pacific Region	13	12	11	23.1	49.0 (35-66)	23.0 (10-34)	20.0 (6-32)	4 (4-5)	10	10	12
Total	76	65	61	17.1	49.0 (35-66)	21.0 (5-42)	18.5 (4-36)	5 (3-5)	50	44	65

<sup>#1=</sup>low 5=excellent \* data of one participant missing

African Region: Cameroon, Nigeria, South Africa, Sudan

Region of the Americas: Argentina, Canada, Mexico, Peru, Trinidad and Tobago, United States of America, Uruguay

South-East Asia Region: India, Republic of Korea, Thailand

European Region: Austria, Bulgaria, Croatia, Finland, France, Germany, Hungary, Iceland, Italy, Kyrgyzstan, Malta, Norway, Portugal, Russia, Serbia and Montenegro, Slovenia, Switzerland, Turkey Eastern Mediterranean Region: Egypt, Iran, Lebanon, Syria, Tunisia,

Western Pacific Region: Australia, Hong Kong China, Japan, Malaysia, New Zealand, Philippines, Vietnam

#### 5.2 Delphi Process

In the first Delphi round, 1330 patients' problems, patients' resources or aspects of environment treated by physicians in patients with OPD were named. 65 of 76 participants (85.5%) returned the second round questionnaire. The third round questionnaire was completed by 61 of 65 (93.8%) participants. The results of round 3 including the percentage of agreement among the participants are presented in Tables 2-6.

#### 5.3 Linking of the responses to the ICF

All components of the ICF were represented by the participants' responses (Tables 2-6). Two fourth-level categories, 26 third-level categories and 25 second-level categories of the component *Body Functions* were linked. Of the component *Body* Structures, two third-level categories and one fourth-level category were assigned to the participants' responses. The component *Activities and Participation* was represented by 33 third-level categories and 18 second-level categories, whereas 21 third-level categories and 20 second-level categories of the component *Environmental factors* were identified. Fourty responses were linked to the not yet developed ICF component *Personal Factors*. The content of the identified 19 responses linked to the ICF component *Personal Factors* refers to coping strategies, personal wishes, helplessness and dependencies.

Health conditions such as 'pneumonia', 'respiratory infection', etc. that were used in many responses as e.g. a substitute or umbrella term for the underlying disease or as an independent risk factor, were assigned to *Health Conditions*. *Health Conditions* are classified and coded in the complementary International Classification of Diseases, ICD 10 (WHO, 1994). Seventeen responses were found not to be covered by the ICF, such as 'oedema', 'exacerbations and prevention of exacerbations', 'expectorations', 'carbon dioxide retention' and 'lung function studies' and were defined *Not Classified*. One hundered and five responses could not be linked as they were not defined sufficiently.

The Kappa statistic for the linking was 0.66 with a 95% bootstrapped confidence interval of 0.63 - 0.69.

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

	Body Functions	Body Structures	Activities & Participation	Environmental Factors	Total
Number of categories identified					
- second level	25	0	18	20	63
- third level	26	2	33	21	82
- fourth level	2	1	-	-	3
Total number of categories identified	53	3	51	41	148
n (%) of categories included in the ICF Core Set at the same level of classification *	15 (28.3%)	0 (0%)	12 (23.5%)	12 (29.3%)	39 (26.4%)
n (%) of categories included in the ICF Core Set at a different level of the classification *	15 (28.3%)	2 (66.6%)	27 (52.9%)	16 (39.0%)	60 (40.5%)
n (%) of categories not included in Core Set with <b>agreement &lt;75</b> %	15 (28.3%)	0 (0%)	12 (23.5%)	13 (31.7%)	40 (27.0%)
n (%) of categories not included in Core Set with <b>agreement</b> ≥ <b>75</b> %	8 (15.1%)	1 (33.3%)	0 (0%)	0 (0%)	9 (6.1%)

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

# 5.4 Representation of the physicians' responses in the Comprehensive ICF Core Set for OPD

#### 5.4.1 Body Functions

The component *Body Functions* of the ICF Core Set for OPD includes 17 second-level categories and two third-level categories. In this validation study, 25 second-level categories, 26 third-level categories and two fourth-level categories of the component Body Functions were identified from the participants' responses.

Fifteen categories (fourteen second-level catgories and one third-level category) linked to the responses of the participants are represented in the Comprehensive ICF Core Set for OPD at the same level of classification (Tables 2 and 3). One of them, *b455 Exercise tolerance functions*, reached an agreement of 100% in the third Delphi round.

Several responses were linked to third-level and fourth-level categories not included in the ICF Core Set for OPD, but represent their corresponding second-level or third-level category respectively. Thus, the third-level categories b1300 Energy level, b1301 Motivation and b1302 Appetite represent the second-level category b130 Energy and drive functions. Likewise, the categories b1342 Maintenance of sleep and b1343 Quality of sleep represent the second-level category b134 Sleep functions. The fourth-level categories b28010 Pain in head and neck and b28011 Pain in chest can be seen as representatives of the third-level category b2801 Pain in body part and the second-level category b280 Sensation of pain. Furthermore, b4100 Heart rate, b4301 Oxygen-carrying functions of the blood, b4350 Immune response and Hypersensitivity reactions, as well as b4550 General physical endurance, b4551 Aerobic capacity, b4552 Fatiguability and b7801 Sensation of muscle spasm relate to the corresponding lower-level and less detailed categories b410 Heart functions, b430 Haematological system functions, b455 Exercise tolerance functions and b780 Sensations related to muscles and movement functions which are included the Comprehensive ICF Core Set for OPD.

Twenty-three categories linked to the participants' responses are not included in the Comprehensive ICF Core Set for OPD. On eight of them, namely b110 Consciousness functions, b1263 Psychic stability, b1265 Optimism, b415 Blood vessel functions, b420 Blood pressure functions, b4200 Increased blood pressure, b545 Water, mineral and electrolyte balance functions and b5500 Body temperature, a high agreement among

the participants (78.0-94.8% in the third Delphi round) was found. The remaining 15 categories were evaluated with 13.8 – 67.8%.

Table 3: ICF component Body Functions: categories included in the ICF Core Set (bold-face font) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (light-face font). Percentage of participants who considered the respective ICF category as relevant in the third round.

ICF Code			ICF Category Title	Round 3
				(n=61)
2nd level	3rd level	4th level		% agreement
b110			Consciousness functions	91.8
	b1263		Psychic stability	85.2
	b1265		Optimism	80.0
	b1266		Confidence	65.5
b130			Energy and drive functions	
	b1300		Energy level	66.1
	b1301		Motivation	76.6
	b1302		Appetite	65.5
b134			Sleep functions	86.4
	b1342		Maintenance of sleep	88.3
	b1343		Quality of sleep	91.7
	b1470		Psychomotor control	50.0
b152			Emotional functions	46.7
	b1522		Range of emotion	
b220			Sensations associated with the eye and adjoining structures	29.5
b280			Sensation of pain	85.2
	b2801		Pain in body part	

		b28010	Pain in head and neck	55.0
		b28011	Pain in chest	93.4
b310			Voice functions	
	b3400		Production of notes	13.8
b410			Heart functions	93.3
	b4100		Heart rate	95.1
b415			Blood vessel functions	80.0
b420			Blood pressure functions	88.1
	b4200		Increased blood pressure	91.7
b430			Haematological system functions	91.7
	b4301		Oxygen-carrying functions of the blood	95.0
b435			Immunological system functions	93.3
	b4350		Immune response	94.9
	b4351		Hypersensitivity reactions	93.2
b440			Respiration functions	98.3
b445			Respiratory muscle functions	98.4
b450			Additional respiratory functions	96.7
b455			Exercise tolerance functions	100.0
	b4550		General physical endurance	96.6
	b4551		Aerobic capacity	96.7
	b4552		Fatiguability	95.1
b460			Sensations associated with cardiovascular and respiratory functions	98.4
	b5104		Salivation	36.1

	b5106	Regurgitation and vomiting	66.1
	b5153	Tolerance to food	34.5
b530		Weight maintenance functions	96.6
b540		General metabolic functions	67.8
b545		Water, mineral and electrolyte balance functions	94.8
	b5500	Body temperature	78.0
b640		Sexual functions	67.2
	b6403	Functions of sexual resolution phase	19.0
b710		Mobility of joint functions	57.6
b730		Muscle power functions	70.0
b735		Muscle tone functions	50.0
b740		Muscle endurance functions	62.1
	b7651	Tremor	62.7
b780		Sensations related to muscles and movement functions	
	b7801	Sensation of muscle spasm	59.3
b810		Protective functions of the skin	48.3
b820		Repair functions of the skin	46.7
	•	<del></del>	

#### 5.4.2 Body Structures

The component *Body Structures* of the ICF Core Set for OPD includes five ICF categories of the second level. Overall, three categories of this component were identified from the participants' responses, more precisely two third-level categories and one fourth-level category. None of the ICF categories linked to the responses is represented in the ICF Core Set at the same level of classification.

The third-level and fourth-level categories *s4301 Lungs* and *s43011 Alveoli*, which received an agreement of 98.1% and 94.0%, represent the corresponding second-level category *s430 Structure of respiratory system*.

The category *s7702 Muscles* of the third level is not included in the ICF Core Set for OPD and does not represent any lower-level category included, but received an agreement of 90.2% in the third Delphi round (see Tables 2 and 4).

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

ICF Code			ICF Category Title	Round 3
				(n=61)
2nd level	3rd level	4th level		% agreement
s410			Structure of cardiovascular system	
s430			Structure respiratory system	
	s4301		Lungs	98.1
		s43011	Alveoli	94.0
s710			Structure of head and neck region	
s720			Structure of shoulder region	
s760			Structure of trunk	
	s7702		Muscles	90.2

#### 5.4.3 Activities and Participation

The ICF Core Set for OPD includes 23 second-level ICF categories and one third-level category of the component *Activities and Participation*. Altogether, a total of 51 categories was linked to the experts' responses and twelve of them are included in the Core Set at the same level of classification (see Tables 2 and 5).

Twelve categories of the component *Activities and Participation* of the ICF Core Set were not identified from the participants' responses, but seven of them are represented by corresponding third-level categories, such as *d570 Looking after one's health* and *d920 Recreation and leisure*, which are represented by *d5702 Maintaining one's health* and *d9204 Hobbies*, to cite an example.

Twelve of the ICF categories linked to the participants' responses are not represented in the Comprehensive ICF Core Set for OPD. These categories showed an agreement of 13.6% to 71.7%. However, none of these categories showed an agreement above 75% in the third Delphi round.

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

ICF Code			ICF Category Title	Round 3 (n=61)
2nd level	3rd level	4th level		% agreement
d230			Carrying out daily routine	61.0
d240			Handling stress and other psychological demand	
d330			Speaking	23.3
d410			Changing basic body position	53.3
	d4100		Lying down	41.7
	d4153		Maintaining a sitting position	33.3

	d4154	Maintaining a standing position	43.3
d430		Lifting and carrying objects	
	d4301	Carrying in the hands	23.3
	d4302	Carrying in the arms	30.5
	d4303	Carrying on shoulders, hip and back	27.6
d450		Walking	65.0
d455		Moving around	48.3
	d4551	Climbing	46.7
d460		Moving around in different locations	50.8
	d4601	Moving around within buildings other than home	45.8
	d4602	Moving around outside the home and other buildings	49.2
d465		Moving around using equipment	
d470		Using transportation	39.0
	d4702	Using public motorized transportation	44.1
d475		Driving	
	d4750	Driving human-powered transportation	
	d4751	Driving motorized vehicles	32.2
d510		Washing oneself	48.3
	d5101	Washing whole body	47.5
	d5202	Caring for hair	28.8
d540		Dressing	
d570		Looking after one`s health	
	d5701	Managing diet and fitness	71.7
	d5702	Maintaining one's health	88.3
d610		Acquiring a place to live	20.7

d620		Acquisition of goods and services	
	d6200	Shopping	25.9
d630		Preparing meals	28.6
d640		Doing housework	31.0
	d6400	Washing and drying clothes and garments	22.4
	d6401	Cleaning cooking area and utensils	25.4
	d6402	Cleaning living area	28.8
d650		Caring for household objects	22.0
d660		Assisting others	
d740		Formal relationships	23.7
	d7400	Relating with persons in authority	21.1
	d7500	Informal relationships with friends	20.3
d760		Family relationships	37.3
d770		Intimate relationships	
	d7702	Sexual relationships	45.6
d820		School education	13.6
d845		Acquiring, keeping and terminating a job	
	d8450	Seeking employment	37.3
	d8451	Maintaining a job	49.2
	d8452	Terminating a job	43.3
d850		Remunerative employment	27.1
d855		Non-remunerative employment	15.3
	d8700	Personal economic resources	21.1

ICF Code			ICF Category Title	Round 3 (n=61)
2nd level	3rd level	4th level		% agreement
d910			Community life	
	d9100		Informal associations	20.3
	d9101		Formal associations	13.6
d920			Recreation and leisure	53.3
	d9200		Play	26.7
	d9201		Sports	41.7
	d9202		Arts and culture	18.3
	d9204		Hobbies	21.7
	d9205		Socializing	25.4

#### 5.4.4 Environmental Factors

Twenty-two second-level categories and one third-level category of the component *Environmental Factors* are included in the Comprehensive ICF Core Set for OPD. Overall, 41 categories were identified from the physicians' responses. Twelve of the identified categories are represented in the ICF Core Set at the same level of classification.

Eight categories of the component *Environmental Factors* of the ICF Core Set for OPD were not identified from the participants' responses, but two of them are represented by corresponding third-level categories, namely e580 Health services, systems and policies, which is represented by e5800 Health services, e5801Health systems and e5802 Health policies and e555 Associations and organizational services, systems and policies, which is represented by e5550 Associations and organizational services.

Thirteen of the ICF categories linked to the participants' responses are not represented in the Comprehensive ICF Core Set for OPD. Yet, there was

no agreement above 75% found concerning these categories - agreement rates ranged from 14.0% to 56.7% (see Tables 2 and 6).

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

ICF Code			ICF Category Title	Round 3	
				(n=61)	
2nd level	3rd level	4th level		% agreement	
e110			Products or substances for personal consumption		
	e1100		Food	57.6	
	e1101		Drugs	86.4	
e115			Products and technology for personal use in daily living	51.7	
	e1151		Assistive products and technology for personal use in daily living	74.1	
e120			Products and technology for personal indoor and outdoor mobility and transportation		
e135			Products and technology for employment	24.6	
e140			Products and technology for culture, recreation and sport	24.1	
e150			Design, construction and building products and technology of buildings for public use	20.7	
e155			Design, construction and building products and technology of buildings for private use	22.4	
	e1650		Financial assets	15.5	
	e2200		Plants	17.9	
	e2201		Animals	17.5	
e225			Climate	51.7	
	e2250		Temperature	67.8	
	e2251		Humidity	64.9	
	e2252		Atmospheric pressure	31.0	
	e2253		Precipitation	36.5	

e575		General social support services, systems and policies	61.7
	e5700	Social security services	56.7
e570		Social security services, systems and policies	51.7
	e5550	Associations and organizational services	50.8
e555		Associations and organizational services, systems and policies	
	e5502	Legal policies	16.9
e540		Transportation services, systems and policies	27.6
e465		Social norms, practices and ideologies	24.6
e460		Societal attitudes	33.9
e450		Individual attitudes of health professionals	89.7
e420		Individual attitudes of friends	
e415		Individual attitudes of extended family members	29.3
e410		Individual attitudes of immediate family members	50.0
e355		Health professionals	96.6
e350		Domesticated animals	36.8
e340		Personal care providers and personal assistants	
e320		Friends	
e315		Extended family	14.0
e310		Immediate family	37.9
	e2601	Outdoor air quality	54.4
	e2600	Indoor air quality	86.2
e260		Air quality	62.7
	e2450	Day/night cycles	
e245		Time-related changes	
e235		Human-caused events	37.1
	e2255	Seasonal variation	54.2
	e2254	Wind	34.9

	e5750	General social support services	62.7
e580		Health services, systems and policies	
	e5800	Health services	85.0
	e5801	Health systems	76.7
	e5802	Health policies	69.0
e585		Education and training services, systems and policies	
e590		Labour and employment services, systems and policies	

#### 5.4.5 Personal Factors

Nineteen responses were linked to the not yet developed ICF component *Personal Factors* (see Table 7). These Personal Factors are related to the patients' handling of the disease, like knowledge about risk factors, medication and inhaler techniques as well as expectations towards treatment, living will and coping strategies. Furthermore, patients' personal wishes, helplessness and dependencies come under the term 'Personal Factors'.

Personal Factors are not yet classified in the ICF. An agreement of 100% among the participants of the third Delphi round was shown in the items "patient's knowledge about the disease", "patient's knowledge about risk factors", "patient's knowledge about medication", "understanding of inhaler techniques", "understanding the principles of therapy", "expectations towards treatment" and "expectations towards activity".

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

Linking	<b>Round 3</b> (n=61)
	% agreement
Patient's knowledge about the diesease	100.0
Patient's knowledge about risk factors	100.0
Patient's knowledge about medication	100.0
Understanding of inhaler techniques	100.0
Understanding principles of therapy	100.0
Expectations towards treatment	100.0
Expectations towards activity	100.0
Barrier to use oxygen when going outside (embarrassment)	98.3
Corticophobia	96.6
Being prone to inactivity	95.0
Feeling helpless	95.0
Coping	94.8
Self-control	91.7
Living will	90.0
Uncertainty of the future	89.8
Loss of independence/autonomy	77.2
Living conditions	58.3
Poor education	45.8
Low social status/poverty	36.7

### 5.4.6 Not Classified

Seventeen responses of participants were found not to be covered by the ICF classification (Table 8).

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

Linking	Round 3 (n=61)
	% agreement
Oedema	100.0
Exacerbations	100.0
Sputum/phlegm/expectorations	100.0
Late/inadequate diagnosis	100.0
Prevention of exacerbations	100.0
Lung function studies	100.0
Dosing schedules of medications	100.0
Mortality	100.0
Risk of carbone dioxide retention	98.3
COPD action plan	96.6
Allergens and asthma triggers	96.6
Education of patient/patient's family	96.6
Knowledge and training of health professionals	96.6
Mismatch between symptoms and blood gas parameters	89.7
Allergy tests	86.0
Research opportunities	80.4
Genetic components of OPD and family screening	76.8

### 6 Discussion

This study recruited physicians experienced in the treatment of OPD by contacting national and international associations for respiratory medicine, conducted a three-round electronic-mail survey of physicians using the Delphi technique, examined the content by linking the concepts to the ICF and generated an inventory which shows the similarities and differences in comparison to the Comprehensive ICF Core Set for OPD.

The components *Body Structures*, *Activities and Participation* and *Environmental Factors* of the current version of the Comprehensive ICF Core Set for OPD were almost perfectly supported by the participants of the study. However, regarding the component *Body Functions*, some aspects were identified which are not included in the Comprehensive ICF Core Set for OPD. Overall, 66.9% of the ICF categories linked to the physicians' responses are included at the same or a different classification level by the Comprehensive ICF Core Set for OPD. There were found 49 categories not included in the ICF Core Set, but only nine of them - eight of the component *Body Functions* and one of the component *Body Structures* - were rated as important by at least 75% of the participants.

This study also identified *Personal Factors* and other aspects treated by physicians in patients with OPD that are not covered by the ICF classification.

### 6.1 Body Functions

Within the ICF component *Body Functions*, more than 90% of the participants agreed that the ICF category *b110 Consciousness functions* represents patients' problems treated by physicians, although this category is not included in the ICF Core Sets for OPD. According to literature, patients with chronic pulmonary affections may present an altered state of consciousness, known as hypercapnic encephalopathy (Butterworth, 1999). Furthermore, an altered level of consciousness plays an important role concerning the application of non-invasive positive pressure ventilation (NPPV) in patients with acute exacerbations of COPD (Scala et al., 2005). Thus, from the perspective of physicians, an inclusion of this category in the ICF Core Sets for OPD might be useful.

The categories b1263 Psychic stability and b1265 Optimism are not included in the ICF Core Sets for OPD, but were considered important by 85% and 80% of the participants respectively. Actually, mood disorders and

depressive symptoms have been found to be common in asthma patients (Nejtek et al., 2001) and patients with chronic OPD (Kunik et al. 2005; Yohannes et al., 1998) and may be addressed by the interventions of physicians. However, the use of these categories is ambiguous. According to the ICF instruction, those categories should only be used to describe mental functions that produce a constitutional disposition and should be avoided to describe temporary states (WHO, 2001). It remains questionable whether e.g. a loss of psychic stability associated with a chronic disease like OPD could be described using category b1263 Psychic stability, or whether psychic stability should be regarded as a *Personal Factor* in this case. This example emphasizes the need for a manual that provides further operationalization to clarify the use of codes. The "Procedural Manual and Guide for a Standardized Application of the ICF" developed by the American Psychological Association in collaboration with the WHO will contribute to close this gap and facilitate the application of the ICF by health professionals (Reed at al., 2005).

Some other ICF categories not included in the Core Sets for OPD but regarded as relevant by at least 80% of the participants address blood vessel functions and blood pressure functions. Pulmonary hypertension as a consequence of pulmonary vascular changes is an important complication of severe COPD (Hopkins et Mc Loughlin, 2002; Pauwels et al., 2001). Therefore, the ICF category *s410 Structure of cardiovascular system* was included in the ICF Core Set for OPD (Stucki et al., 2004). It might be a consequential completion to also include the categories *b415 Blood vessel functions*, *b420 Blood pressure functions* and *b4200 Increased blood pressure*.

The ICF category *b545 Water, mineral and electrolyte balance functions* is not included in the ICF Core Sets for OPD, but was seen as a relevant problem by 94.8% of the participants regarding treatment of patients with OPD. Even though there is only few data to be found concerning the fluid homeostasis in patients with OPD, one can discover salt and water retention, reduced renal blood flow and diminished glomerular filtration rate as well as neurohumoral abnormalities (Anand et al., 1992; De Leeuw et Dees, 2003). Since sodium retention and resulting volume congestion often lead to massive oedema, a common problem of patients with OPD treated by physicians, it may therefore be useful to integrate the ICF category *b545 Water, mineral and electrolyte balance functions* into the Comprehensive ICF Core Set for OPD.

78% of the participating experts regarded the ICF category *b5500 Body temperature* as a relevant aspect treated by physicians in patients with OPD. However, this category is not included in the Comprehensive ICF Core Set for OPD. Acute exacerbations of chronic OPD can be characterized by systemic clinical descriptors such as increased body temperature amongst other things (Rodriguez-Roisin, 2000; Lieberman et al., 2003). With regard to diagnostics of exacerbations, one could consider an inclusion if the ICF category *b5500 Body temperature* in the Comprehensive ICF Core Set for OPD.

In addition to the categories discussed above, there are some more categories of the ICF component Body Functions, e.g. b1342 Maintenance of sleep, b28011 Pain in chest, b4100 Heart rate, b4350 Immune response, b4351 Hypersensitivity reactions, b4550 General physical endurance, b4551 Aerobic capacity etc. that are not included in the ICF Core Sets for OPD at the specific level of classification, but covered by less specific (lower-level) categories and are observably important for physicians since these categories received an agreement of 90% and above. It may therefore be reasonable to investigate by means of further studies or practical application of the ICF Core Sets for OPD if it is necessary to include these more specific categories as well.

### 6.2 Body Structures

Only three ICF categories of the ICF component *Body Structures*, namely *s4301 Lungs*, *s43011 Alveoli* and *s7702 Muscles*, were identified by the linking process of the physicians' responses. The third-level category *b4302 Lungs* and the fourth-level category *b43011 Alveoli* represent the second-level category *s430 Structure of respiratory system*, which is included in the Comprehensive ICF Core Set for OPD. These two categories received a high agreement of 98.1% and 94% respectively in the third Delphi round.

The category *s7702 Muscles* is not included in the Comprehensive ICF Core Set for OPD, but received an agreement of 90.2%. In fact, the ICF categories *s710 Structure of head and neck region*, *s720 Structure of shoulder region* and *s760 Structure of trunk*, which are included in the Core Set for OPD, also comprise muscles of the respective region. Muscle weakness in chronic OPD concerns respiratory muscles, which leads to accelerated exhaustion, especially during physical efforts and exercise. Furthermore, limb muscles, particularly of the lower extremity, often atrophy in consequence of disuse

(MacIntyre, 2006). Thus, it should be considered whether it is helpful to include the category *s7702 Muscles* additionally in the Comprehensive ICF Core Set for OPD for the possibility to focus on musculoskeletal structures related to movement.

### 6.3 Activities and Participation

A considerable number of the participants' responses was linked to ICF categories assigned to the component *Activities and Participation*. Participation, meaning involvement in life situations and activities of daily living are often impaired in patients with OPD. Sports and leisure, habitual physical activity and sexual life, but also social activities and family life can be affected by the disease (Álvarez-Gutiérrez et al., 2007).

In this study, within the component Activities and Participation, many thirdlevel ICF categories were detected that are represented by second-level categories in the Comprehensive ICF Core Set for OPD. For instance, the categories d5701 Managing diet and fitness and d6400 Washing and drying clothes and garments are represented by the second-level categories d570 Looking after one's health and d640 Doing housework respectively. In fact, the participants' responses linked to the component Activities and Participation were often detailed listings of patients' problems in daily living, e.g. "staying away from work", "need to avoid provoking factors", "moving around in houses with stairs", "incompetent inhalation", "financial problem for long term oxygen therapy", "sexual life" and many more, so that the responses could be linked to the more detailed higher-level categories. However, of all categories identified from the participants' responses, only d5701 Managing diet and fitness and d5702 Maintaining one's health received an agreement of 70% and more in the third Delphi round, precisely 71.7% and 88.3% respectively. These two categories are represented in the Comprehensive ICF Core Set for OPD by the second-level category d570 Looking after one's health. Nutrition and exercise play an important role in the management of COPD since body mass index and exercise capacity are associated with disease progression and mortality (Celli et al., 2004; Landbo et al., 1999). Therefore, the category d5701 Managing diet and fitness constitutes an important part of patients' activities involving physicians as well. Many responses concerning patients' adherence to medication use, inhalation and avoiding of risk factors were linked to the category d5702 Maintaining one's health. Incorrect inhalator use is common among patients with asthma and COPD and reduces efficacy of therapy (Lavorini et al., 2008; Virchow et al., 2008). Thus, patients' compliance concerning inhalation and medication use is a major concern of physicians treating patients with OPD. Risk factor management, especially smoking cessation which also requires help and advice from physicians (GOLD, Updated 2008), is also included in the category d5702 Maintaining one's health. It could therefore be considered if the inclusion of this category in the Comprehensive ICF Core Set for OPD was useful.

#### 6.4 Environmental Factors

With 96.9%, the category with the highest confirmation within the component Environmental Factors, is e355 Health professionals. The category e450 Individual attitudes of health professionals was agreed upon by 89.7% of the participants. The category e5800 Health services, which is represented in the Comprehensive ICF core Set for OPD by the category e580 Health services, systems and policies, received an agreement of 85.0%. Health professionals and Health services play a crucial role in OPD management. Health professionals involved in the treatment and management of chronic airway diseases include primary care professionals, pulmonologists and other health professionals like physiotherapists, nurses and diet specialists (Garrod et Lasserson, 2007; Kuzma et al., 2008). Early diagnosis in patients at risk is most likely to be made by a primary care professional, as well as patient education concerning the recognition of symptoms and risk factors mostly come under primary care (Bellamy et Smith, 2007). Health services, according to the ICF, comprise prevention services, acute care, rehabilitation, long-term care, general and speciality hospitals, i.e. "services and programmes (...) aimed at delivering interventions to individuals for their physical, psychological and social wellbeing" (WHO, 2001). Access to health services is a central environmental factor for patients with chronic OPD and asthma.

Six third-level categories and one second-level category of the component *Environmental Factors* that are referring to climate and weather conditions were identified from the participants' responses, namely e2250 *Temperature*, e2251 *Humidity*, e2252 *Atmospheric pressure*, e2253 *Precipitation*, e2254 *Wind*, e2255 *Seasonal variation* and the second-level category e225 *Climate*. These categories received agreement rates of 31.0% to 67.8%. Climate and weather conditions are influential factors in the course of respiratory diseases (Kurmi et Ayres, 2007). For instance, cold weather is associated with an increase of hospital admissions of patients with COPD (Donaldson et al.,

1999) and cold air has been found out to be a potent bronchoconstrictor for many asthma patients, especially during physical effort (Gorjanc et al., 1999). Moreover, aeroallergens like pollen and air pollutants can worsen respiratory diseases (Kurmi et Ayres, 1999). Responses referring to these concepts were linked to the ICF category e2601 Outdoor air quality, which was agreed upon by 54.4% of the participants. The ICF category e2600 Indoor air quality received an agreement of 86.2% in the third Delphi round. Dusts and gases, allergens, cigarette smoke and chemicals like detergents influence indoor air quality in an occupational setting or at home. These environmental factors can aggravate the burden of respiratory diseases. Many of these factors affecting indoor air quality can be reduced by patient education and interventions (Chauhan et Johnston, 2003; Kurmi et Ayres, 2007). The corresponding second-level category e260 Air quality, which is included in the ICF Core set for OPD, received an agreement of 62.7% in the third Delphi round. Since there are numerous factors affecting obstructive pulmonary diseases subsumed under the category e2260 Air quality, an inclusion of the third-level categories e2600 Indoor air quality and e2601 Outdoor air quality in the Comprehensive ICF Core Set for OPD might be discussed.

### 6.5 Personal Factors

A large number of the participants' responses were identified as *Personal Factors* according to the ICF language. Personal factors are contextual factors that relate to the individual such as age, gender, education, coping styles, overall behaviour pattern, character style and individual psychological assets (WHO, 2001). However, they are not yet classified in the ICF. There is consensus in literature that personal factors like coping styles, self-efficacy, optimistic attitude etc. contribute to medical treatment and quality of life in patients with chronic OPD and asthma (Arnold et al., 2006; De Vries et Petermann, 2007; Kubzansky et al., 2002; Smith et al., 2007). It may therefore be helpful to provide a classification of these factors in future to enable a systematic identification of all personal factors influencing functioning of a certain person.

#### 6.6 Not classified

Seventeen responses of participants were found not to be covered by the ICF classification. Looking at these responses more closely, one can notice

that common problems, risks and important interventions in the treatment and management of OPD could not be classified as ICF categories. For instance, the items "exacerbations" and "prevention of exacerbations", "sputum" and "expectorations", "risk of carbon dioxide retention" as well as "lung function studies" and "COPD action plan" received high rates of agreement up to 100%. To improve the use of the ICF for physicians, an inclusion of these common and important, but yet unclassified items may be discussed and investigated in future.

It is noticeable that several categories – specifically categories assigned to the ICF components *Activities and Participation* and *Environmental Factors* – were named by the participants in the first Delphi round, but in the following rounds there was little consistency that these categories represented patients' problems treated by physicians. Some participants probably did not consider that they should only list aspects that are *treated by physicians*. However, this misunderstanding in the first Delphi round did not affect the final results substantially since the participants had the possibility to disagree with the respective categories in the following rounds.

### 7 Limitations

The Delphi technique proved to be an appropriate method for this study objective. In contrast to the mean attrition rates of 50% or higher from round to round reported in literature, response rates between the rounds ranging from 77 to 94 % were achieved in our study (Geschka, 1977; Race et Planek, 1992).

However, there are some limitations regarding the external validity of this study. Although the authors were successful in recruiting 76 physicians from 44 countries, the sample predominantly consists of physicians from Europe. Especially from the African, South East Asian and Eastern Mediterranean world region, only few physicians could be recruited. Therefore, this sample does not represent the whole spectrum of physicians experienced in the treatment of OPD patients worldwide.

Since no database includes the target population was available, random sampling was not possible. However, the impossibility of random sampling characterizes qualitative research methods in general and the Delphi method in particular (Hasson et al., 2000; Williams et Webb, 1994). Further validation

studies including physicians from countries not sufficiently represented in this study should be conducted.

### 8 Conclusion

Although minor shortcomings of the current version of the Comprehensive ICF Core Sets for OPD concerning the representation of several body functions and personal factors from the physicians' perspective could be detected in this study, the Comprehensive ICF Core Sets for OPD can be a useful method in clinical practice to enhance communication within multi-professional teams by referring to the common framework of the ICF model (WHO, 2001). The specific impairments, limitations of activities, restrictions in participation and influential environmental factors of an individual can be described on the basis of the Comprehensive ICF Core Set for OPD. Also, a functioning profile of the patient can be provided and used as a reference for follow-up. Since the treatment of chronic conditions such as OPD also requires a coordinated longitudinal care involving different health professions, a problem-solving approach like the one described by Steiner et al. (2002) that can structure the management among the different health professionals involved is needed. The Comprehensive ICF Core Set for OPD provides a useful starting point in such a process.

More results on the content validity of the Comprehensive ICF Core Set for OPD will be available from a currently finished study on the perspective of physical therapists.

Furthermore, the results of an ongoing worldwide multi-center data collection using the Comprehensive ICF Core Set for OPD will provide more information about the feasibility in clinical practice. These results would also demonstrate whether it was clinically relevant to further divide the Comprehensive ICF Core Set for OPD into subsets for asthma versus COPD. The data of all validation studies will serve as a basis for any further revision of the Comprehensive ICF Core Sets for OPD.

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# 10 Attachments (Anhang)

# 10.1 Comprehensive ICF Core Set for Obstructive Pulmonary Diseases

# **Body Functions**

ICF Code			ICF Category Title
2nd level	3rd level	4th level	
b130			Energy and drive functions
b134			Sleep functions
b152			Emotional functions
	b1522		Range of Emotion
b280			Sensation of pain
	b2801		Pain in body part
b310			Voice functions
b410			Heart functions
b430			Haematological system functions
b435			Immunological system functions
b440			Respiration functions
b445			Respiratory muscle functions
b450			Additional respiratory functions
b455			Exercise tolerance functions
b460			Sensations associated with cardiovascular and respiratory functions
b530			Weight maintenance functions
b730			Muscle power functions
b740			Muscle endurance functions
b780			Sensations related to muscles and movement functions

## **Body Structures**

ICF Code			ICF Category Title
2nd level	3rd level	4th level	
s410			Structure of cardiovascular system
s430			Structure of respiratory system
s710			Structure of head and neck
s720			Structure of shoulder region
s760			Structure of trunk

# **Activities and Participation**

ICF Code			ICF Category Title
2nd level	3rd level	4th level	
d230			Carrying out daily routine
d240			Handling stress and other psychological demand
d330			Speaking
d410			Changing basic body position
d430			Lifting and carrying objects
d450			Walking
d455			Moving around
d460			Moving around in different locations
d465			Moving around using equipment
d470			Using transportation
d475			Driving
	d4750		Driving human-powered transportation
d510			Washing oneself
d540			Dressing
d570			Looking after ones health
d620			Acquisition of goods and services
d640			Doing housework
d650			Caring for household objects
d660			Assisting others
d770			Intimate relationships
d845			Acquiring, keeping and terminating a job
d850			Remunerative employment
d910			Community life
d920			Recreation and leisure

## **Environmental factors**

ICF Code			ICF Category Title
2nd level	3rd level	4th level	
e110			Products or substances for personal consumption
e115			Products and technology for personal use in daily living
e120			Products and technology for personal indoor and outdoor mobility and transportation
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
e245			Time-related changes
	e2450		Day/night cycles
e260			Air quality
e310			Immediate family
e320			Friends
e340			Personal care providers and personal assistants
e355			Health professionals
e410			Individual attitudes of immediate family members
e420			Individual attitudes of friends
e450			Individual attitudes of health professionals
e460			Societal attitudes
e540			Transportation services, systems and policies
e555			Associations and organizational services, systems and policies
e575			General social support services, systems and policies
e580			Health services, systems and policies
e585			Education and training services, systems and policies
e590			Labour and employment services, systems and policies

# 10.2 Questionnaire of the First Delphi Round

Delphi Exercise Round 1	Health Profession: Physicians					
What are the patients' problems, patients' resources and aspects of environment treated by physicians in patients with chronic obstructive pulmonary disease and asthma (OPD)?						
Please list your answers in the following lin	es. problem, per patients' resource or per aspect of the environment.					
	Some information about yourself:					
	Age years Gender					
	Specialties/Certifications					
	Current professional activity					
	Professional experience years					
	Practical experience with patients with OPD? years					
	Do you treat OPD patients mainly in the					
	acute situation ? early-postacute situation ? chronic situation ?					
	How would you rate your expertise in the treatment of patients with OPD?					
	Please chose an number between 1 (low) and 5 (excellent)	64				

## 10.3 Questionnaire of the Second Delphi Round (first page)

## **Delphi Exercise Round 2**

## **Physicians**

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

ICF code	ICF category title	ICF category description	YES/NO
b110	Consciousness functions	General mental functions of the state of awareness and alertness, including the clarity and continuity of the wakeful state.	
b1263	Psychic stability	Mental functions that produce a personal disposition that is even-tempered, calm and composed, as contrasted to being irritable, worried, erratic and moody.	
b1265	Optimism	Mental functions that produce a personal disposition that is cheerful, buoyant and hopeful, as contrasted to being downhearted, gloomy and despairing.	
b1266	Confidence	Mental functions that produce a personal disposition that is self-assured, bold and assertive, as contrasted to being timid, insecure and self-effacing.	
b1300	Energy level	Mental functions that produce vigour and stamina.	
b1301	Motivation	Mental functions that produce the incentive to act; the conscious or unconscious driving force for action.	
b1302	Appetite	Mental functions that produce a natural longing or desire, especially the natural and recurring desire for food and drink.	
b134	Sleep functions	General mental functions of periodic, reversible and selective physical and mental disengagement from one's immediate environment accompanied by characteristic physiological changes.	
b1342	Maintenance of sleep	Mental functions that sustain the state of being asleep.	
b1343	Quality of sleep	Mental functions that produce the natural sleep leading to optimal physical and mental rest and relaxation.	

### 10.4 Questionnaire of the Third Delphi Round (first page)

#### Delphi | Exercise Round 3 **OPD Physicians** Taking into account the answer of the group and your individual answer in the second round, do you agree that this ICF category represents patients' problems, patients' resources or aspects of the environment treated by physicians in patients with OPD? ICF code ICF category title YES/NO ICF category description ID-number % agreement b110 Consciousness functions General mental functions of the state of awareness and alertness, 1, 2, 3, 8, 10, 11, 14, 17, 18, 73,85% including the clarity and continuity of the wakeful state. 19, 21, 22, 23, 26, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 42, 43, 44, 45, 46, 48, 49, 50, 54, 56, 57, 58, 60, 63, 64, 66, 67, 68, 69, 70, 74, 75 b1263 Psychic stability Mental functions that produce a personal disposition that is even-1, 2, 3, 8, 10, 11, 14, 17, 18, 73,85% 19, 21, 22, 23, 26, 28, 29, 30, tempered, calm and composed, as contrasted to being irritable, worried, erratic and moody. 31, 32, 33, 34, 35, 36, 37, 39, 40, 42, 43, 44, 45, 46, 48, 49, 50, 54, 56, 57, 58, 60, 63, 64, 66, 67, 68, 69, 70, 74, 75 70,77% b1265 Optimism Mental functions that produce a personal disposition that is cheerful, 1, 2, 3, 8, 10, 11, 17, 18, 19, buoyant and hopeful, as contrasted to being downhearted, gloomy and 21, 22, 23, 24, 26, 27, 29, 30, despairing. 31, 32, 33, 36, 37, 39, 40, 42, 44, 45, 46, 48, 50, 51, 56, 57, 58, 59, 60, 61, 64, 65, 66, 67, 68, 69, 70, 74, 75 b1266 Confidence Mental functions that produce a personal disposition that is self-2, 3, 8, 9, 10, 11, 17, 18, 19, 64,62% assured, bold and assertive, as contrasted to being timid, insecure and 21, 22, 23, 26, 27, 29, 31, 32, self-effacing. 33, 36, 37, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 50, 56, 57, 59, 60, 65, 66, 67, 68, 70, 74,

75

## 10.5 Results from the second and third Delphi Round

# **Body Functions**

ICF Cat	egory		ICF Category Title	<b>Round 2</b> n=65	Round 3 n=61
b110			Consciousness functions	73.8%	91.8%
	b1263		Psychic stability	73.8%	85.2%
	b1265		Optimism	70.8%	80.0%
	b1266		Confidence	64.6%	65.5%
b130			Energy and drive functions		
	b1300		Energy level	63.1%	66.1%
	b1301		Motivation	67.2%	76.7%
	b1302		Appetite	64.1%	65.5%
b134			Sleep functions	73.8%	86.4%
	b1342		Maintenance of sleep	75.0%	88.3%
	b1343		Quality of sleep	78.1%	91.7%
	b1470		Psychomotor control	56.9%	50.0%
b152			Emotional functions	58.5%	46.7%
	b1522		Range of emotion	47.7%	41.7%
b220			Sensations associated with the eye and adjoining structures	46.0%	29.5%
b280			Sensation of pain	74.6%	85.2%
	b2801		Pain in body part		
		b28010	Pain in head and neck	58.5%	55.0%
		b28011	Pain in chest	93.8%	93.4%
b310			Voice functions		
	b3400		Production of notes	34.9%	13.8%

ICF Category		ICF Category Title	<b>Round 2</b> n=65	Round 3 n=61
b410		Heart functions	87.5%	93.3%
	b4100	Heart rate	95.3%	95.1%
b415		Blood vessel functions	72.6%	80.0%
b420		Blood pressure functions	82.5%	88.1%
	b4200	Increased blood pressure	84.6%	91.7%
b430		Haematological system functions	84.4%	91.7%
	b4301	Oxygen-carrying functions of the blood	92.3%	95.0%
b435		Immunological system functions	89.1%	93.3%
	b4350	Immune response	85.9%	94.9%
	b4351	Hypersensitivity reactions	85.7%	93.2%
b440		Respiration functions	96.9%	98.3%
b445		Respiratory muscle functions	92.2%	98.4%
b450		Additional respiratory functions	90.6%	96.7%
b455		Exercise tolerance functions	96.6%	100.0%
	b4550	General physical endurance	85.9%	96.6%
	b4551	Aerobic capacity	87.3%	96.7%
	b4552	Fatiguability	82.8%	95.1%
b460		Sensations associated with cardiovascular and respiratory functions	90.8%	98.4%
	b5104	Salivation	51.6%	36.1%
	b5106	Regurgitation and vomiting	70.3%	66.1%
	b5153	Tolerance to food	56.9%	34.5%
b530		Weight maintenance functions	90.8%	96.6%
b540		General metabolic functions	70.8%	67.8%

ICF Category		ICF Category Title	<b>Round 2</b> n=65	Round 3 n=61
b545		Water, mineral and electrolyte balance functions	83.1%	94.8%
	b5500	Body temperature	72.3%	78.0%
b640		Sexual functions	64.6%	67.2%
	b6403	Functions of sexual resolution phase	34.4%	19.0%
b710		Mobility of joint functions	56.9%	57.6%
b730		Muscle power functions	64.6%	70.0%
b735		Muscle tone functions	54.7%	50.0%
b740		Muscle endurance functions	60.3%	62.1%
	b7651	Tremor	69.2%	62.7%
b780		Sensations related to muscles and movement functions		
	b7801	Sensation of muscle spasm	60.0%	59.3%
b810		Protective functions of the skin	58.5%	48.3%
b820		Repair functions of the skin	56.9%	46.7%

## **Body Structures**

ICF Category		ry	ICF Category Title	Round 2	Round 3
	ı	,		n=65	n=61
s410			Structure of cardiovascular system		
s430			Structure of respiratory system		
	s4301		Lungs	96.0%	98.1%
		s43011	Alveoli	87.8%	94.0%
s710			Structure of head and neck region		
s720			Structure of shoulder region		
s760			Structure of trunk		
	s7702		Muscles	80.0%	90.2%

# **Activities and Participation**

ICF Category		ICF	Category Title	Round 2	Round 3
				n=65	n=61
d230		Са	rrying out daily routine	58.5%	61.0%
d240			ndling stress and other psychological mand		
d330		Sp	eaking	35.4%	23.3%
d410		Ch	anging basic body position	58.5%	53.3%
	d4100	Lyi	ng down	48.4%	41.7%
	d4153	Ма	intaining a sitting position	45.3%	33.3%
	d4154	Ма	intaining a standing position	51.6%	43.3%
d430		Lif	ting and carrying objects		
	d4301	Ca	rrying in the hands	38.5%	23.3%
	d4302	Ca	rrying in the arms	41.5%	30.5%
	d4303	Са	rrying on shoulders, hip and back	38.5%	27.6%
d450		Wa	alking	60.9%	65.0%
d455		Мо	oving around	54.7%	48.3%
	d4551	Clii	mbing	53.1%	46.7%
d460		Мо	oving around in different locations	53.1%	50.8%
	d4601	Mo hor	oving around within buildings other than me	53.1%	45.8%
	d4602		ving around outside the home and other ildings	53.1%	49.2%
d465		Мо	oving around using equipment		
d470		Us	ing transportation	46.9%	39.0%
	d4702	Us	ing public motorized transportation	50.0%	44.1%
d475		Dri	iving		
	d4750	Dri	iving human-powered transportation		

ICF Category		ICF Category Title	Round 2 n=65	Round 3 n=61
	d4751	Driving motorized vehicles	44.4%	32.2%
d510		Washing oneself	51.6%	48.3%
	d5101	Washing whole body	49.2%	47.5%
	d5202	Caring for hair	39.1%	28.8%
d540		Dressing		
d570		Looking after one's health		
	d5701	Managing diet and fitness	69.8%	71.7%
	d5702	Maintaining one's health	76.6%	88.3%
d610		Acquiring a place to live	31.7%	20.7%
d620		Acquisition of goods and services		
	d6200	Shopping	35.4%	25.9%
d630		Preparing meals	39.1%	28.6%
d640		Doing housework	43.1%	31.0%
	d6400	Washing and drying clothes and garments	33.8%	22.4%
	d6401	Cleaning cooking area and utensils	33.8%	25.4%
	d6402	Cleaning living area	38.5%	28.8%
d650		Caring for household objects	31.3%	22.0%
d660		Assisting others		
d740		Formal relationships	36.9%	23.7%
	d7400	Relating with persons in authority	31.3%	21.1%
	d7500	Informal relationships with friends	31.7%	20.3%
d760		Family relationships	41.5%	37.3%
d770		Intimate relationships		

ICF Cate	egory	ICF Category Title	Round 2 n=65	Round 3 n=61
	d7702	Sexual relationships	49.2%	45.6%
d820		School education	29.7%	13.6%
d845		Acquiring, keeping and terminating a job		
	d8450	Seeking employment	46.9%	37.3%
	d8451	Maintaining a job	50.0%	49.2%
	d8452	Terminating a job	46.8%	43.3%
d850		Remunerative employment	42.2%	27.1%
d855		Non-remunerative employment	37.1%	15.3%
	d8700	Personal economic resources	33.3%	21.1%
d910		Community life		
	d9100	Informal associations	37.1%	20.3%
	d9101	Formal associations	29.0%	13.6%
d920		Recreation and leisure	52.4%	53.3%
	d9200	Play	37.5%	26.7%
	d9201	 Sports	49.2%	41.7%
	d9202	Arts and culture	32.8%	18.3%
	d9204	Hobbies	34.4%	21.7%
	d9205	Socializing	40.6%	25.4%

## **Environmental Factors**

ICF Cate	egory	ICF Category Title	Round 2	<b>Round 3</b> n=61
e110		Products or substances for personal consumption		
	e1100	Food	58.7%	57.6%
	e1101	Drugs	79.4%	86.4%
e115		Products and technology for personal use in daily living	54.7%	51.7%
	e1151	Assistive products and technology for personal use in daily living	68.8%	74.1%
e120		Products and technology for personal indoor and outdoor mobility and transportation		
e135		Products and technology for employmen	t 41.3%	24.6%
e140		Products and technology for culture, recreation and sport	36.5%	24.1%
e150		Design,construction and building products and technology of buildings for public use	33.3%	20.7%
e155		Design, construction and building products and technology of buildings for private use	38.1%	22.4%
	e1650	Financial assets	28.6%	15.5%
	e2200	Plants	33.9%	17.9%
	e2201	Animals	33.3%	17.5%

ICF Category		ICF Category Title	Round 2 n=65	Round 3 n=61
e225		Climate	52.4%	51.7%
	e2250	Temperature	59.4%	67.8%
	e2251	Humidity	58.1%	64.9%
	e2252	Atmospheric pressure	38.1%	31.0%
	e2253	Precipitation	36.5%	27.6%
	e2254	Wind	34.9%	27.6%
	e2255	Seasonal variation	53.2%	54.2%
e235		Human-caused events	37.1%	22.4%
e245		Time-related changes		
	e2450	Day/night cycles		
e260		Air quality	59.4%	62.7%
	e2600	Indoor air quality	75.8%	86.2%
	e2601	Outdoor air quality	58.3%	54.4%
e310		Immediate family	47.6%	37.9%
e315		Extended family	27.4%	14.0%
e320		Friends		
e340		Personal care providers and personal assistants		
e350		Domesticated animals	49.2%	36.8%
e355		Health professionals	81.0%	96.6%

ICF Category		ICF Category Title	Round 2 n=65	Round 3 n=61
e410		Individual attitudes of immediate family members	51.7%	50.0%
e415		Individual attitudes of extended family members	39.7%	29.3%
e420		Individual attitudes of friends		
e450		Individual attitudes of health professionals	71.4%	89.7%
e460		Societal attitudes	43.5%	33.9%
e465		Social norms, practices and ideologies	34.9%	24.6%
e540		Transportation services, systems and policies	38.7%	27.6%
	e5502	Legal policies	30.6%	16.9%
e555		Associations and organizational services, systems and policies		
	e5550	Associations and organizational services	50.0%	50.8%
e570		Social security services, systems and policies	52.4%	51.7%
	e5700	Social security services	56.5%	56.7%
e575		General social support services, systems and policies	57.1%	61.7%
	e5750	General social support services	54.8%	62.7%
e580		Health services, systems and policies		
	e5800	Health services	77.6%	85.0%

ICF Category		ICF Category Title	Round 2 n=65	Round 3 n=61
	e5801	Health systems	66.7%	76.7%
	e5802	Health policies	63.5%	69.0%
e585		Education and training services, systems and policies		
e590		Labour and employment services, systems and policies		

## **Personal Factors**

Linking	<b>Round 2</b> (n=64)	<b>Round 3</b> (n=61)
	% agreement	% agreement
Patient's knowledge about the disease	98.4	100.0
Patient's knowledge about risk factors	100.0	100.0
Patient's knowledge about medication	98.5	100.0
Understanding of inhaler techniques	95.4	100.0
Understanding principles of therapy	96.9	100.0
Expectations towards treatment	90.8	100.0
Expectations towards activity	89.2	100.0
Barrier to use oxygen when going outside (embarrassment)	93.8	98.3
Corticophobia	85.7	96.6
Being prone to inactivity	89.2	95.0
Feeling helpless	84.6	95.0
Coping	87.1	94.8
Self-control	80.0	91.7
Living will	75.4	90.0
Uncertainty of the future	80.0	89.8
Loss of independence/autonomy	69.2	77.2
Living conditions	56.9	58.3
Poor education	50.8	45.8
Low social status/poverty	46.2	36.7

## Not covered

Linking	Round 2	Round 3
	(n=64)	(n=61)
	% agreement	% agreement
Oedema	95.4	100.0
Exacerbations	100.0	100.0
Sputum/phlegm/expectorations	100.0	100.0
Late/inadequate diagnosis	93.8	100.0
Prevention of exacerbations	98.5	100.0
Lung function studies	93.8	100.0
Dosing schedules of medications	95.4	100.0
Mortality	90.8	100.0
Risk of carbone dioxide retention	92.3	98.3
COPD action plan	92.3	96.6
Allergens and asthma triggers	90.8	96.6
Education of patient/patients' family	90.8	96.6
Knowledge and training of health professionals	90.8	96.6
Mismatch between symptoms and blood gas	76.9	89.7
Allergy tests	78.5	86.0
Research opportunities	72.3	80.4
Genetic components of OPD and family screening	73.8	76.8

#### 10.6 ICF Definitions

**Body Functions** are the physiological functions of the body systems (including psychological functions).

**Body Structures** are the anatomical parts of the body such as organs, limbs and their components.

**Impairments** are problems in body function or structure such as a significant deviation or loss.

Activity is the execution of a task or action by an individual.

**Participation** is involvement in a live situation.

**Activity limitations** are difficulties an individual may have in executing activities.

**Participation restrictions** are problems an individual may experience in involvement in life situations.

**Environmental Factors** make up the physical, social and attitudinal environment in which people live and conduct their lives.

#### 10.7 Curriculum Vitae

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