Aus dem Institut für Medizinische Informationsverarbeitung, Biometrie und Epidemiologie der Ludwig-Maximilians-Universität München

Lehrstuhl für Public Health und Versorgungsforschung
Direktor: Prof. Dr. rer. nat. Ulrich Mansmann

Validation of the International Classification of Functioning, Disability and Health (ICF) Core Set for Diabetes Mellitus: a Worldwide Delphi Survey Among Physicians.

Dissertation
zum Erwerb des Doktorgrades der Medizin
an der medizinischen Fakultät der
Ludwig-Maximilians-Universität zu München

vorgelegt von
Silvia Margarete Müller
aus Kulmbach
2014

Mit Genehmigung der medizinischen Fakultät
der Universität München

Berichterstatter:	Prof. Dr. rer. biol. hum. Alarcos Cieza, MPH
Mitberichterstatter:	Prof. Dr. med. Hans Uwe Janka
Mitbetreuung durch den promovierten Mitarbeiter:	Dr. rer. biol. hum. Inge Kirchberger, MPH
Dekan:	Prof. Dr. med. Dr. h.c. Maximilian Reiser, FACR, FRCR
Tag der mündlichen Prüfung:	16.01.2014

Danksagung

Mein herzlichster Dank gilt meiner Doktormutter Frau Professor Dr. Alarcos Cieza für die Möglichkeit diese Promotionsarbeit übernehmen und beenden zu dürfen. Ich bedanke mich außerdem sehr für Ihre hervorragende Betreuung, die gute Zusammenarbeit sowie für die herzliche Aufnahme in das Team.

Ein sehr großes Dankeschön geht an meine Betreuerin Frau Dr. Inge Kirchberger für ihre herausragende Unterstützung und der wahrlich perfekten Begleitung während der gesamten Studie sowie der stets bestehenden Erreichbarkeit bei Fragen und Erstellung der Promotionsarbeit insbesondere Ihrer Geduld und individuellen Beratung.

Außerdem geht mein Dank an Frau Dr. Andrea Gläßel und Frau Dr. Catherine Glocker für die sehr gute Zusammenarbeit am Linking Prozess im Rahmen der Studie.

Dem gesamten Team des Instituts möchte ich für seine ausgezeichnete Mitarbeit und Hilfsbereitschaft danken.

Mein ganz besonderer Dank geht an meine Eltern und meinen Partner Herrn Stefan Göz, M.A., für die unermüdliche Unterstützung und den tiefen Glauben an mich sowie an Herrn Prof. Dr. Burkard Lippert für den bedeutenden Rückhalt.

Schließlich danke ich recht herzlich allen Teilnehmern der Studie.

Table of Contents

Inhaltsverzeichnis

1 German abstract (Deutsche Zusammenfassung)

Hintergrund: Zur klinischen Anwendung der Internationalen Klassifikation von Funktionsfähigkeit, Behinderung und Gesundheit (ICF) wurde das „Umfassende ICF Core Set für Diabetes mellitus (DM)“ entwickelt. Es repräsentiert das typische Spektrum von Funktionsproblemen bei Patienten mit Diabetes mellitus.

Ziel: Die Validierung des umfassenden ICF Core Set für Diabetes mellitus (DM) aus der Perspektive von Ärzten war Ziel dieser Studie.

Methoden: Es wurden erfahrene Ärzte zu Problemen, Ressourcen der Patienten und Umweltfaktoren, welche bei der Behandlung von Patienten mit Diabetes mellitus relevant sind, befragt. Die Befragung erfolgte anhand der Delphi-Methode in drei Runden via elektronische Post (E-Mail). Die Antworten der Experten wurden nach definierten Regeln von zwei darin erfahrenen Mitarbeiterinnen in die Fachsprache der ICF übertragen. Der Grad der Übereinstimmung dieser Ergebnisse wurde mit dem Kappa-Koeffizienten berechnet.

Resultate: 84 Ärzte aus 38 Ländern nannten 1220 Probleme von Patienten mit Diabetes mellitus, die alle Komponenten der ICF abdeckten. Die Antworten wurden 212 ICF Kategorien zugeordnet. Von diesen Kategorien waren 22 bislang nicht im „Umfassenden ICF Core Set für Diabetes mellitus (DM)“ erfasst, obwohl mindestens 75% der Teilnehmer diese als wichtig erachteten. 45 Antworten wurden der noch nicht klassifizierten Komponente der „Personenbezogenen Faktoren“ zugeordnet und 11 Sachverhalte wurden durch die ICF Klassifikation nicht abgedeckt.

Schlussfolgerung: Die Validität des „Umfassenden ICF Core Set für Diabetes mellitus (DM)“ wurde von der teilnehmenden Ärzten für die Komponenten „ Aktivität und Teilnahme“ und „Umweltfaktoren“ größtenteils bestätigt. Die Komponente der „Körperfunktionen“ und der „Körperstrukturen“ fand hingegen weniger Unterstützung. Es zeigten sich einige Antworten und Sachverhalte, die weiterer Untersuchung bedürfen.

2 Abstract

Aims: The Comprehensive ICF Core Set for diabetes mellitus (DM) is a specific application of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization for clinical and research purposes involving the disorder. It represents the typical spectrum of problems in functioning of patients with DM. The objective of this study was to validate the Comprehensive ICF Core Set for DM from the perspective of physicians.

Methods: A three-round electronic-mail survey using the Delphi technique was conducted. Physicians experienced in DM treatment were asked about the patients' problems, patients' resources and aspects of environment that physicians took care of. The responses were linked to the ICF.

Results: 84 physicians in 38 countries named 1220 patients' problems that covered all ICF components. 212 ICF categories have been linked to these answers. 22 ICF categories were not represented in the Comprehensive ICF Core Set for DM although at least 75% of the participants have rated them as important. 45 answers have been linked to the not yet developed ICF component *Personal Factors* and 11 categories were not covered by the ICF classification.

Conclusion: The validity of the ICF components *Activities* and *Participation* and E*nvironmental Factors* has almost perfectly been supported by the physicians whereas there has been less support for the validity of the components *Body Structures* and *Body Functions*. Several issues arose that are not covered and need to be investigated further.

3 Introduction

3.1 Definition, epidemiology, pathogenesis and classification of DM

Diabetes mellitus (DM) is characterized as a collective term for various metabolic diseases. Strictly speaking DM is a clinical syndrome connected to chronic hyperglycaemia due to deficiency and/or impaired effectiveness of insulin action and the risk of serious organ damage up to failure over time (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003; Alberti et Zimmet, 1998).

Already 1500 BC references to diabetes were written by ancient Egyptian physicians in the Ebers Papyrus when they describe diabetic symptoms without naming the disease (Papaspyros, 1964). In the following centuries and millennia, notably in the 19th century, the understanding of interweaved aspects of diabetes arose and the handling with diabetes mellitus and new insulin preparations developed (Ahmed, 2002; Zajac et al., 2010).

In every region of the world you can find individuals with DM. The leading countries are China, India and the United States of America (IDF, 2011). Current data from the World Health Organization and the International Diabetes Federation show that more than 347 million people suffer from DM worldwide (WHO, 2013). Predictions are that the world prevalence among 20-79 years old adults will increase up to 439 million adults by 2030, or 7.7% of the analog population. The International Diabetes Federation prognosticates for 2030 even 552 million people suffering from diabetes (IDF, 2011; Shaw, 2010). So far, adults aged between 40-59 years represent the major division of individuals suffering from DM. Actually, the difference in gender plays not a major role. In 2030 it is predicted that 275 million women and 277 million men will have DM (IDF, 2011). However, the prevalence in men is expected to be higher than in women (Wild, 2004).

Another important group are children and adolescents because the incidence of DM, particularly type 1 diabetes, is increasing in this age group in many populations worldwide. Annually, about 78,000 children under the age of 15 worldwide are expected to develop type 1 diabetes. Furthermore, there is

an increasing number of children and adolescents with type 2 diabetes most likely due to the progressive prevalence of obesity and lack of activity (Fagot-Campagna, 2000; IDF, 2011; Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003).

The etiologic classification splits DM into four groups (Powers, 2004): type 1 diabetes, type 2 diabetes, gestational diabetes mellitus (GDM) and other specific types due to other causes e.g. genetic defects of ß-cell function also known as Maturity-onset-diabetes of the young, MODY (Olek, 2006), genetic defects in insulin action and secondary diabetes. The latter one compromises inflammatory or neoplastic diseases in exocrine pancreas, endocrinopathies like acromegaly or Cushing's syndrome, drug- or chemical-induced diabetes caused by nicotinic acid or glucocorticoids (Powers, 2004), infections like congenital rubella or cytomegalovirus, uncommon forms of immune mediated diabetes like the "Stiff-man"-syndrome or other genetic syndromes sometimes associated with diabetes like Down's syndrome, Klinefelter's syndrome or Turner's syndrome. Based on this etiologic variety the development of DM is caused by several pathogenetic processes originating from an inadequate effect of insulin on target tissues (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003).

Furthermore, there exist intermediate levels of glucose intolerance like impaired glucose tolerance (IGT) and impaired fasting glucose (IFG). Therefore, individuals with these intermediate levels do not suffer from DM. These types share some characteristics with type 2 diabetes, e.g. the connection with excessive weight increase, insulin resistance and insulin secretory malfunctions. They have a much higher risk for developing type 2 diabetes and cardiovascular disease (CVD) in the following years (Alberti, 1996; IDF, 2011).

Type 1 diabetes shows a deficiency of insulin secretion because of a cellular-mediated autoimmune destruction of the insulin-producing ß-cells of the pancreas. It appears in 5-10% of those with diabetes, particularly in children, but it may occur in any age of life. Additionally, this form could also arise idiopathic without any indication of autoimmunity (ADA, 2012). Currently, no prevention is known partly because the mechanism of type 1 diabetes is not

fully understood. Nevertheless this form of DM is an established endocrine and metabolic disease in childhood (IDF, 2011; WHO, 2013).

In relation to all diabetes cases type 2 diabetes represents up to 95%. An essential characteristic of this form of diabetes is its wide spread range from insulin resistance with relative insulin deficiency to an insulin secretory defect. In general, type 2 diabetes appears after the age of 40 years. The appearance and the manifestation of type 2 diabetes are noticeably associated with a lack of physical activity and obesity or increased percentage of visceral body fat (ADA, 2012; WHO, 2013). This intraabdominal fat, the emerging insulin resistance towards the insulin-dependent tissues like the muscle-cells and the compensatory hyperinsulinaemia in tissues leads to metabolic disorders and finally to the metabolic syndrome. This syndrome is a cluster of associated risk factors and goes along with type 2 diabetes, atherosclerosis and cardiovascular diseases (Duvnjak et Duvnjak, 2009).

In addition, it is important to look at the DM occurrence in a family due to the high heritability. The pathogenesis of type 2 diabetes is a result of environmental and multiple genetic factors. In the last years several studies have identified a multiplicity of susceptibility loci of the genome associated with type 2 diabetes (Sladek et al, 2007; Palmer et al, 2012; Patel et al, 2013; Scott et al, 2007; Sanghera et Blackett, 2012; Unoki et al, 2008). Although there is a clearly strong genetically incidence, the exact pathway of heredity is not identified yet (Hansen, 2003). However, a risk prediction for developing type 2 diabetes in adults based only on the analysis of the genes should currently not be supported due to less specificity (Vassy et Meigs, 2012).

The worldwide increase in incidence and the long-term consequences of this illness make DM a medical problem first grade (Harris et al, 1998; Geiss et al, 2006). Moreover, it is an expensive disease. In 2011 about 11% of the worldwide total healthcare expenditures refer to DM. Considering global differences in purchasing power, the global expenditures expressed in International Dollars (ID) were 499 billion in 2011. It is estimated that 2030 this rate will increase to ID 654 billion. In contrast to the world’s economically richest countries the developing countries have to pay a larger percentage of the accumulating expenditures because their medical care systems are less developed. In addition, the loss in productivity and economic growth due to the

loss of gains, work days, a lower productivity at work, mortality and the disability induced by DM costs even more billion US Dollars. The largest economic damage regarding DM is followed from disability, loss of life and the diabetes complications (IDF, 2011).

3.2 Clinical features, complications and treatment of DM

Currently, three criteria for the diagnosis of DM exist: elevated fasting glucose, abnormal oral glucose tolerance test and elevated random plasma glucose concentration with symptoms of DM.

The symptoms of DM could be just as various as their complications and are mostly accompanied by them (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003; Alberti et Zimmet, 1998). They appear in people with type 1 diabetes almost immediately and severe with hyperglycaemia and ketoacidosis (ADA, 2012; IDF, 2011). In contrast, people with type 2 diabetes often develop hyperglycaemia rather successively and in stages. Since typical symptoms are often less pronounced, the diagnosis of type 2 diabetes may be delayed (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003). The typical appearance of people with type 2 diabetes is an overweight person. Diabetic symptoms include in many cases unspecific general symptoms like fatigue, loss of efficiency, abnormal appetite and sweating. Polyuria and polydipsia are the consequences of osmotic diuresis resulting for glucosuria as well as the following thirst (WHO, 2013; Roche et al, 2005). Some patients with hidden DM are incidentally diagnosed by skin infections or infections of the urinary or genital tract (Fonseca et John-Kalarickal, 2010). Furthermore, the quality of life in men with DM could be impacted by modified sexual dysfunction, which exists in more than 50% of patients with DM (Penson et al, 2003).

A familiar problem in diabetic patients is the cutaneous appearance of DM with a frequency of about 30% in the course of the disease (Ahmed et Goldstein, 2006). The skin involvement shows many different shapes like the rare disease necrobiosis lipoidica diabeticorum (Pestoni et al, 2003) or the most common diabetic dermopathy (Shemer et al, 1998). Furthermore,

diabetic pharmacological management e.g. with Sulfonylureas or Insulin can provoke unrequested skin reactions with pruritus, erythema and lipoarthophy or allergic skin reactions (Sood et James, 2000). The dreaded skin problem of the so-called diabetic foot is the result of manifold pathological processes and develops because of diabetic neuropathy with motoric and sensory involvement, insufficient blood circulation and ischaemia. Mostly there is an initiating injury which results from thermal, acute or chronical mechanical origin (Boulton, 1988; Cavanagh et al, 2005) combined with concomitant risk factors resulting in an exacerbated and complicated infection of the foot ulcer to limb or even life-threatening situations (Hampton, 2006).

Additionally, there is a rare development due to complex changes of the diabetic foot into the transformation to a charcot foot with bone and joint destruction and following foot deformity (Rajbhandari et al, 2002). Despite of the availability of good foot care management there is a 15 times higher overall risk of amputation compared to persons without DM (Most et Sinnock, 1983). However, the dermatological problems of patients with DM are in a lot of cases bacterial and candidal skin infections (Ahmed, Muhammad et Qayum, 2009) regularly seen in poorly controlled diabetics. Potential reasons for the disposition for infections are again complex and range from vascular insufficiency and neuropathy to impairment of immune response (Ahmed et Goldstein, 2006; Wheat, 1980).

Over the time DM can damage many different organs and tissues in the body, which leads to various acute or chronic complications. Due to the delayed diagnosis in lots of people with undetected and initially asymptomatic type 2 diabetes, the first recognized disorders could be characteristics of the so far hidden and associated complications. These problems and complications are basically related to damages of the vasculature called macro- and microangiopathy (Alberti et Zimmet, 1998). The morbidity, the mortality and the disability in people with type 2 diabetes are highly associated with macrovascular problems including coronary arterial disease, cerebrovascular disease as well as peripheral vascular disease. Arteriosclerosis and consequently macroangiopathic conditions arise earlier and more rapidly in people with DM because of the high influence of hyperglycaemia, hyerinsulinaemia and insulin resistance (Massi-Benedetti et

Federici, 1999; UKPDS Group, 1998; Nishimura, 2011). DM has a multiplying effect on the cardiovascular risk in the presence of other cardiovascular risk factors like hypertension or dyslipidaemia. Due to the fact that the cardiovascular disease is the main reason of morbidity and mortality in DM there is a need to include glycaemic control to the relevant variables like the classical risk factors as blood pressure, dyslipidaemia and smoking to appraise the cardiovascular disease and atherosclerosis risk (Fuller et al, 2001; Avogaro,2007; Sowers, 2001). Not only the higher risk to get a myocardial infarction compared to the general population but also the one-year mortality after a myocardial infarction is notably higher in patients with DM. Furthermore, succumbing sudden cardiac death is more likely in diabetic patients with a myocardial infarction and also having an increased risk of death from cardiovascular disease is more frequent as in non-diabetics (Pappone et Santinelli 2010; Boudina et Abel, 2010; Miettinen et al, 1998). Particularly diabetic women have a higher possibility of death from stroke and in association with that the duration of DM collaborates to the risk of sustaining a stroke. A reduction as little as 5 - 6 mmHg of the diastolic blood pressure is connected with one-third fewer strokes and one-fifth fewer coronary heart disease events (MacMahon, 1990; Almdal, 2004; Tuomilehto, 1996).

The microangiopathy, the damage of the small vasculature strongly correlates with the duration of DM, glycaemic control as well as blood pressure and lipid control (Girach et al, 2006; Girach et Vignati, 2006). Endothelial dysfunction and a lot of other complex intracellular signaling mechanisms induce complications in different parts of the body and the outcomes include the characteristic diabetic nephropathy, diabetic retinopathy, diabetic neuropathy and small vessel disease (Hadi et Suwaidi, 2007; UKPDS Group, 1998).

The worldwide increased incidence of diabetic nephropathy shows that in developed countries up to 50% of the patients with end-stage renal disease (ESRD) are patients with DM (Ritz et al, 2011). Main predictors of diabetic nephropathy up to ESRD are progressive albuminuria, high blood pressure, smoking and poor glycaemic control. The first clinical sign of diabetic renal affection is microalbuminuria, which should signalize the start of appropriate interventions in order to prohibit the development of nephropathy. It is also an

important risk factor for coronary heart disease and stroke in patients with DM because this marker reflects endothelial dysfunction and elevated oxidative stress. The complexity of pathogenesis and evolution of the diabetic nephropathy leads to multi-level interventions in therapy to avoid the threatened and often deadly ESRD and the potential early haemodialysis or renal transplantation (Ritz, 2006; Ritz et Tarng, 2001; Hadi et Suwaidi, 2007).

A further microvascular complication is the diabetic retinopathy. It is more precisely characterized as nonproliferative or proliferative retinopathy with typical vascular modifications in the funduscopic examination. Its development is strongly dependent on the duration of hyperglycaemia and DM. After 15 years of DM visual impairment and the prevalence of proliferative diabetic retinopathy increases up to 25%. Even 1 % suffers from blindness globally due to diabetic changes (WHO, 2012; Cowie et al, 2006). The treatment and prevention strategies to lower the risk of developing and exacerbating diabetic retinopathy and preventing severe vision loss range from control of blood pressure and blood sugar, several medications to laser photocoagulation and vitrectomy (Wilkinson-Berka et Miller, 2008).

Microvascular complications also affect different parts of the nervous system resulting in diabetic neuropathy. At the time of DM diagnosis the prevalence is about 10% (Boulton et al, 2005). Thomas (1997) and Boulton et al (2005) classify diabetic neuropathy into generalized symmetric polyneuropathies, focal and multifocal neuropathies. The most common diabetic neuropathies are the chronic sensorimotor distal polyneuropathy (DPN) and the autonomic neuropathy (DAN) which belongs to the generalized symmetric polyneuropathies. The typical symptoms of DPN like burning and stabbing pain, electrical sensations, paraesthesia or hypersensitivity are commonly located in the lower limbs and in the feet. A careful clinical examination is necessary in order to discover problems such as sensory loss of vibration, pressure, pain and temperature. Loss of ankle reflexes, autonomic dysfunctions like warm or cold feet, dry skin, wound healing disorders and painless ulcers are also characteristic signs (Boulton et al 2005). The diabetic autonomic neuropathy (DAN) regarding the sympathetic and parasympathetic nervous system influences a variety of organ systems. DAN is associated with increased mortality not least due to that fact that the autonomic neuropathy

affects the cardiovascular system (CAN) and can induce silent myocardial ischaemia and cardiovascular death. Possible further complications are related to the gastrointestinal tract, the sexual organs or could appear as unsuspicious symptoms like anhidrosis or just dry skin (Vinik et al, 2003).

Regarding the possible acute complications of DM the diabetic ketoacidosis (DKA) and hyperosmolar hyperglycaemic state (HHS) have to be considered. The clinical presentation of these patients is heterogeneous, ranging from thirst, nausea, vomiting, abdominal pain, increased urinary excretion, dehydration with signs of shock, weakness to dizziness resulting in coma and in case of DKA additionally with a sweet acetone-like breath and a rapid Kussmaul respiration. The mortality rate in DKA is in maximum 5% and in HHS about 15% (ADA, 2001). The factor that mediates decompensation possibly leading to multiple organ failure, brain edema and death is relative or absolute insulin deficiency. Infections like pneumonia, several medications like corticosteroids or simply an irregular use of insulin could start these severe metabolic disturbances. The treatment should be in an intensive care setting with an aggressive rehydration, electrolyte adjustment and particularly in case of DKA, efficient use of insulin and correction of the metabolic acidosis (Kitabchi et al, 2001).

A differential diagnosis of the diabetic comatose state is the hypoglycaemic coma. The blood glucose level decreases below 30 mg/dl (circa 1.6 mM/L) and can produce seizures and neurologic problems leading to death. In fact for patients suffering from DM hypoglycaemia with neurogenic and neuroglycopenic symptoms is a common problem because of e. g. insufficient insulin management, missed food uptake or increased exercise without adapting the antidiabetic drugs (McAulay et al, 2001; Davis 2010).

The treatment of DM as a chronic disease is complex und multifactorial. All aspects of prevention to avoid type 2 diabetes, to avoid and treat metabolic disorders und to treat diabetes-related illnesses have to be considered. A multidisciplinary physician-led cooperation is essential including diabetologists, endocrinologists, general practitioners, podiatrists, nurses, dental specialists, dietitians, physical therapists, rehabilitation specialists and other health professionals with expertise in DM. Diabetes associations and the national

health care system make also important contributions. The American Diabetes Association (ADA) established clinical practice recommendations and the International Diabetes Federation (IDF) developed a global guideline for type 2 diabetes. Additionally to the extended medical care the diabetes self-management by each patient is essential (Funnell, 2012; IDF, 2012; ADA, 2013).

The main target of treatment in DM is glucose monitoring; particularly the self-monitoring of blood glucose (SMBG) is a component of effective therapy. As a glycaemic goal the A1C level, as an index of chronic glycaemia, should stay below 7%. Depending on the value of hyperglycaemia or new-onset type 2 diabetes, an oral glucose lowering medication has to start if lifestyle interventions such as weight loss, dietary change and increased physical activity failed to stabilize the target levels of blood glucose. The so-called first line therapy includes medication with one oral agent e.g. metformin. In the second line up to fourth line therapy the addition of other oral agents like sulfonylurea or the addition of insulin is recommended (IDF, 2012; ADA, 2013). Moreover, screening and treatment of DM complications is indispensible as well as the preventive treatment options like medical nutrition therapy (MNT), diabetes self-management education (DSME), psychosocial assessment and care, immunization against special infections or even the possibility of bariatric surgery. To optimize interventions aimed at maintaining functioning and minimizing disability, a proper understanding of the patients' functioning and health status is needed.

3.3 The International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health (ICF) belongs to the international classifications developed by the World Health Organization (WHO). Based on a revision of the International Classification of Impairments, Disability and Handicaps (ICIDH) published in the 1980s, in May 2001 the ICF was announced for international use by the 54th World Health Assembly. Health conditions, diseases and disorders are basically represented in the worldwide well-known tenth revision of

International Classification of Diseases (ICD-10) to schedule them and to provide a diagnosis which is used as a diagnostic implement for health management, clinical purposes and epidemiology (WHO, 2011). Complementary to the ICD-10, the ICF reflects functioning and disability which are indispensable connected to each health condition. The ICF provides detailed and systematic information about all bio-psycho-social aspects of consequences of illnesses and disorders in consideration of the relevant contextual factors. To describe sufficiently health states and the need of rehabilitation resulting from all different disorders the ICF complements the ICD-10. Using both classifications, the health status of the population can be specified and compared at national and international levels.

The ICF aims at generating a uniformed language and a standardized coding scheme for the description and classification of health and health-related states to develop and improve the communication between health professionals, researchers as well as the public. It also provides a universal framework for health information systems and health outcome measurement (WHO, 2001). The application of the ICF is diversified and comprehensive. It is used e.g. in the statistical, research, clinical or social policy sector as well as in the scope of insurance, education, economical or environmental modification. Overall, the aims of the ICF are orientated towards an understanding of the patient's needs and situation to improve therapy and rehabilitation.

The ICF organizes information regarding human functioning and its limitations in two parts. The first part deals with functioning and disability which is divided into *Body Functions (b)* and *Body Structures (s)* as well as *Activities and Participation (d).* In the second part the Contextual Factors are included which are split in two parts *Environmental Factors (e)* and *Personal Factors*. Regarding their association with social and cultural variety *Personal Factors* in the ICF such as gender, habits, coping style, age or education are not classified yet. The component *Body Functions* refers to the physiological and psychological alterations of the body, whereas *Body Structures* describe changes in the anatomical parts like organs or extremities. Both components are created to work together side by side.

The component *Activities and Participation* deals with tasks and actions of a person and consequently with the possibility to execute, perform and to have the capacity to do them including the individual and environmental perspective. The distance between capacity and performance to solve problems in an individual demonstrates effectively what can be done to the environment to optimize the performance. The component *Environmental Factors* represents external influences on functioning and disability of an individual which facilitate or cumber physical, social and psychic issues. These influences can be found in the direct environment of a person like home, workplace and school and include also social structures, services such as organizations, government agencies and laws (WHO, 2001).

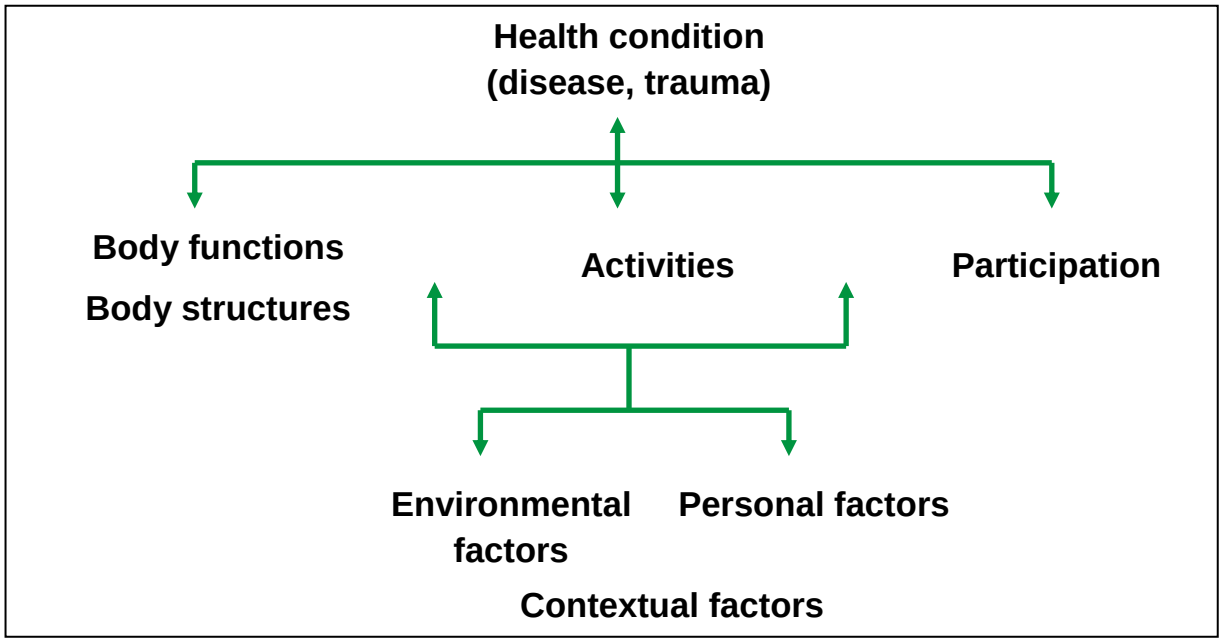

Figure 1: The integrative biopsychosocial model of the ICF (WHO, 2001)

This multidimensional approach to merge different perspectives of health and health-related problems is described as a biopsychosocial model arising from synthesis of the medical model and the social model. *Body Functions* and *Body Structures* as well as *Activities and Participation* interact between the *Health condition* as a disorder or disease and the Contextual Factors *Environmental Factors* and *Personal Factors* (see figure 1).

The ICF is systematically organized with the help of interlinked levels and hierarchic alignment. Each component has a letter code for characterizing (*b*, *s*, *d* and *e*) and consists of a numeric succession of chapters which are arranged in a reasonable way and suitable to their common characteristics. This sequence of chapters represents the first level of classification. Within every chapter more detailed levels can be reached. The ascending second, third and fourth level in each component describes even more specific the human functioning and disability. Hence, the letter abbreviation for each component is followed by a numeric code consisting in a maximum of five digits representing the levels. Therefore, more detailed higher-leveled categories comprise all the aspects applicable for the lower-leveled category of which it is a member, but not contrariwise. Figure 2 shows the general structure of the ICF as a stem-branch-leaf-order.

To complete the ICF code the severity of the health condition is marked as a number ranging from zero to four. This number, known as *qualifier*, is added after a point to the relevant category and is increasing with the seriousness of the disease (WHO, 2001).

The application of this full length ICF classification with 1454 categories in clinical routine is illustrated for a number of health conditions, including DM, with the development of simplified versions, namely the ICF Core Sets (Ruof et al, 2004). A collaborative project of the ICF research branch of the WHO FIC Collaborating Center (DIMDI) at the Department of Physical Medicine and Rehabilitation of the Ludwig-Maximilians-University in Munich with the Classification, Assessment, Surveys and Terminology Group (CAS) of WHO and several worldwide partner organizations evolved from the whole ICF classification this internationally accepted and empirically based ICF Core Sets (Üstün et al, 2004; Stucki et Grimby, 2004; Cieza et al, 2004; Stucki et al, 2002).

These lists of ICF categories for specific conditions can serve as Comprehensive ICF Core Sets which contain the characteristics and detailed scope of problems in functioning in patients relating to the corresponding health-state e.g. to guide multidisciplinary assessments or as Brief ICF Core

Sets to describe the problems in a more shortened way with a small number of categories for a better practical use e.g. in clinical studies (Cieza et al, 2004).

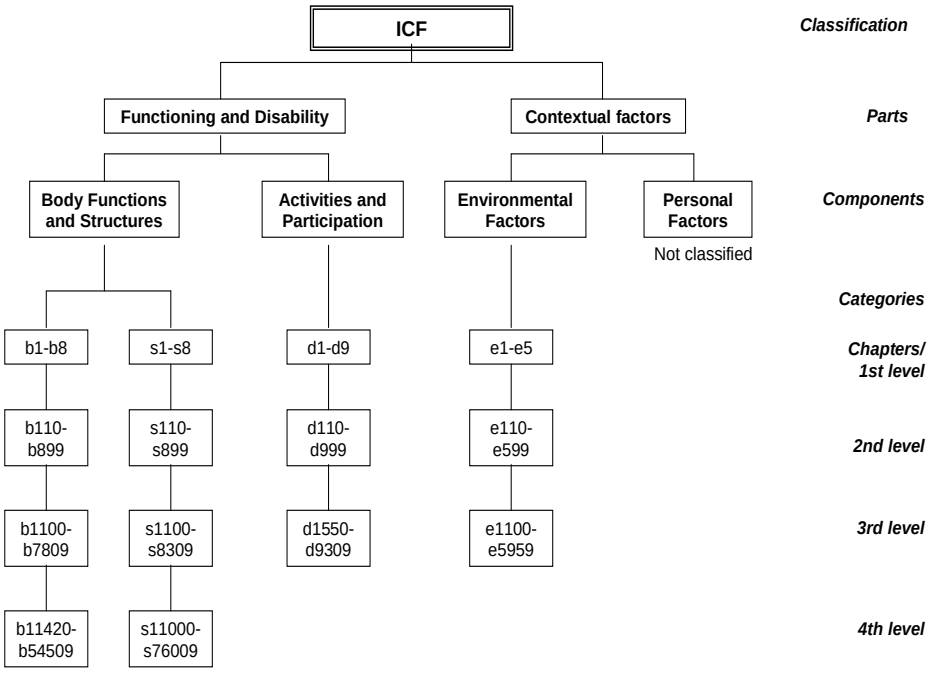

Figure 2: Structure of the International Classification of Functioning, Disability and Health; hierarchical arrangement (modified figure, WHO, 2001)

The development of the ICF Core Sets for each health condition assembled from the view of different involved health professionals followed a standard approach including a formal decision-making and consensus process detecting evidentiary information from expert opinions and preparatory studies. The method educing the perspective of experts, researches and patients used the Delphi technique, a systematic review and an empirical data collection (Cieza et al, 2004; Weigl et al, 2004). Weigl et al. reported the identification of 57 ICF categories as most typical and relevant categories for patients with DM in a Delphi exercise.

Furthermore, a systematic review with the analysis of outcome measures of 227 randomized controlled trails on DM and 19 different health status questionnaires was implemented between the years 1993 and 2003.

After identification and comparison of the extracted concepts they were linked to the ICF (Wolff et al, 2004). More data was collected in a multi-centre, cross sectional study using the ICF checklist on 67 patients with DM to identify the most common problems due to their health condition. Altogether, the collected data of these pre-conference studies (Weigl et al, 2004; Wolff et al, 2004; Ewert et al, 2004) regarding the health condition DM showed 99 ICF categories from *Body Functions*, 40 from *Body Structures*, 55 from *Activities and Participations* and 59 from *Environmental Factors*.

In the following International ICF Core Sets Consensus Conferences in 2003, 15 international experts from nine different countries identified the most relevant ICF categories for the ICF Core Sets for DM (Ruof et al, 2004; Cieza et al, 2004). In conclusion, the Comprehensive ICF Core Set includes 99 categories with 36 categories regarding *Body Functions,* 16 categories from *Body Structures*, 18 from *Activities and Participations* and 29 from the component *Environmental Factors*. The Brief ICF Core Set of DM includes altogether 33 second-level categories, namely 12 applying to the *Body Functions,* six to *Body Structures*, five to *Activities and Participation* and ten regarding the *Environmental Factors* (Ruof et al, 2004).

Patients with chronic diseases including DM need intensive, professional and interdisciplinary treatment and care. The advantages of multidisciplinary care assume a competent interconnected collaboration of different parties of the health care system. The collaboration of clinicians, patient educators, medical specialists and other health professionals permits an exchange of information and coordination of therapeutic procedures (Wagner, 2000).

In a population-based study differences were assessed in processes of care between different health care specialists and suggested that diabetic care can be improved (Gnavi et al, 2009). Therefore the constant proceeding improvement of quality of care and the therapeutic approach demand a common language and reference system to ensure interprofessional communication and simplifying multidisciplinary responsibility (Steiner et al, 2002).

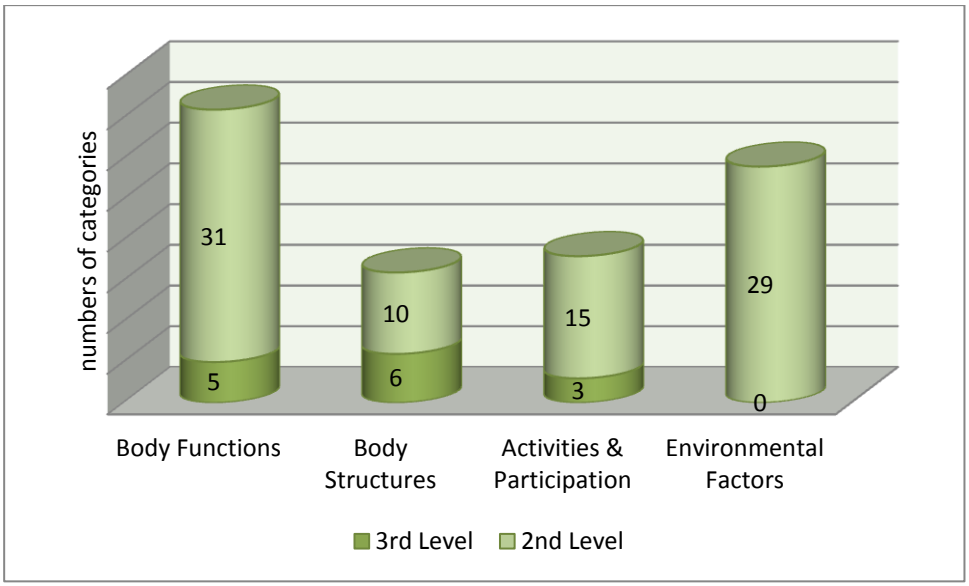

Figure 3: Comprehensive ICF Core Set for DM

The ICF comprising the Comprehensive ICF Core Set for DM supplies a useful tool in cross-linking this interdisciplinary health care and rehabilitation system. With this classification it is possible to describe the impairments of respective patients with DM, the limitations and restrictions in participation and activities of the daily life as well as the affecting environmental factors. Consequently it is possible to construct a functioning profile which can be used for follow-up (Cieza et Stucki, 2006).

3.4 Objective

So far, a variety of worldwide tests and studies has been performed and confirmed the importance, accurateness and application of the ICF Core Sets in clinical practice and research. Different approaches were used to reach this aim. The validation of the so far existing ICF Core Sets is an ongoing process.

The worldwide testing of the content validity of the Comprehensive Core Set for DM includes international multi-center validation studies and validation from the different perspectives of health professionals as well as from the patients' point of view (Kirchberger et al, 2009; Awad et al, 2009; Abdullah et al, 2011). The particular interest applies to the validation from the perspective of the user especially the physicians as a guide in the management of DM.

The reflection of the patients' needs and treatment approaches in the different categories of the Comprehensive Core Set from the physicians' perspective is highly necessary since the ICF Core Sets should provide a standard for multiprofessional assessment in clinical trials.

The objective of this study was to validate the Comprehensive ICF Core Set for DM from the perspective of physicians. Using this approach the study initially intends to identify the patients' problems, resources and environmental issues treated by physicians. The representation of these aspects by the current version of the Comprehensive ICF Core Sets for DM was finally tested.

4 Methods

4.1 The Delphi method

An electronic-mail survey of physicians was performed in three rounds. The method of this survey used the Delphi technique (Linstone et al, 1975; Duffield 1993; Goodman, 1987). The Delphi method was designed in the 1950s and was made for organizing and structuring a group communication process by developing a systematic multi-stage survey.

The achievement of consensus from a panel of commonly titled 'experts' is the principal aim of the Delphi technique. The 'experts' are individuals, who have knowledge of the investigated area of research (McKenna, 1994; Crisp et al, 1999; Snyder-Halpern et al, 2000).

The Delphi method is a multi-stage process where each stage builds on the results of the previous one. The development of a questionnaire is the starting point of collecting information about a particular subject. Each single questionnaire gathers the descriptions of the respective participant in a series of successional rounds, in this case three rounds. After returning the fulfilled questionnaires the results of the particular round are summarized and the outcome of this open up into another new questionnaire heralding the next round. Avoiding the dominance of single participants in a group the technique

is characterized by its anonymity. Free phrasing of the own opinion is allowed by each individual. The different rounds as a term of iteration permit the panel members to re-examine and change their opinions in the following rounds. Furthermore, the controlled feedback shows the distribution of the group's responses as well as each individual's previous responses.

Consensus methods such as the Delphi technique have the benefit of being suitable for participants in areas where published information is difficult to achieve. It is necessary to consider the geographical conditions because they could limitate a sufficient participation in this study. A further positive effect resulted from the respect of time and costs (Linstone et al, 1975; Adler et Ziglio, 1996). Moreover, this consensus method is more appropriate for extensive ranges of information than statistical models (Jones et Hunter, 1995).

4.2 Recruitment of participants

In the initial phase of the survey experts in diabetes treatment were identified. It was essential that all WHO defined world regions are represented in the expert sample. A total of 233 international and national diabetes associations, 506 individual experts and 13 former cooperation partners of the ICF Research Branch Munich were identified and contacted. All associations and 163 individual experts have been found by internet search, 336 experts by literature search and seven experts were named by other colleagues or associations. Only experts with available e-mail and/or fax number had been included.

In the cover letter of the preparatory phase of the study it was pointed out that the participants should be "physicians experienced in the treatment of diabetes mellitus" to assure that the connected experts are 'informed individuals' with sufficient expertise. Experts were selected using the method of Purposive Sampling. In this sampling method, the researchers' knowledge about a population is the basis for the decision which persons should be included in the sample (Tongco, 2007). The first contact consisted of an email including an invitation to participate and detailed information about the aims of

the project, the Delphi process and the timeline. Only persons who agreed to participate had been included in the expert sample and received the questionnaire for the first Delphi round (see attachment 10.2).

4.3 Delphi process

The process and the verbatim questions of the electronic-mail survey are displayed in figure 4. The participating experts had overall three weeks to return their responses for each Delphi round. Reminders in a form of an email notice were sent about one week before deadline, at the day of the deadline and two days after deadline, when necessary.

In **round 1** of the Delphi process an information letter including study instructions and an Excel file containing an open-ended questionnaire were sent to all participants. In this questionnaire the participants were asked to list all the patients' problems, patients' resources and aspects of environment treated by physicians in patients with DM. In addition, the experts were asked to respond to questions on demographic characteristics namely gender and age as well as their professional experience, the experience with DM and their self-rated expertise on this disorder (see attachment 10.2). The replies were gathered, the basic concepts identified and finally linked to the ICF.

In the **second** Delphi round, a list of the ICF categories linked to the responses of the first round (see attachment 10.3) were sent to the experts. The listed ICF categories were ordered according to the structure of the ICF. The experts' responses which could not be connected to an existing ICF category were classified by the research team and listed as *Personal Factors*, health conditions or categories not yet classified by the ICF. The participants were requested to agree or disagree in the questionnaire whether the respective ICF category represents patients' problems, patients' resources or aspects of environment treated by physicians in patients with DM.

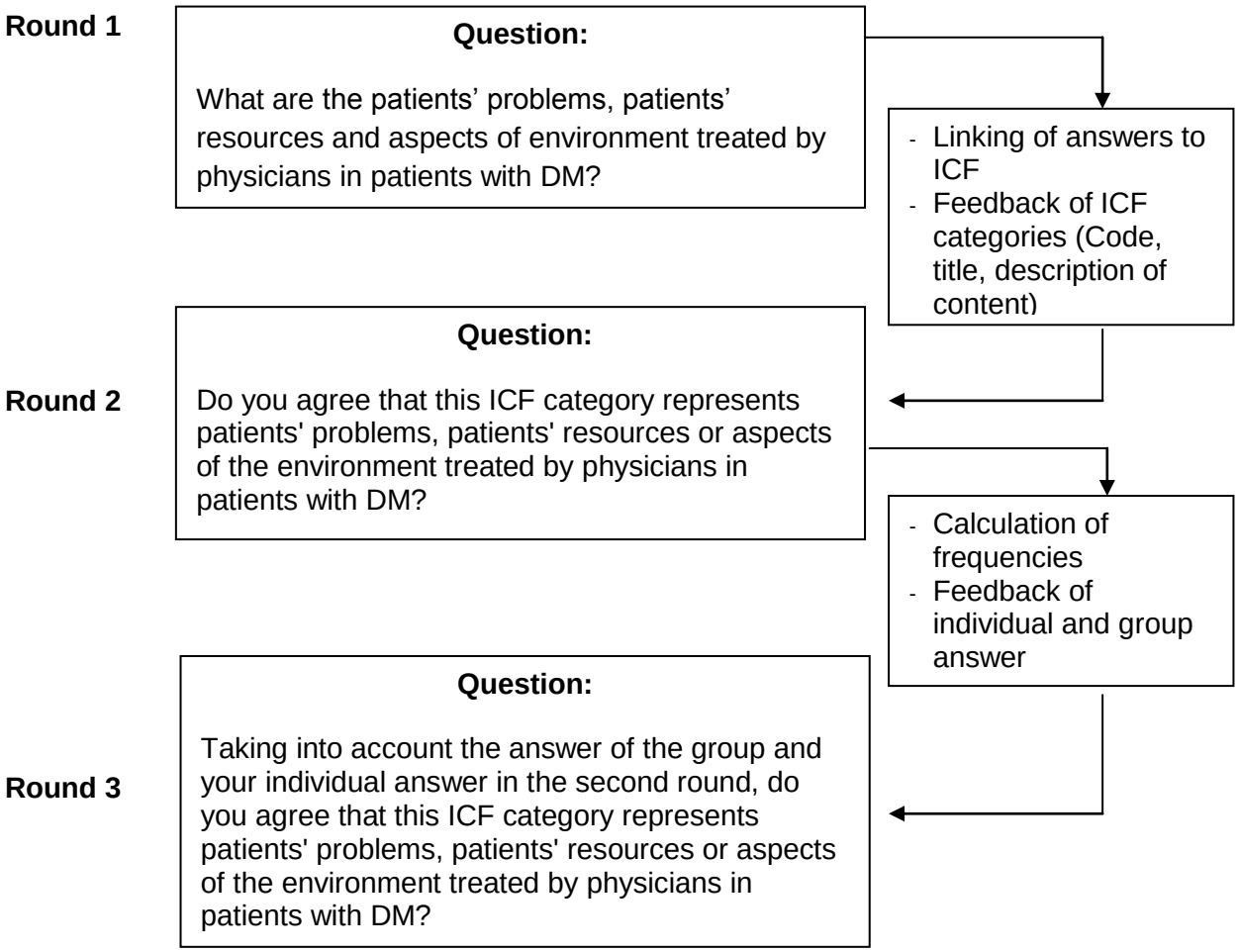

Figure 4: Description of the Delphi-exercise

In the **third** and last Delphi round the participants received by email a list of the ICF categories including the quota 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 DM (see attachment 10.4). The participants were requested to answer the same question as in round two but considering the responses of the group as well as their previous response.

4.4 Linking

An ICF category is coded by the component letter and a suffix of one to five digits. The letters *b*, *s*, *d*, and *e* refer to the components *Body Functions* (*b*), *Body Structures* (*s*), *Activities and Participation* (*d*) and *Environmental Factors* (*e*) (see figure 1). This letter is followed by a one digit number indicating the chapter, the code for the second level (two digits) and the third and fourth levels (one digit each).

Within each component, the categories are arranged in a stem-branch-leaf scheme (WHO, 2001). Consequently a higher-level (more detailed) category shares the aspects of lower-level categories of which it is the member, so 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:

Component	*b*	*Body Functions*
Chapter (1st level)	*b2*	*Sensory functions and pain*
2nd level	*b280*	*Pain*
3rd level	*b2801*	*Pain in body part*
4th level	*b28015*	*Pain in lower limb*

Each response of the first Delphi round was linked to the most precise ICF category. The linkage was performed by a trained doctoral student on the basis of 10 linking rules, established in previous studies (Cieza et al 2002; Cieza et al, 2005). For example categories containing the expression “other specified” or “not specified” or “no specified” as well as all ending by the numbers “eight” and “nine” were not used. In such cases a lower leveled, less

precise category was applied. Concepts related to health or quality of life in general were classified as “nd-gh” (not definable-general health) or “nd-qol” (not definable-quality of life). Moreover, concepts that are not included in the ICF as a category, but defined as a *Personal Factor* by the classification were listed by “pf”. If the concept contained a diagnosis or health state, “hc” (health condition) was assigned to it. Finally, concepts neither included in the ICF nor describing a personal factor were declared “nc” (not covered).

If a response contained more than one concept, several ICF categories could be linked. 50% of the responses were linked separately by two trained health professionals. Consensus between the health professionals was used to decide which ICF category should be linked to each response. In case of disagreement between the two health professionals, the suggested categories were discussed by a team consisting of three health professionals. Based on this discussion a joint decision was made. The whole linking procedure including the four linking steps is explained in table 1.

4.5 Statistical methods

Statistical analysis was performed using SAS for Windows V8. Descriptive statistics were used to characterize the sample and frequencies of responses. Kappa statistics with bootstrapped confidence intervals were used to describe the agreement between the two individuals who performed the linking (Cohen, 1960; Vierkant, 2004).

Table 1: Example of the four linking steps

Step 1			Step 2	Step 3		Step 4
Answer of the participant	**Identified concept linker A**	**Identified concept linker B**	**Agreed on concept**	**Linked ICF category linker A**	**Linked ICF category linker B**	**Agreed on ICF category**
Poor dietary knowledge	Poor dietary knowledge	Poor dietary knowledge	Poor dietary knowledge	pf	pf	pf
Diabetic foot ulcers	Diabetic foot ulcers	Diabetic foot ulcers	Diabetic foot ulcers	b810 s8104	b810 s8104	b810 s8104
Herbal treatment	Herbal treatment	Herbal treatment	Herbal treatment	e5800	e1101	e5800 e1101
learning of specific skills related to self monitoring of blood glucose	learning of specific skills self monitoring of blood glucose	learning of specific skills related to self monitoring of blood glucose	learning of specific skills learning self monitoring of blood glucose	d1551 d1551 d5702	d1551 d1551 d5702	d1551 d1551 d5702

5 Results

5.1 Recruitment and participants

Two hundred thirty three associations specialized in DM from 146 different countries found by internet research were contacted in the first selection. Seven associations forwarded our invitation to their members or other experts and societies. One of them sent the invitation email to all physicians in their electronic database. Another association named one expert, who was contacted and shared in the study as well.

Finally, 26 physicians from four different associations agreed to participate. One hundred and sixty three single experts were found by further

internet search and 18 of them agreed to participate in the study. By literature search 336 experts had been contacted of whom 55 approved participation. Another four participants have been named by other professionals. Furthermore 13 former cooperation partners of the ICF Research Branch Munich were informed of which one refused its participation and three failed email delivery.

Out of the finally 103 physicians from 43 different countries who had agreed to participate in this study and agreed to provide information for the research on the Comprehensive ICF Core Set for DM 84 physicians (81.6%) returned a completed first round questionnaire.

The percentage of German participating physicians was 7.8%, demonstrating no overrepresentation although being a study established in Germany. Though the rate of European participants amounts 34.5% in the first Delphi round they did not significantly differ from the other participating physicians in terms of demographic and professional characteristics. Moreover, there existed no significant changes of demographic sample characteristics regarding the attrition of participants during the three Delphi rounds. The demographic data and professional characteristics of the participating experts are shown in table 2 and in figure 5.

5.2 Delphi process

In the first Delphi round 84 experts from 38 countries named 1220 patients' problems, patients' resources or aspects of environment treated by physicians in patients with DM. Seventy nine of 84 participants (94.0%) filled in the second-round questionnaire and the third-round questionnaire was completed by 76 of 79 participants (96.2%). These results including the percentage of agreement among the participants are shown in tables 3 – 9.

Table 2: Attrition of participants between the Delphi rounds, demographics and professional experience of the round 1 participants

WHO Region	**Round1** (n)	**Round2** (n)	**Round3** (n)	**Female** (%)	**Age** Median (Min-Max)	**Professional experience** [years] Median (Min-Max)	**DM Experience** [years] Median (Min-Max)	**Self-rating Expertise DM #** Median (Min-Max)	**Mainly treating patients in acute situations** (n)	**Mainly treating patients in early-postacute situations** (n)	**Mainly treating patients in chronic situations** (n)
African Region[1]	6	6	6	50.0%	48.5 (39-62)	23.0 (15-35)	20.0* (10-30)	4.5 (3-5)	6	3	6
Eastern Mediterranean Region[2]	6	5	4	16.7%	48.0 (43-60)	22.0 (6-30)	14.5 (12-25)	4.75 (3-5)	4	4	6
European Region[3]	29	27	26	34.5%	45.0 (38-55)	18.0 (7-30)	15.0 (4-29)	4.0* (3-5)	16	15	29
Region of the Americas[4]	10	9	9	40.0%	48.5 (43-56)	21.0 (15-25)	18.0 (10-23)	5.0 (4-5)	1	2	10
South East Asia Region[5]	18	17	16	11.1%	52.0 (45-63)	25.0 (17-35)	19.5 (9-31)	4.6 (1-5)	17	13	18
Western Pacific Region[6]	15	15	15	46.7%	42.0 (28-56)	10.0 (4-30)	10.0 (3-28)	3.0 (3-5)	2	3	13*
Total	**84**	**79**	**76**	**32.1%**	**47.0 (28-63)**	**20.0 (4-35)**	**15.0* (3-31)**	**4.5* (1-5)**	**46**	**40**	**82***

1=low, 5=excellent ; * data of one participant missing

1 Ghana, Namibia, Nigeria, South Africa
2 Bahrain, Iran, Morocco, Pakistan
3 Belgium, Bulgaria, Denmark, France, Finland, Germany, Greece, Ireland, Italy, Malta, The Netherlands, Poland, Russia, Serbia and Montenegro, Slovakia, Slovenia, Sweden, Turkey, United Kingdom
4 Argentina, Barbados, Brazil, Mexico, USA
5 Bangladesh, India, Indonesia, Nepal, Thailand, Vietnam
6 Australia, China, Japan, Republic of Korea, Taiwan

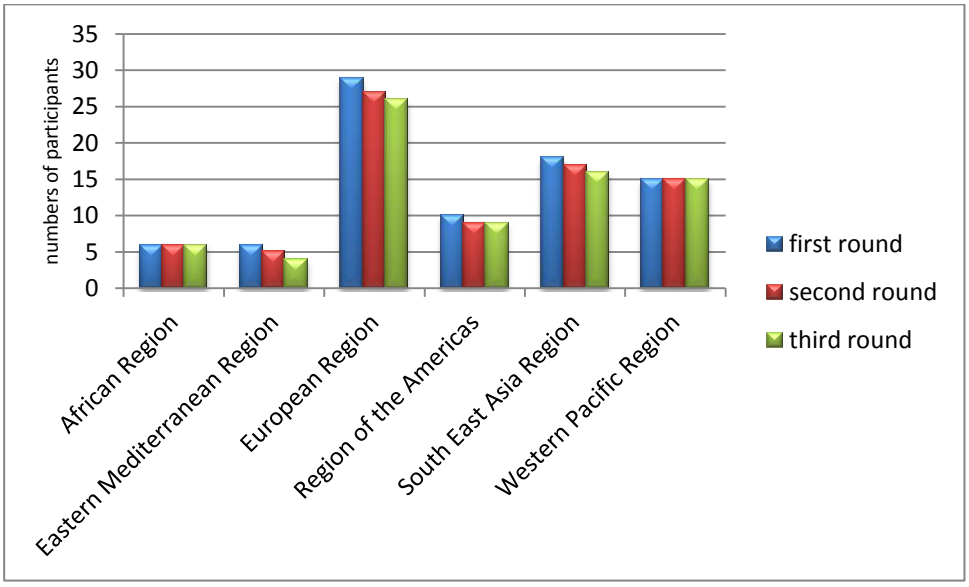

Figure 5: Attrition of participants between the Delphi rounds

5.3 Linking of the responses to the ICF

Two-hundred and twelve ICF categories were linked to the participants' responses and all components of the ICF were represented (see table 3-7). To the component *Body Functions* 34 second-level categories, 51 third-level categories and five fourth-level categories were linked. Fifteen second-level categories, 24 third-level categories and two fourth-level categories were linked to the component *Body Structures.* Sixteen second-level categories and 12 third-level categories were linked to the component *Activities and Participation.* Twenty eight second-level categories and 25 third-level categories were linked to the component *Environmental Factors.* Fifteen responses were assigned to the not-yet-developed component *Personal Factors* exclusive the 30 different health conditions. Eleven responses were not classified by the ICF. The Kappa statistics for the linking was 0.69 with a 95% bootstrapped confidence interval of 0.66 – 0.72.

Table 3: Representation of identified ICF categories in the Comprehensive ICF Core Set for diabetes mellitus: summary of results

	Body Functions	**Body Structures**	**Activities & Participation**	**Environmental Factors**	**Total**
Number of categories identified					
- second level	34	15	16	28	93
- third level	51	24	12	25	112
- fourth level	5	2	-	-	7
Total number of categories identified	90	41	28	53	212
n (%) of categories included in the ICF Core Set at the **same level of classification**	26 (28.8%)	15 (36.6%)	11 (39.3%)	20 (37.7%)	72 (34.0%)
n (%) of categories included in the ICF Core Set at a **different level of classification**	42 (46.7%)	9 (22.0%)	4 (14.3%)	16 (30.2%)	71 (33.5%)
n (%) of categories not included in the ICF Core Set with **agreement <75%**	11 (12.2%)	6 (14.6%)	13 (46.4%)	17 (32.1%)	47 (22.2%)
n (%) of categories not included in the ICF Core Set with **agreement ≥75%**	11 (12.2%)	11 (26.8%)	0 (0%)	0 (0%)	22 (10.4%)

The use of a more detailed ICF category (e.g. *b1301 Motivation*) implies that the less detailed (lower-level) ICF category (e.g. *b130 Energy and drive functions*) is applicable.

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

5.4.1 Body Functions

Body Functions was considered the most important area in which patients experienced limitations, because 90 categories were linked to it. Twenty six ICF categories linked to the participants' responses are

represented in the Comprehensive ICF Core Set for DM at the same level of classification (see table 4). Several responses by the participants were linked to the more detailed, higher third-level ICF category, namely *b1100 State of consciousness, b1301 Motivation, b1303 Craving, b6600 Functions related to fertility, b6601 Functions related to pregnancy* and *b6602 Functions related to childbirth*, which are represented in the Core Set for DM by the second-level categories *b110 Consciousness functions, b130 Energy and drive functions* and *b660 Procreation functions*, respectively. However, there are six ICF categories that are included in the Core Set which could not be linked to the data provided by the study population: *b1300 Energy level*, *b1302 Appetite*, *b140 Attention functions*, *b260 Proprioceptive function*, *b4551 Aerobic capacity*, *b630 Sensations associated with urinary functions*.

Furthermore, 22 of the participants' categories were not represented by the Comprehensive ICF Core Set for DM. Among these, 11 ICF categories are not even represented by a different level category, although at least 75% of the participants' answers have considered them as important. Strictly speaking these are *b2401 Dizziness*, categories covering functions related to the digestive system (*b5106 Regurgitation and vomiting*, *b525 Defecation functions*, *b5251 Faecal consistency*, *b5252 Frequency of defecation*, *b5253 Faecal continence*, *b535 Sensations associated with the digestive system*, *b5350 Sensation of nausea*), categories concerning genital and reproductive functions (*b650 Menstruation functions*, *b6700 Discomfort associated with sexual intercourse*) and *b830 Other functions of the skin* as a category due to functions of the skin. The further 11 categories which were not represented by the Comprehensive ICF Core Set for DM reached an agreement among the participants from 40.0 % to 72.0 %.

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

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th level		
	b110			**Consciousness functions**	
		b1100		State of consciousness	98.7%
	b130			**Energy and drive functions**	
		b1300		**Energy level**	
		b1301		Motivation	86.8%
		b1302		**Appetite**	
		b1303		Craving	68.4%
	b134			**Sleep functions**	82.9%
	b140			**Attention functions**	
	b152			**Emotional functions**	88.0%
		b1522		Range of emotion	88.2%
	b210			**Seeing functions**	86.7%
		b2100		Visual acuity functions	97.4%
		b2102		Quality of vision	94.7%
			b21023	Visual picture quality	85.1%
	b230			Hearing functions	62.7%
		b2401		Dizziness	92.0%
	b260			**Proprioceptive function**	

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th level		
	b265			**Touch function**	97.3%
	b270			**Sensory functions related to temperature and other stimuli**	98.7%
		b2702		Sensitivity to pressure	94.7%
		b2703		Sensitivity to a noxious stimulus	98.7%
	b280			**Sensation of pain**	97.3%
			b28011	Pain in chest	92.0%
			b28014	Pain in upper limb	88.0%
			b28015	Pain in lower limb	100%
			b28016	Pain in joints	73.3%
	b410			**Heart functions**	94.7%
		b4101		Heart rhythm	85.3%
		b4103		Blood supply to the heart	93.3%
	b415			**Blood vessel functions**	97.3%
		b4150		Functions of arteries	100%
		b4151		Functions of capillaries	93.1%
		b4152		Functions of veins	68.0%
	b420			**Blood pressure functions**	96.0%
		b4200		Increased blood pressure	98.7%
		b4201		Decreased blood pressure	88.0%
		b4202		Maintenance of blood pressure	98.7%
	b430			**Haematological system functions**	77.3%

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th level		
		b4300		Production of blood	58.1%
		b4302		Metabolite-carrying functions of the blood	64.0%
		b4303		Clotting functions	73.3%
	b435			**Immunological system functions**	94.7%
		b4350		Immune response	94.7%
	b440			Respiration functions	66.7%
	b455			**Exercise tolerance functions**	
		b4550		**General physical endurance**	92.0%
		b4551		**Aerobic capacity**	
		b4552		**Fatiguability**	90.5%
		b5104		Salivation	65.3%
		b5105		Swallowing	68.9%
		b5106		Regurgitation and vomiting	82.7%
	b515			**Digestive functions**	90.7%
		b5150		Transport of food through stomach and intestines	94.7%
		b5151		Breakdown of food	60.0%
		b5153		Tolerance to food	57.3%
	b525			Defecation functions	89.3%
		b5251		Faecal consistency	76.0%
		b5252		Frequency of defecation	85.3%
		b5253		Faecal continence	77.0%

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th level		
	b530			**Weight maintenance functions**	93.3%
	b535			Sensations associated with the digestive system	81.3%
		b5350		Sensation of nausea	82.7%
	b540			**General metabolic functions**	98.7%
		b5401		Carbohydrate metabolism	97.3%
		b5403		Fat metabolism	95.9%
	b545			**Water, mineral and electrolyte balance functions**	93.3%
		b5450		Water balance	86.7%
		b5451		Mineral balance	81.1%
	b555			**Endocrine gland functions**	95.9%
	b610			**Urinary excretory functions**	92.0%
		b6100		Filtration of urine	96.0%
	b620			**Urination functions**	96.0%
		b6201		Frequency of urination	97.3%
		b6202		Urinary continence	90.7%
	b630			**Sensations associated with urinary functions**	
	b640			**Sexual functions**	97.3%
		b6400		Functions of sexual arousal phase	78.7%
		b6401		Functions of sexual preparatory phase	86.5%
	b650			Menstruation functions	77.0%
	b660			**Procreation functions**	

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th level		
		b6600		Functions related to fertility	72.6%
		b6601		Functions related to pregnancy	94.7%
		b6602		Functions related to childbirth	89.3%
		b6700		Discomfort associated with sexual intercourse	84.0%
	b710			**Mobility of joint functions**	73.3%
		b7100		Mobility of a single joint	73.3%
		b7102		Mobility of joints generalized	62.7%
		b7200		Mobility of scapula	48.0%
	b730			**Muscle power functions**	66.7%
	b740			Muscle endurance functions	65.3%
	b770			Gait pattern functions	72.0%
		b7800		Sensation of muscle stiffness	64.0%
		b7801		Sensation of muscle spasm	58.7%
	b810			**Protective functions of the skin**	88.0%
	b820			**Repair functions of the skin**	93.3%
	b830			Other functions of the skin	81.3%
	b840			**Sensation related to the skin**	96.0%
	b850			Functions of hair	40.0%
	b860			Functions of nails	70.7%

5.4.2 Body Structures

Fifteen categories of the component *Body Structures* of the current Comprehensive ICF Core Set for DM were represented in the participants' responses at the same level of classification (see table 5). The category *s630 Structure of reproductive system* is represented in the Core Set by the corresponding fourth-level category *s63033 Vaginal canal* and the third-level category *s6306 Prostate.* Therefore all categories of *Body Structures* in the Comprehensive ICF Core Set for DM are covered by the responses of the participants. Nevertheless, there are 11 ICF categories, which are not represented in the Core Set, showing an agreement beyond 75% among the participants. Two categories covering structures involved in voice and speech (*s3200, s3301),* one category addressing structures of respiratory system (*s430*), four categories concerning structures related to the digestive, metabolic and endocrine systems (*s5400, s5401, s560, s5801*) and another four categories covering structures related to movement (*s73021, s7700, s7701, s7702*). Another six categories (*s320, s530, s720, s7201, s730, s7302*) were considered to be important by 58.1% to 71.6% of the participants although they are not yet part of the Core Set.

5.4.3 Activities and Participation

Eleven categories of the component *Activities and Participation* could be linked to the participants' responses at the same level of classification (see Table 6). These in the Comprehensive ICF Core Set included categories are *d440, d475, d570, d620, d750, d760, d770, d845, d850, d920*. However, there are seven ICF categories that are included in the Comprehensive ICF Core Set for DM which could not be linked to the data provided by the study population. The second-level category *d920 recreation and leisure* is covered in the Core Set by the responses as well and represents as a less-detailed category the non-responded categories *d9204 hobbies* and *d9205 socializing*, which are also part of the given Comprehensive ICF Core Set. Furthermore, 13 categories (*d1551, d230, d2301, d2302, d6505, d660, d820, d840, d855,*

d8700, d910, d9100, d9101) that were addressed by the participants' responses are not represented in the current Comprehensive ICF Core Set for DM, however none of them reached an agreement of 75% or higher. The range of agreement was between 23.7% and 60.0%.

Table 5: ICF component Body Structures: ICF categories included in the ICF Comprehensive Core Set (boldface letters) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (lightface letters). Percentage of participants who considered the respective ICF category as relevant in the last round.

ICF Code				**ICF Category**	**% Agreement in final round**
1st level	2nd level	3rd level	4th Level		
	s140			**Structure of sympathetic nervous system**	89.3%
	s150			**Structure of parasympathetic nervous system**	88.0%
	s220			**Structure of eyeball**	69.9%
		s2203		Retina	97.3%
		s2204		Lens of eyeball	98.7%
	s320			Structure of mouth	64.4%
		s3200		Teeth	94.7%
		s3301		Oral pharynx	76.0%
	s410			**Structure of cardiovascular system**	94.7%
		s4100		**Heart**	98.7%
		s4101		**Arteries**	98.7%
		s4102		**Veins**	85.3%
		s4103		**Capillaries**	93.3%
	s430			Structure of respiratory system	77.3%

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
	s530			Structure of stomach	67.6%
		s5400		Small intestine	80.0%
		s5401		Large intestine	80.0%
	s550			**Structure of pancreas**	84.0%
	s560			Structure of liver	86.7%
		s5801		Thyroid gland	89.3%
	s610			**Structure of urinary system**	88.0%
		s6100		**Kidneys**	97.3%
		s6102		Urinary bladder	94.7%
	s630			**Structure of reproductive system**	
			s63033	Vaginal canal	78.4%
		s6306		Prostate	65.3%
	s720			Structure of shoulder region	58.1%
		s7201		Joints of shoulder region	62.7%
	s730			Structure of upper extremity	58.1%
		s7302		Structure of hand	71.6%
			s73021	Joints of hand and fingers	77.3%
	s750			**Structure of lower extremity**	80.0%
		s7500		Structure of thigh	68.0%
		s7501		Structure of lower leg	82.7%
		s7502		**Structure of ankle and foot**	96.0%
		s7700		Bones	82.7%

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
		s7701		Joints	80.0%
		s7702		Muscles	86.7%
	s810			**Structure of areas of skin**	92.0%
		s8102		Skin of upper extremity	77.3%
		s8104		Skin of lower extremity	96.0%
	s830			**Structure of nails**	91.8%

Table 6: ICF component Activities and Participation: ICF categories included in the ICF Comprehensive Core Set (boldface letters) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (lightface letters). Percentage of participants who considered the respective ICF category as relevant in the last round.

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
		d1551		Acquiring complex skills	50.7%
	d230			Carrying out daily routine	56.0%
		d2301		Managing daily routine	56.0%
		d2302		Completing the daily routine	60.0%
	d240			**Handling stress and other psychological demands**	
	d440			**Fine hand use**	59.5%
	d450			**Walking**	
	d455			**Moving around**	

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
	d475			**Driving**	58.7%
		d4751		Driving motorized vehicles	53.3%
	d520			**Caring for body parts**	
	d570			**Looking after one's health**	85.1%
		d5701		Managing diet and fitness	91.8%
		d5702		Maintaining one's health	88.0%
	d620			**Acquisition of goods and services**	41.3%
	d630			**Preparing meals**	
		d6505		Taking care of plants, indoors and outdoors	23.7%
	d660			Assisting others	36.8%
	d750			**Informal social relationships**	39.5%
	d760			**Family relationships**	59.2%
	d770			**Intimate relationships**	68.4%
	d820			School education	56.0%
	d840			Apprenticeship (work preparation)	44.7%
	d845			**Acquiring, keeping and terminating a job**	61.8%
		d8450		Seeking employment	48.7%
	d850			**Remunerative employment**	48.0%
	d855			non-remunerative employment	28.9%
		d8700		Personal economic resources	42.1%
	d910			Community life	40.8%
		d9100		Informal associations	40.8%

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
		d9101		Formal associations	35.5%
	d920			**Recreation and leisure**	67.1%
		d9201		**Sports**	77.6%
		d9204		**Hobbies**	
		d9205		**Socializing**	

5.4.4 Environmental Factors

Twenty categories of the component *Environmental Factors* were linked to participants' responses. They are included in the Comprehensive ICF Core Set for DM at the same level of classification (see table 7). The responses and categories *e110 Products or substances for personal consumption*, *e550 Legal services, systems and policies*, *e590 Labour and employment services, systems and policies*, *e595 Political services, systems and policies* were linked to the more detailed, third-level ICF category. This is shown by *e1100 Food* and *e1101 Drugs* which are represented in the Comprehensive ICF Core Set for DM by the corresponding second-level category *e110 Products or substances for personal consumption*, respectively. Moreover, there are five ICF categories that are included in the Core Set which could not be linked to the data provided by the study population. Although 17 further categories were identified by the participants' responses which are not included in the Comprehensive ICF Core Set for DM (*e120, e1250, e130, e1300, e1650, e2151, e2250, e2255, e230, e335, e460, e530, e5350, e540, e5401, e565, e5650*) the range of agreement was between 30.3% and 64.5 %. None of these categories reached a significant agreement of more than 75%.

5.4.5 Personal Factors

The *Personal Factors* are related to the patients' way of dealing with their condition, like *knowledge about the disease*, *compliance* and *coping strategies* as well as *healthy lifestyle* and *self management* including the *understanding of therapeutic strategies.* Fifteen answers were linked to this not-yet-developed ICF component (see table 8). The participants agreed on the importance of all mentioned *Personal Factors* by a percentage between 82.7 % and 98.7%. Additionally the *Personal Factors* include other health conditions as well (Geyh et al, 2011). The thirty responses regarding these health conditions are separately listed in Table 9.

Table 7: ICF component Environmental Factors: ICF categories included in the ICF Comprehensive Core Set (boldface letters) and ICF categories linked to participants' responses, but not included in the ICF Comprehensive Core Set (lightface letters). Percentage of participants who considered the respective ICF category as relevant in the last round.

ICF Code				**ICF Category**	**% Agreement in final round**
1st level	2nd level	3rd level	4th Level		
	e110			**Products or substances for personal consumption**	
		e1100		Food	90.8%
		e1101		Drugs	90.8%
	e115			**Products and technology for personal use in daily living**	55.3%
		e1150		General products and technology for personal use in daily living	49.3%
		e1151		Assistive products and technology for personal use in daily living	68.9%
	e120			Products and technology for personal indoor and outdoor mobility and transportation	56.0%
		e1250		General products and technology for communication	50.7%
	e130			Products and technology for education	48.7%

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
		e1300		General products and technology for education	51.3%
		e1650		Financial assets	30.3%
		e2151		Population density	30.3%
		e2250		Temperature	46.1%
		e2255		Seasonal variation	47.4%
	e230			natural events	38.2%
	e310			**Immediate family**	69.7%
	e315			**Extended family**	53.9%
	e320			**Friends**	
	e325			**Acquaintances, peers, colleagues, neighbours and community members**	53.9%
	e330			**People in positions of authority**	52.6%
	e335			People in subordinate positions	36.8%
	e340			**Personal care providers and personal assistants**	64.0%
	e355			**Health professionals**	89.3%
	e360			**Other professionals**	51.3%
	e410			**Individual attitudes of immediate family members**	71.1%
	e415			**Individual attitudes of extended family members**	55.3%
	e420			**Individual attitudes of friends**	63.2%
	e425			**Individual attitudes of acquaintances, peers, colleagues, neighbours and community members**	59.2%
	e430			**Individual attitudes of people in positions of authority**	

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
	e440			**Individual attitudes of personal care providers and personal assistants**	
	e450			**Individual attitudes of health professionals**	73.7%
	e455			**Individual attitudes of other professionals**	
	e460			Societal attitudes	64.5%
	e465			**Social norms, practices and ideologies**	60.5%
	e510			**Services for the production of consumer goods**	
	e530			Utilities services, systems and policies	32.0%
		e5350		Communication services	40.0%
	e540			Transportation services, systems and policies	33.3%
		e5401		Transportation systems	58.7%
	e550			**Legal services, systems and policies**	
		e5500		Legal services	32.0%
	e555			**Associations and organizational services, systems and policies**	40.0%
		e5550		Associations and organizational services	49.3%
		e5552		Associations and organizational policies	49.3%
	e560			**Media services, systems and policies**	48.0%
		e5600		Media services	64.0%
	e565			Economic services, systems and policies	38.7%
		e5650		Economic services	40.0%
	e570			**Social security services, systems and policies**	61.3%
		e5700		Social security services	71.6%

ICF Code				ICF Category	% Agreement in final round
1st level	2nd level	3rd level	4th Level		
		e5701		Social security systems	61.6%
	e575			**General social support services, systems and policies**	65.3%
		e5750		General social support services	67.6%
	e580			**Health services, systems and policies**	92.0%
		e5800		Health services	94.6%
		e5801		Health systems	88.9%
		e5802		Health policies	85.1%
	e585			**Education and training services, systems and policies**	68.5%
	e590			**Labour and employment services, systems and policies**	
		e5900		Labour and employment services	50.0%
	e595			**Political services, systems and policies**	
		e5951		Political systems	39.2%

Table 8: ICF component Personal Factors: Percentage of participants who considered the respective response as relevant in the third round.

Answer **Personal Factors**	**% Agreement in final round**
Comorbidities	98.7%
Compliance	98.7%
Conviction	82.7%
Coping	93.3%
Health literacy	93.3%

Answer Personal Factors	% Agreement in final round
Healthy lifestyle	98.7%
Heritability of diabetes	92.0%
Knowledge about disease	98.7%
Lack of self-confidence	97.3%
Patient education about disease	98.7%
Self empowerment	93.3%
Self management	98.7%
Self-decision making	94.7%
Understanding of therapeutic strategies	98.7%
Loss of liberty	86.7%

Table 9 Health conditions: Percentage of participants who considered the respective response as relevant in the third round

Answer Health conditions	% Agreement in final round
Abscess	98.6%
Anaemia	91.9%
Arthritis	80.0%
Cardiovascular diseases	100%
Carpal tunnel syndrome	94.7%
Cataract	97.3%
Cerebrovascular disease	100%
Coeliac disease	80.0%
Depression	100%

Answer Health conditions	% Agreement in final round
Diabetes neuropathy	100%
Diabetic foot	100%
Diverticulitis	53.3%
Endocrine disorders	98.7%
Gestational diabetes	98.7%
Gout	87.8%
Intercurrent pneumonia	93.3%
Nephropathy	100%
Obesity	100%
Osteomyelitis	93.3%
Osteoporosis	88.0%
Peripheral vascular disease	100%
Pregnancy	94.7%
Pulmonary TBC infection	82.7%
Renal hypertension	93.3%
Retinopathy	97.3%
Scleroedema of skin	66.7%
Sepsis	97.3%
Sleep apnea	89.3%
Type 1 Diabetes	100%
Type 2 Diabetes	100%

5.4.6 Not classified

Eleven responses of the participants including *aggravation of diabetes, diabetic research, insulin resistance* and *screening for relatives* were declared "not covered by the ICF" (see Table 10). However, the answer *neuropathy problems* reached an agreement of 100%.

Table 10: Responses that could not be linked to a specific ICF category since the concept is not classified by ICF. Percentage of participants who considered the respective responses as relevant in the last round.

Answer **Not classified**	**% Agreement in final round**
Aggravation of diabetes	97.3%
Antibiotic resistance	78.4%
Dealing with the complex medicines and eating dosage regimen	98.6%
Diabetic research	93.2%
Exercise opportunity	95.9%
Insulin resistance	97.3%
Lack of communication between patient and physician	97.3%
Neuropathy problems	100%
Patients are always on the lookout for the proverbial 'cure'	97.8%
Screening for relatives	93.2%
Swelling in their joints	70.3%

6 Discussion

Overall the different components of the current version of the Comprehensive ICF Core Set for DM namely *Body Functions*, *Body Structures*, *Activities and Participation* and the *Environmental Factors* were almost completely represented by the participants' responses in this validation study. The responses of the participants of this study confirmed 67.5% of the already included categories at the same or at a different level. Of the components *Activities and Participation* and *Environmental Factors* no categories were identified by the participants which had an agreement of at least 75%, but are not included in the current version of the Comprehensive ICF Core Set for DM. However, 22 categories of the components *Body Functions* and *Body Structures* were found which are not included in the ICF Core Set and were rated as important by at least 75% of the participants. These categories indicate a lack of validity from the perspective of physicians and will be discussed in the following section.

6.1 Body Functions

More than 90% of the participants agreed that the ICF category *b2401 Dizziness* represents an important aspect, although this category is not included in the ICF Core Sets for DM. Dizziness describes a variety of sensations that limit the patients' daily activities. Possible reasons for the inability to maintain the sense of balance can be a manifestation of dysfunction of the neurologic, cardiovascular, psychiatric, or vestibular systems (Chan, 2009). Dizziness is a familiar symptom of diabetic complications, such as hypoglycaemia e.g. due to overdosed insulin injection (Hepburn et al, 1991), diabetic ketoacidosis (DKA) and hyperosmolar hyperglycaemic syndrome (HHS) (ADA, 2001; Kitabchi, 2001). Furthermore, complications like reduced cardiovascular autonomic function based on diabetic neuropathy, in particular autonomic neuropathy (Vinik et al, 2003), acute coronary syndrome (DeVon et al, 2008) and stroke (Mohr, 2004) can go along with dizziness. Actually

dizziness is a nonspecific, subjective and commonly treated symptom but it is not to be underestimated as a medical condition in patients with DM.

A sizeable number of publications support a relationship between DM and upper and lower gastrointestinal symptoms. Almost 75% of patients (Chandrasekharan et Srinivasan, 2007) with DM have symptoms like delayed gastric emptying, vomiting, nausea, bloating, heartburn, abdominal pain, dysphagia, diarrhea with watery stool interchanging with constipation and fecal incontinence due to a weak sphincter tone. Especially motility disorders like gastroparesis are common problems. This dysfunction of the gastrointestinal system in case of DM is caused mainly by great fluctuations in blood glucose, the presence of irreversible autonomic neuropathy with alteration in neuron number and size and coexisting psychiatric illnesses (Bytzer et al, 2001; Chandrasekharan et Srinivasan, 2007; Vinik et al, 2003). Due to these facts it is not surprising that the experts in this survey support the ICF categories *b5106 Regurgitation and vomiting, b525 Defecation functions* and the more detailed categories *b5251 (Faecal consistency), b5252 (Frequency of defecation), b5253 (Faecal continence)* although these categories are not included in the Comprehensive ICF Core Set for DM.

Additionally the categories *b535 Sensations associated with the digestive system* and the more detailed one *b5350 Sensation of nausea* as well as the *body structure* categories *s5400 Small instestine* and *s5401 Large instestine* were rated as important with over 80% acceptance. In the study from the perspective of the patients of Kirchberger et al 2009 the category *b525 Defecation functions* was also endorsed. This intensifies the potential need of including this category to the ICF Core Sets.

The management of DM is partly gender specific, above all in items due to genital and reproductive functions. In reference to that, the ICF category *b650 Menstruation functions* was considered to be relevant in the treatment of DM by the participants. Many studies confirmed that type 1 diabetes in young women is associated with menstrual irregularities like later menarche, oligo- and amenorrhea or long cycles and heavy menstruation (Strotmeyer et al, 2003). The cause of these disorders could be located in an uncontrolled DM induced dysfunction of the hypothalamic-pituitary-gonadal axis (Griffin et al, 1994). Menstrual cycle disturbances in older women with type 2 diabetes have

not been well examined in contrast to type 1 diabetes in young adults. They are related basically to problems concerning menopause. Nevertheless it should be mentioned that women with unbalanced menses have an enlarged risk for type 2 diabetes (Solomon et al, 2001), especially women of childbearing potential with the endocrine disorder Polycystic Ovary Syndrome (PCOS) have this risk factor. PCOS could follow from insulin resistance and hyperinsulinaemia. More than 5% of the women with this syndrome have manifest DM. Furthermore, the physiological decrease of hormones in menopause could affect the well adjusted blood glucose level. Premenopausal diabetic women often have to adjust the management of DM, because the modification of the hormone status induces a reduced need for insulin and hence hypoglycaemia. Due to the similar symptoms of menopause and low blood sugar, e.g. hot flushes, it is necessary to measure the blood-glucose level at frequent intervals and to intensify the support by physicians. A hormonal replacement therapy could as well be beneficial, because the insulin demand turns to premenopausal levels and the risk of developing heart disease abates (Jovanovic, 2004).

Moreover, 84% of the experts in this survey named the ICF category *b6700 Discomfort associated with sexual intercourse*. Sexual dysfunction for men and women is quite common in DM and is mainly caused by vascular and neuropathic failure. Endocrine changes are responsible for mood swings, reduced libido and sexual arousal. The typical problems of men, e.g. erectile dysfunction, are mainly caused by vascular and neuropathic failure. The reduced libido and mood swings are consequences of a lower level of the hormone testosterone (Hijazi, 2004). The female sexual dysfunction is also induced by neuropathic vascular complications and endocrine changes. Characteristic symptoms are reduced sexual arousal and lack of sexual desire. Furthermore, the disturbed vaginal lubrication and sensitivity provokes dyspareunia and discomfort during the intercourse (Fatemi et Taghavi, 2009).

The diabetic autonomic neuropathy comprises multiple symptoms and impairments in a variety of organs. For instance the sudomotor function of the skin is affected. A reduced sympathetic skin response as for example lower sweat secretion up to anhidosis, heat intolerance and dry skin generates fissures and leaks in the skin. Thus, the infection risk with pathogenetic agents

is increased (Vinik et al, 2003, Asahina et al, 2008). Moreover, a rare symptom of diabetic neuropathy due to sudomotor function is the phenomenon of gustatory sweating. This excessively sweating around head and neck during or after food intake (Blair et al, 2002) can be traced back to a reinnervated nerve function within the autonomous nerve system. In reference to these constrictions the participants deemed the not yet included ICF category *b830 Other functions of the skin* to be important, as well as the patients' themselves in the study of Kirchberger et al 2009.

6.2 Body Structures

Many of the patients' problems treated by physicians are represented by categories assigned to the component *Body Structures*. These are the anatomical parts of the body such as organs or limbs and the participants were asked about impairments like deviation, qualitative changes in structure or loss.

The ICF categories *s3200 Teeth* and *s3301 Oral pharynx* belonging to the component *Body Structures* were supported by the experts in DM but they are not included in the ICF Core Sets for DM. According to literature (Skamagas et al, 2008), perioral diseases like acute infections with bacteria or candida are increased in diabetic patients. The oral and oropharyngeal symptomatology includes acute infections with bacteria, candida and other opportunistic pathogenetic microorganisms. Uncontrolled inflammation, tooth loss and tissue destruction up to necrosis are the result of e.g. peridontitis. Furthermore, DM is a risk factor for possible precancerous lesions and malignant oral neoplasm. To control these implications the oral hygiene has to be improved.

The ICF category *s430 Structure of respiratory system* includes, on a more detailed level, the trachea, the lungs, the thoracic cage and the muscles of respiratory system. The participants rated this category to be a relevant structure affected by DM. A number of publications have controversial attitudes towards the question, whether the lung is a target to DM or not. Some studies could show a diabetic microangiopathy in the lungs for example a thickened

epithelial and capillary basal membrane, hyalinosis of vessels and insudation (Kodolova et al, 1982). However, in situations such as aging, smoking or primary lung diseases the subclinical dysfunction of the diabetic lung could become significant (Kaparianos et al, 2008). Commonly, diabetic patients have an increased risk of acquiring infections, such as pulmonary fungal diseases, tuberculosis and other opportunistic pathogens. These infections may lead to inflammation with tissue destruction or invasion in vascular structures (Marvisi et al, 1996). Furthermore, it has to be mentioned that the inhalable insulin as a noninvasive medication option makes only small modifications in lung function and lesions in structures are not associated (Strack, 2006).

Some other ICF categories not included in the ICF Core Sets for DM but regarded as relevant by the participants are *s5400 Small intestine* and *s5401 Large intestine.* The dysfunction in intestinal motility is caused by structure damaging of the enteric nervous system described as neurodegenerative processes. Axonal swelling, alteration in neuron number and size, varied expressed neurotransmitters and nerve-immune interactions generate the motility related problems. In addition, there are multiple triggers like poor glycaemic control, psychiatric disorders and other metabolic derangements deduced by DM (Bytzer et al, 2001; Chandrasekharan et Srinivasan, 2007).

A further category identified in this survey by the experts that is not included in the Comprehensive ICF Core Set for DM is *s560 Structure of liver*. In diabetic patients almost 70% have liver function disturbances like Non-Alcoholic Fatty Liver Disease (NAFLD). Insulin resistance, Hyperinsulinaemia, intensified oxidative stress to the hepatocytes and other comorbidities like obesity and hypertriglyceridaemia are associated. The inoffensive form of NAFLD shows an accumulation of fat with no significant liver destruction. A progression of NAFLD with specific inflammation changes and fibrosis could lead to Non-Alcoholic Steatohepatitis (NASH) with hepatocellular necrosis and to severe liver damage such as cryptogenic cirrhosis and hepatocellular carcinoma. To prevent diabetic patients with NAFLD or NASH from aggravation and early mortality an efficient diagnosis, optionally by liver biopsy, lifestyle intervention and a controlled carbohydrate metabolism is indicated (Cusi, 2009; Podolsky, 2004; Yu et Keeffe, 2002). Additionally there is an independent and less recognized complication of long lasting

hyperglycaemia named glycogenic hepatopathy (GN), which mostly occurs in patients with type 1 diabetes (Torbenson et al, 2006). It is characterized by elevated liver enzymes, glycogen accumulation in swollen hepatocytes and hepatomegaly.

Although type 1 diabetes has only a prevalence of about 5%, it seems as if the physicians that participated in this study still treat many patients with type 1 diabetes. This is most likely the reason why the experts rated the ICF category *s5801 Thyroid gland* with 89.3% as an important structure which is affected by DM and which has to be included in the Comprehensive ICF Sore Set for DM. Thyroid diseases, in particular induced by autoimmune dysregulations, are frequent in patients with type 1 diabetes (Hansen et al, 1999). The relationship between patients with type 2 diabetes and thyroid diseases is not well documented in literature. About 15% of patients with DM have thyroid affections which are mainly caused by immunological and genetic factors. The chronic autoimmune thyroiditis is most commonly and mainly caused by immunological and genetic factors. Clinical signs are e.g. hypothyroidism and goiter (Schroner et al, 2008; Dayan et Daniels, 1996).

DM is also associated with several musculoskeletal disorders of the hand and fingers. The ICF category *s73021 Joint of hand and fingers* was considered as relevant by the participating experts. That explains the occurrence of the corresponding category *s73021 Joint of hand and fingers* because amongst diabetic patients impairments such as Limited joint mobility (LJM), Dupuytren's disease (DD), Carpal tunnel syndrome (CTS) and stenosing tendosynovitis (trigger finger) have an increased incidence compared to the general population. Due to connective tissue changes, neuropathy and vasculopathy, these impairments are leading to increased stiffness, palpable palmar and digital nodules, contractures and thickening of ligaments and peritendinousus tissue (Fitzgibbons et Weiss, 2008). The ICF category *s7701 Joints,* which is also not yet included in the ICF Core Sets for DM, but was regarded as important by the experts addresses similar contents. In particular the small joints of the hands are involved resulting in a cheiroarthropathy, frozen shoulder, Dupuytren's contracture or trigger finger (Aljahlan et al 1999; Aydeniz et al 2008). However, the joints in general could be affected by long-term DM and they become passively more inflexible. The

other way round the syndrome of limited joint mobility affects the joints of diabetic feet and increases the risk to ulceration and amputation.

Furthermore, Diabetic osteoarthropathy, also known as Charcot's joint, is a common complication of DM and compromises joints and bones. It is regularly associated to diabetic neuropathy. The joints which are strained by weight become progressively destructed and the results are subsequent dislocations, fractures, and deformities (Shah et Hugghins, 2002). Thus, not least the ICF category *s7700 Bones* was considered as affected by DM by the participants. In addition, diabetic structure alterations in bone quality and quantity result in an increased risk of fractures, like in hip and proximal humerus. However, there are different causes for fractures in patients with type 1 and type 2 diabetes. In patients with type 1 diabetes a reduced bone mineral density (BMD) is measured whereas in patients with type 2 diabetes the BMD is normal to elevated. Although this seems to be paradox, the bone could be impacted in various other ways, including e.g. poor bone quality, changes in insulin level, hyperglycaemia with higher concentrations of advanced glycation end products in collagen, microangiopathy, inflammation or frequent falls due to secondary diseases like diabetic retinopathy, stroke or peripheral polyneuropathy with balance disturbances (Schwartz, 2002).

Although Insulin has an anabolic and strengthening effect to the bone architecture, the fracture risk persists in people with hyperinsulinaemic states. This supports the assumption that there is a multifactorial genesis of bone affection in DM (Thrailkill et al, 2005).

Finally, the ICF category *s7702 Muscles* was identified by the participating physicians. A study (Park et al, 2009) supports this opinion by investigating that type 2 diabetes has a significant influence on excessive loss of skeletal muscle mass in older patients. Additionally, impairments and atrophy of the skeletal muscle caused by distinct diabetic neuropathy do often occur. Muscle weakness is the associated symptom especially at the ankle and knee (Andresen, 1999). A rare complication, diabetic myonecrosis, takes a special position in muscle structure damage and arises in patients with long-standing DM with complications like neuropathy, retinopathy or nephropathy. The involved muscle is painfully swollen, the muscle strength is decreased and sometimes there is a palpable tender mass, consisting of muscle necrosis and

edema (Glauser et al, 2008). Furthermore, muscle structure changes in DM could also result from diabetic amyotrophy whose pathogenesis is still unknown. Microvasculitis and secondary ischaemia of the lumbosacral plexus could be the reason (Bhanushali et Muley, 2008).

Due to the reduced immune system functions of patients with DM infectious and inflammatory problems like pyomyositis, abscess, necrotizing fasciitis, osteomyelitis, dermatomyositis and polymyostitis could come up with severe structure damage as well (Glauser et al, 2008).

6.3 Personal Factors

A large number of participants' responses were identified as *Personal Factors*. According to the ICF language *Personal Factors* are Contextual Factors related to the individual such as age, gender, character style, other health conditions, education, and coping styles (WHO, 2001). They are not yet classified in the ICF. Final agreements of more than 90% have been reached in 35 issues in the study. This finding highlights the importance of *Personal Factors* to the physicians' treatment of patients with DM.

In this survey especially other health conditions, coping styles and self management were mentioned by the participants. This is not surprising considering that DM is a disease which affects the body in multifactorial ways. The complications and secondary diseases could be mild, severe or even life-threatening, if there is no medical care available.

Patients suffering from DM use a combination of coping strategies and the perception of control over DM can be a relevant factor (Macrodimitris et Endler, 2001).

Furthermore, perceived autonomous support from health care providers is positively associated with autonomous self-regulation. Perceived autonomous support and perceived competence both were clearly associated with quality of life, adherence to medications and glycaemic control in diabetic patients. Diabetes-related health outcome could be advanced by improving the self-management (Williams et al, 2009). However, all mentioned *Personal*

Factors emphasize the need of self-management and regular checkups due to the possible severe complications.

A systematic literature review from Geyh et al (2011) and a qualitative approach from Grothkamp (2012) stress this need of development and the relevance for *Personal Factors* in the use of the ICF in clinical, administrative and research settings. The implementation of the *Personal Factors* could be various and illustrates the individuals' attitudes and needs, especially related to the variety in different cultural and social positions. The processing of the *Personal Factors* in the ICF could be an approach to get a comprehensive and complete description of relevant aspects influencing a patient's functioning and health and to sustain the claim of people with disabilities. In general a classification of the *Personal Factors* would improve the diagnostic and therapeutic strategies in patients with DM in each nation.

6.4 Not covered

There are some results that are not sufficiently covered by the ICF. The role of non-oral drugs in the treatment of patients with DM is a very important matter. In type 1 diabetes and in advanced stage of type 2 diabetes it is essential for patients to inject or in some cases to inhale Insulin (Nathan et al, 2009). The ICF category *e110 Products or substances for personal consumption* includes on a more detailed level *Drugs* in its definition. The definition contains the phrase "for ingestion", which is just related to oral medication. At this point a more detailed subcategory on the level like *e1101 Drugs* would be helpful und could complete the ICF classification.

Furthermore, the experts named various difficulties in patients with DM addressed to the self-management, such as the necessary skills handling insulin injections, monitoring the blood glucose level and the management of physical activity and diet. The category *d570 Looking after one's health* and the related, more detailed categories do not fully cover these explicit patients' problems. Also the category *d1551 Acquiring complex skills* cannot solve the problem of a specific category. As Kirchberger et al, 2009 and Awad et al.,

2009 correctly mentioned the complex problem of self management is not covered by a definite ICF category. Depending on these analogue findings the implementation of a specific category has to be considered.

The component *Body Structures* is divided in its first chapter into the different structures of the nervous system. In this schedule the categories for peripheral nerves are not perfectly represented. Due to the importance of the cumulative complications of the diabetic neuropathy and the subsequently following problems, it is necessary to include a further category besides *s198 Structures of the nervous system, other specified* and *s199 Structures of the nervous system, unspecified*. In particular chronic sensorimotor distal polyneuropathy (DPN) is mentioned by burning and stabbing pain or paraesthesia of the proximal lower extremities. Although there are different theories trying to define the precise cause of the diabetic neuropathy, the electrophysiological deficits demonstrates the structure damage of the nerve fibers (Chin et Rubin, 2009).

7 Limitations

The reliability of this study is demonstrated by the response rates and the inter-rater reliability as assessed with the Kappa statistics and its 95% bootstrapped confidence interval. The Kappa statistics for the linking was 0.69 with a 95% bootstrapped confidence interval of 0.66 – 0.72 and reflects a moderate agreement between the health professionals who performed the linking. The Kappa coefficient ranges from 0 to 1. The complete agreement between two raters, in this case trained health professionals, would result in a value of 1. Contrary, a coefficient of 0 represents no additional agreement beyond what is expected by chance alone (Vierkant, 2007). The reported attrition rates of roughly 50% have been exceeded conspicuously by response rates between 81.6% and 96.2% in the single rounds. Therefore, to

accomplish the aim of the study the Delphi technique seemed to be an adequate method (Geschka, 1977).

The worldwide prevalence of DM is represented in the international provenance of the participants from all six world regions. These regions are defined by the World Health Organization and the recruitment provides a wide spread of expert opinion. Anyhow, the representativeness of this survey results and the external validity are restricted, because some world regions such as the African region and the Eastern Mediterranean region seem to be underrepresented with four participants in the third Delphi round. This fact may show a supposable lack of experts in DM in this region. However, the reasons of underrepresentation of experts could be various. It is always important to consider the infrastructure, the political and social situations in some states and therefore the possibility to get access to an email server and other multimedia communication systems. Another factor for limited representativeness is that there was no random sample of the participants available, most likely due to the absence of target population databases. Hence, this sample does not represent the full spectrum of the physicians experienced in the treatment of DM patients worldwide. Therefore, further validation studies should be accomplished to investigate the experience of physicians in DM from the underrepresented countries in this study.

8 Conclusion

The requirement for practicability led to the development of the ICF Core Sets in order to use them in daily practice. The Comprehensive Core Set for DM reflects the entire spectrum of typical problems in patients with DM and defines a list of the most relevant ICF categories in relation to the functioning in patients with DM. Hence, the definition of “what to measure” and not “how to measure” was generated. The use of the ICF Core Sets provides the interdisciplinary and comprehensive description of functioning and a common

language for health professionals (Stucki et al, 2002). The creation of standardized functioning profiles supplies the identification of necessary follow-up treatment and intervention goals. Furthermore, the use promotes patient-orientated goal setting and treatment as well as creating assessment schedules is facilitated. To find guidance on how to use the ICF Core Sets a manual for clinical practice has been created. This useful guideline should help the health professionals to structure the clinical description and assessment of functioning (Bickenbach et al, 2012). So far 33 ICF Core Sets have been developed (ICF Research Branch, 2013 DIMDI 2013), whereas the development projects are still ongoing for different other health conditions.

The validity of the Comprehensive Core Set for DM from the different perspectives including the health professionals' and the patients' perspective was confirmed in this and other different studies. (Rouf et al, 2004; Weigl et al, 2004; Awad et al, 2009; Kirchberger et al 2009; Abdullah et al, 2011). Further modified versions of the Comprehensive Core Set for DM would be important to discuss due to progressive changes of understanding, diagnosis and treatment of health conditions over time. Particularly a very important aspect of functioning would be the interaction between health conditions and the contextual factors as *Environmental* and *Personal Factors*. Further validation research in this area is a direction for future studies. At present the use of the ICF and the ICF Core Sets in clinical practice is developing (Bickenbach et al, 2012).

9 References

1. Abdullah MF, Nor NM, Mohd Ali SZ, et al. Validation of the comprehensive ICF core sets for diabetes mellitus: a Malaysian perspective. *Ann Acad Med Singapore*. 2011 Apr; 40(4): 168-78.

2. Adler M, Ziglio E. Gazing into the oracle: the Delphi method and its application in social policy and public health. Bristol, PA: Jessica Kingsley Publishers, 1996.

3. Ahmed AM. History of diabetes mellitus. *Saudi Med J.* 2002 Apr; 23 (4): 373-8.

4. Ahmed I, Goldstein B. Diabetes mellitus. *Clin Dermatol*. 2006 Jul-Aug; 24(4): 237-46.

5. Ahmed K, Muhammad Z, Qayum I. Prevalence of cutaneous manifestations of diabetes mellitus. *J Ayub Med Coll Abbottabad*. 2009 Apr-Jun; 21(2): 76-9.

6. Alberti KG. The clinical implications of impaired glucose tolerance. *Diabetic Medicine*. 1996 Nov; 13 (11): 927-37.

7. Alberti KG, Zimmet PZ. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Part 1: Diagnosis and Classification of Diabetes Mellitus. Provisional report of a WHO Consultation. *Diabetic Medicine.* 1998 Jul; 15 (7): 539–53.

8. Aljahlan M, Lee KC, Toth E. Limited joint mobility in diabetes. *Postgrad Med*. 1999 Feb; 105(2): 99-101, 105-6.

9. Almdal T, Scharling H, Jensen JS, et al. The independent effect of type 2 diabetes mellitus on ischemic heart disease, stroke, and death: a population based study of 13,000 men and women with 20 years of follow up. *Arch Intern Med*. 2004 Jul 12; 164(13): 1422-6.

10. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care*. 2012 Jan; 35 Suppl 1: 64-71. doi: 10.2337/dc12-s064.

11. American Diabetes Association. Executive summary: Standards of medical care in diabetes--2013. *Diabetes Care*. 2013 Jan; 36 Suppl 1: 4-10. doi: 10.2337/dc13-S004.

12. American Diabetes Association. Hyperglycemic crises in patients with diabetes mellitus. *Diabetes Care*. 2001 Nov; 24(11): 1988-96.

13. American Diabetes Association. Position statement: Standards of medical care in diabetes--2013. *Diabetes Care*. 2013 Jan; 36 (Suppl 1):11-66. doi: 10.2337/dc13-S011.

14. Andresen H. Motor function in diabetic neuropathy. *Acta Neurol Scand*. 1999 Oct; 100 (4): 211-220.

15. Asahina M, Yamanaka Y, Akaogi Y, et al. Measurements of sweat response and skin vasomotor reflex for assessment of autonomic dysfunction in patients with diabetes. *J Diabetes Complications*. 2008 Jul-Aug; 22(4): 278–83. doi:10.1016/j.jdiacomp.2007.03.009. Epub 2008 Apr 16.

16. Avogaro A, Giorda C, Maggini M, et al. Incidence of coronary heart disease in type 2 diabetic men and women: impact of microvascular complications, treatment, and geographic location. *Diabetes Care*. 2007 May; 30(5): 1241-7. Epub 2007 Feb 8.

17. Awad H, Cieza A, Coenen M, et al. Validation of the Comprehensive ICF Core Set for Diabetes Mellitus: The perspective of physical therapists. Poster presented at the Interact PhD Symposium, Munich, 2009. Available at: http://www.contoo.de/en_US/congress/paper/id/116/c_cult/en/lyt/c. Last accessed 08. April 2013.

18. Aydeniz A, Gursoy S, Guney E. Which musculoskeletal complications are most frequently seen in type 2 diabetes mellitus? *J Int Med Res*. 2008 May-Jun; 36(3): 505-11.

19. Bickenbach J, Cieza A, Rauch A, Stucki G (eds). ICF Research Branch, in cooperation with the WHO Collaborating Centre for the Family of International Classifications in Germany (at DIMDI). ICF Core Sets. Manual for clinical practice. Germany: Hogrefe, 2012.

20. Bhanushali MJ, Muley SA. Diabetic and non-diabetic lumbosacral radiculoplexus neuropathy. *Neurol India* 2008 Oct-Dec; 56(4):420-5.

21. Blair DI, Sagel J, Taylor I, et al. Diabetic Gustatory Sweating. *South Med J.* 2002 Mar; 95(3): 360–2.

22. Boudina S, Abel ED. Diabetic cardiomyopathy, causes and effects. *Rev Endocr Metab Disord*. 2010 Mar; 11(1): 31-9. doi:10.1007/s11154-010-9131-7.

23. Boulton AJ. The diabetic foot. *Med Clin North Am*. 1988 Nov; 72(6): 1513-30.

24. Boulton AJ, Vinik AI, Arezzo JC, et al. Diabetic neuropathies: a statement by the American Diabetes Association. *Diabetes Care*. 2005 Apr; 28(4): 956-62.

25. Bytzer P, Talley NJ, Leemon M, et al. Prevalence of Gastrointestinal Symptoms Associated With Diabetes Mellitus: A Population-Based Survey of 15 000 Adults. *Arch Intern Med*. 2001 Sep; 161(16): 1989–96.

26. Cavanagh PR, Lipsky BA, Bradbury AW et al. Treatment for diabetic foot ulcers. *Lancet*. 2005 Nov 12; 366(9498): 1725-35.

27. Chan Y. Differential diagnosis of dizziness. *Curr Opin Otolaryngol Head Neck Surg*. 2009 Jun; 17(3): 200-3. doi:10.1097/MOO.0b013e32832b2594.

28. Chandrasekharan B, Srinivasan S. Diabetes and the enteric nervous system. *Neurogastroenterol Motil* 2007 Dec; 19(12): 951-960. Epub 2007 Oct 17.

29. Chin EL, Rubin M. Diabetic Neuropathy. In: Poretsky L, ed. Principles of diabetes mellitus. 2nd ed. New York, USA: Springer, 2009: 362-65.

30. Cieza A, Brockow T, Ewert T, et al. Linking health-status measurements to the International Classification of Functioning, Disability and Health. *J Rehabil Med.* 2002; 34(5): 205-210.

31. Cieza A, Ewert T, Üstün B, et al. Development of ICF Core Sets for patients with chronic conditions. *J Rehabil Med.* 2004; Suppl 44: 9-11.

32. Cieza A, Geyh S, Chatterji S, et al. ICF linking rules: an update based on lessons learned. *J Rehabil Med*. 2005 Jul; 37(4): 212–8.

33. Cieza A, Stucki G. International Classification of Functioning, Disability and Health (ICF): A basis for multidisziplinary clinical practice. In: Bartlett SJ, Bingham CO, Maricic MJ, Icerson MD, Ruffing V, eds. Clinical Care in the rheumatic diseases, Association of Rheumatology Health Professionals 2006, Atlanta: 79-87.

34. Cohen J. A Coefficient of Agreement for Nominal Scales. *Educ Psychol Meas*. 1960; 20: 37-46.

35. Cowie CC, Rust KF, Byrd-Holt DD, et al. Prevalence of diabetes and impaired fasting glucose in adults in the U.S. population: National Health And Nutrition Examination Survey 1999-2002. *Diabetes Care*. 2006 Jun; 29(6): 1263-8.

36. Crisp J, Pelletier D, Duffield C, Nagy S, Adams A. It's all in a name. When is a 'Delphi study' not a Delphi study? *Aust J Adv Nurs*. 1999 Mar-May; 16(3): 32-7.

37. Cusi K. Nonalcoholic fatty liver disease in type 2 diabetes mellitus. *Curr Opin Endocrinol Diabetes Obes* 2009 Apr; 16(2): 141–9. doi:10.1097/MED.0b013e3283293015.

38. Davis SN. Hypoglycemia and hypoglycemic syndroms. In: Jameson JL, DeGroot LJ, eds. *Endocrinology: Adult and Pediatric*. 6th ed. Philadelphia: Saunders Elsevier; 2010: 873-96.

39. Dayan CM, Daniels GH. Chronic Autoimmune Thyroiditis. *NEJM*. 1996 Jul; 11; 335(2): 99-107.

40. DeVon HA, Ryan CJ, Ochs AL, et al. Symptoms Across the Continuum of Acute Coronary Syndromes: Differences Between Women and Men. *Am J Crit Care.* 2008 Jan; 17(1): 14–24. quiz 25.

41. DIMDI**,** Deutsches Institut für Medizinische Dokumentation und Information. ICF-Projects in German-speaking countries. Available at: http://www.dimdi.de/static/de/klassi/icf/icf-projekte.html. Last accessed: 09 April 2013.

42. Duffield C. The Delphi technique: a comparison of results obtained using two expert panels. *Int J Nurs Stud.* 1993 Jun; 30(3): 227-237.

43. Duvnjak L, Duvnjak M. The metabolic syndrome – an ongoing story. *J Physiol Pharmacol*. 2009 Dec; 60 Suppl 7: 19-24.

44. Ewert T, Fuessl M, Cieza A, et al. Identification of the most common patient problems in patients with chronic conditions using the ICF checklist. *J Rehabil Med.* 2004; Suppl 44: 22-29.

45. Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care.* 2003 Jan; 26 Suppl 1: 5-20.

46. Fagot-Campagna A, Pettitt DJ, Engelgau MM et al. Type 2 diabetes among North American children and adolescents: an epidemiologic review and a public health perspective. *J Pediatr*. 2000 May; 136 (5): 664-72.

47. Fatemi SS, Taghavi SM. Evaluation of sexual function in women with type 2 diabetes mellitus. *Diab Vasc Dis Res.* 2009 Jan; 6(1): 38–9. doi:10.3132/dvdr.2009.07.

48. Fitzgibbons PG, Weiss AP. Hand manifestations of diabetes mellitus. *J Hand Surg Am*. 2008 May-Jun; 33(5): 771-5. doi:10.1016/j.jhsa.2008.01.038.

49. Fonseca V, John-Kalarickal J. Chapter 13: Type 2 Diabetes Mellitus:Epidemiology, Genetics, Pathogenesis, and Clinical Manifestations. In: Poretsky L, ed. Principles of Diabetes Mellitus. 2nd ed. New York: Springer, 2010: 203-20.

50. Fuller JH, Stevens LK, Wang SL. Risk factors for cardiovascular mortality and morbidity: the WHO Mutinational Study of Vascular Disease in Diabetes. *Diabetologia*. 2001 Sep; 44 Suppl 2: 54-64.

51. Funnell MM, Brown TL, Childs BP, et al. National standards for diabetes self-management education. *Diabetes Care*. 2012 Jan; 35 (Suppl 1): 101-8. doi:10.2337/dc12-s101.

52. Geyh S, Peter C, Müller R, et al. The Personal Factors of the International Classification of Functioning, Disability and Health in the literature - a systematic review and content analysis. *Disabil Rehabil*. 2011;33 (13-14): 1089-102. doi:10.3109/09638288.2010.523104. Epub 2010 Oct 6.

53. Geiss LS, Pan L, Cadwell B, et al. Changes in incidence of diabetes in U.S. adults, 1997-2003. *Am J Prev Med*. 2006 May; 30(5): 371-7.

54. Geschka H. Delphi. In Bruckmann G, ed. Longterm prognosis. Würzburg/Wien: Heibert, 1977.

55. Girach A, Manner D, Porta M. Diabetic microvascular complications: can patients at risk be identified? A review. *Int J Clin Pract*. 2006 Nov; 60(11): 1471-83.

56. Girach A, Vignati L. Diabetic microvascular complications--can the presence of one predict the development of another? *J Diabetes Complications*. 2006 Jul-Aug; 20(4): 228-37.

57. Glauser SR, Glauser J, Hatem SF. Diabetic muscle infarction: a rare complication of advanced diabetes mellitus. *Emerg Radiol*. 2008 Jan; 15(1):61-5. Epub 2007 May 31

58. Gnavi R, Picariello R, Karaghiosoff L, et al. Determinants of quality in diabetes care process: The population-based Torino Study. *Diabetes Care*. 2009 Nov; 32(11): 1986-92. doi:10.2337/dc09-0647. Epub 2009 Aug 12.

59. Goodman CM. The Delphi technique: a critique. *J Adv Nurs*. 1987 Nov; 12(6): 729-34.

60. Griffin ML, South SA, Yankov VI, et al. Insulin-dependent diabetes mellitus and menstrual dysfunction. *Annals of medicine* 1994 Oct; 26(5): 331–40.

61. Grotkamp S, Cibis W, Nüchtern E, et al. Personal factors of the ICF. *Gesundheitswesen*. 2012 Jul; 74(7): 449-58. doi:10.1055/s-0032-1314823. Epub 2012 Jul 17.

62. Hadi HA, Suwaidi JA. Endothelial dysfunction in diabetes mellitus. *Vasc Health Risk Manag*. 2007; 3(6): 853-76.

63. Hampton S. Caring for the diabetes patient with a foot ulcer. *Br J Nurs*. 2006 Aug 10-Sep 13; 15(15): 22-7.

64. Hansen D, Bennedbæk FN, Hansen LK, et al. Thyroid function, morphology and autoimmunity in young patients with insulin-dependent diabetes mellitus. *Eur J Endocrinol.* 1999 Jun; 140 (6): 512-518.

65. Hansen L. Candidate genes and late-onset type 2 diabetes mellitus. Susceptibility genes or common polymorphisms? *Dan Med Bull*. 2003 Nov; 50 (4): 320-46.

66. Harris MI, Flegal KM, Cowie CC, et al. Prevalence of diabetes, impaired fasting glucose, and impaired glucose tolerance in U.S. adults. The Third National Health and Nutrition Examination Survey, 1988-1994. *Diabetes Care*. 1998 Apr; 21(4): 518-24.

67. Hepburn DA, Deary IJ, Frier BM, et al. Symptoms of acute insulin-induced hypoglycemia in humans with and without IDDM. Factor-analysis approach. *Diabetes Care.* 1991; 14(11): 949–57.

68. Hijazi R, Betancourt-Albrecht M, Cunningham G. Gonadal and Erectile dysfunction in diabetics. *Med Clin North Am.* 2004 Jul; 88(4): 933-45, xi.

69. ICF Research Branch, in cooperation with the WHO Collaborating Centre for the Family of International Classifications in Germany (at DIMDI). ICF Core Sets projects. Available at: http://www.icf-research-branch.org/icf-core-sets-projects-sp-1641024398. Last accessed 09 April 2013.

70. International Diabetes Federation, Clinical Guidelines Task Force. Global Guideline for Type 2 Diabetes. Brussels, Belgium: International Diabetes Federation, 2012. Available at: www.idf.org. Last accessed on 07 Febuary 2013.

71. International Diabetes Federation. IDF Diabetes Atlas, 5th edn. Brussels, Belgium: International Diabetes Federation, 2011. Available at http://www.idf.org/diabetesatlas/. Last accessed 26 January 2013.

72. Jones J, Hunter D. Consensus methods for medical and health services research. *BMJ*. 1995 Aug 5; 311(7001): 376-80.

73. Jovanovic L. Advances in diabetes for the millennium: diabetes in women. *MedGenMed* 2004 Oct; 6 (3 Suppl): 3.

74. Kaparianos A, Argyropoulou E, Sampsonas F, et al. Pulmonary complications in diabetes mellitus. *Chron Respir Dis.* 2008; 5(2): 101–8. doi:10.1177/1479972307086313

75. Kirchberger I, Coenen M, Hierl FX, et al. Validation of the International Classification of Functioning, Disability and Health (ICF) core set for diabetes mellitus from the patient perspective using focus groups. *Diabet Med*. 2009 Jul; 26(7): 700-7. doi:10.1111/j.1464-5491.2009.02762.x.

76. Kitabchi AE, Umpierrez GE, Murphy MB, et al. Management of hyperglycemic crises in patients with diabetes. *Diabetes Care*. 2001 Jan; 24(1): 131-53.

77. Kodolova IM, Lysenko LV, Saltykov BB. Changes in the lungs in diabetes mellitus. *Arkh Patol.* 1982; 44: 35-40.

78. Linstone HA, Turoff M, Helmer O. The Delphi method: Techniques and applications. Reading, Mass., London: Addison-Wesley, 1975.

79. MacMahon S. Antihypertensive drug treatment: the potential, expected and observed effects on vascular disease. *J Hypertens Suppl*. 1990 Dec; 8(7): 239-44.

80. Macrodimitris SD, Endler NS. Coping, control, and adjustment in type 2 diabetes. *Health Psychol*. 2001 May; 20(3): 208–16.

81. Marvisi M, Marani G, Brianti M, et al. Pulmonary complications in diabetes mellitus. *Recenti Prog Med.* 1996 Dec; 87(12): 623-7.

82. Massi-Benedetti M, Federici MO. Cardiovascular risk factors in type 2 diabetes: the role of hyperglycaemia. *Exp Clin Endocrinol Diabetes*. 1999; 107 Suppl 4: 120-3.

83. McAulay V, Deary IJ, Frier BM. Symptoms of hypoglycaemia in people with diabetes. *Diabet Medicine.* 2001 Sep; 18(9): 690-705.

84. McKenna HP. The Delphi technique: a worthwhile research approach for nursing? *J Adv Nurs*. 1994 Jun; 19(6): 1221-5.

85. Miettinen H, Lehto S, Salomaa V, et al. Impact of diabetes on mortality after the first myocardial infarction. The FINMONICA Myocardial Infarction Register Study Group. *Diabetes Care*. 1998 Jan; 21(1): 69-75.

86. Mohr JP. Stroke: Pathophysiology, diagnosis, and management. 4th ed. Philadelphia, PA: Churchill Livingstone, 2004.

87. Most RD, Sinnock P. The epidemiology of lower extremity amputations in diabetic individuals. *Diabetes Care*. 1983 Jan-Feb; 6(1): 87-91.

88. Nathan DM, Buse JB, Davidson MB, et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care* 2009 Jan; 32(1): 193-203. doi: 10.2337/dc08-9025. Epub 2008 Oct 22.

89. Nishimura H. Diabetes mellitus and atherosclerosis. *Nippon Rinsho*. 2011 Jan; 69(1): 131-7.

90. Olek K. Maturity-onset diabetes of the young: an update. *Clin Lab*. 2006; 52 (11-12): 593-8.

91. Palmer ND, McDonough CW, Hicks PJ, et al. A genome-wide association search for type 2 diabetes genes in African Americans. *PLoS One*. 2012; 7(1): e29202. doi:10.1371/journal.pone.0029202. Epub 2012 Jan 4.

92. Papaspyros NS. The history of diabetes. In: Verlag GT, ed. The History of Diabetes Mellitus. Stuttgart: Thieme; 1964: 4-5.

93. Pappone C, Santinelli V. Cardiac electrophysiology in diabetes. *Minerva Cardioangiol*. 2010 Apr; 58(2): 269-76.

94. Park SW, Goodpaster BH, Lee JS, et al. Exessive loss of skeletal muscle mass in older adults with type 2 diabetes. *Diabetes Care.* 2009 Nov; 32 (11): 1993-7. doi:10.2337/dc09-0264. Epub 2009 Jun 23.

95. Patel CJ, Chen R, Kodama K, et al. Systematic identification of interaction effects between genome- and environment-wide associations in type 2 diabetes mellitus. 2013 Jan; 20. [Epub ahead of print].

96. Penson DF, Latini DM, Lubeck DP, et al. Do impotent men with diabetes have more severe erectile dysfunction and worse quality of life than the general population of impotent patients? Results from the Exploratory Comprehensive Evaluation of Erectile Dysfunction (ExCEED) database. *Diabetes Care*. 2003 Apr; 26(4): 1093-9.

97. Pestoni C, Ferreirós MM, de la Torre C, et al. Two girls with necrobiosis lipoidica and type I diabetes mellitus with transfollicular elimination in one girl. *Pediatr Dermatol*. 2003 May-Jun; 20(3): 211-4.

98. Podolsky DK. Infiltrative, genetic, and metabolic diseases affecting the liver. In: Kasper DL, Braunwald E, Fauci AS, et al, eds. Harrison's Principles of Internal Medicine. 16th ed. USA: McGraw-Hill Companies, 2004: 1869-71.

99. Powers AC. Diabetes Mellitus. In: Kasper DL, Braunwald E, Fauci AS, et al, eds. Harrison's Principles of Internal Medicine. 16th ed. USA: McGraw-Hill Companies, 2004: 2152-80.

100. Rajbhandari SM, Jenkins RC, Davies C, et al. Charcot neuroarthropathy in diabetes mellitus. *Diabetologia*. 2002 Aug; 45(8): 1085-96. Epub 2002 Jul 11.

101. Roche EF, Menon A, Gill D, et al. Clinical presentation of type 1 diabetes. *Pediatr Diabetes*. 2005 Jun; 6(2): 75-8.

102. Ritz E. Diabetic nephropathy. *Saudi J Kidney Dis Transpl*. 2006 Dec; 17(4): 481-90.

103. Ritz E, Tarng DC. Renal disease in type 2 diabetes. *Nephrol Dial Transplant*. 2001; 16 Suppl 5: 11-8.

104. Ritz E, Zeng XX, Rychlík I. Clinical manifestation and natural history of diabetic nephropathy. *Contrib Nephrol*. 2011; 170: 19-27. doi: 10.1159/000324939. Epub 2011 Jun 9.

105. Ruof J, Cieza A, Wolff B, et al. ICFCore Sets for Diabetes Mellitus. *J Rehabil Med.* 2004; Suppl. 44: 100-106.

106. Sanghera DK, Blackett PR. Type 2 Diabetes Genetics: Beyond GWAS. *J Diabetes Metab*. 2012 Jun 23; 3 (198). pii: 6948.

107. Schroner Z, Lazurova I, Petrovicova J. Autoimmune thyroid diseases in patients with diabetes mellitus. *Bratisl Lek Listy* 2008; 109(3): 125-9.

108. Schwartz AV. Diabetes Mellitus: Does it Affect Bone? *Calcif Tissue Int*. 2003 Dec; 73(6): 515–9. Epub 2003 Oct 2.

109. Scott LJ, Mohlke KL, Bonnycastle LL, et al. A genome-wide association study of type 2 diabetes in Finns detects multiple susceptibility variants. *Science*. 2007 Jun 1; 316 (5829): 1341-5. Epub 2007 Apr 26.

110. Shah MK, Hugghins SY. Charcot's joint: an overlooked diagnosis. *J La State Med Soc.* 2002; 154(5): 246-50.

111. Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. *Diabetes Res Clin Pract*. 2010 Jan; 87 (1): 4-14. doi:10.1016/j.diabres.2009.10.007. Epub 2009 Nov 6.

112. Shemer A, Bergman R, Linn S, et al. Diabetic dermopathy and internal complications in diabetes mellitus. *Int J Dermatol*. 1998 Feb; 37(2): 113-5.

113. Skamagas M, Breen TL, LeRoith D. Update on diabetes mellitus: prevention, treatment, and association with oral diseases. *Oral Dis*. 2008 Mar; 14: 105-114. doi:10.1111/j.1601-0825.2007.01425.x.

114. Sladek R, Rocheleau G, Rung J, et al. A genome-wide association study identifies novel risk loci for type 2 diabetes. *Nature*. 2007 Feb 22; 445 (7130): 881-5. Epub 2007 Feb 11.

115. Snyder-Halpern R, Thompson CB, Schaffer J. Comparison of mailed vs. Internet applications of the Delphi technique in clinical informatics research. Proc AMIA Symp. 2000: 809-13.

116. Solomon CG, Hu FB, Dunaif A, et al. Long or highly irregular menstrual cycles as a marker for risk of type 2 diabetes mellitus. *JAMA.* 2001 Nov; 286(19): 2421–6.

117. Sood S, James WD. 45 Cutaneous Manifestations of Diabetes Mellitus. In: Davidson JK, ed. Clinical diabetes mellitus: a problem oriented approach. 3rd ed. New York, USA: Thieme, 2000: 753-66.

118. Sowers JR, Epstein M, Frohlich ED. Diabetes, hypertension, and cardiovascular disease: an update. *Hypertension*. 2001 Apr; 37(4): 1053-9.

119. Steiner WA, Ryser L, Huber E, et al. Use of the ICF model as a clinical problem-solving tool in physical therapy and rehabilitation medicine. *Phys Ther*. 2002 Nov; 82(11): 1098-107.

120. Strack TR. Inhaled human insulin. *Drugs today (Barc).* 2006 Apr; 42(4): 207-21.

121. Strotmeyer ES, Steenkiste AR, Foley TP, et al. Menstrual cycle differences between women with type 1 diabetes and women without diabetes. *Diabetes Care* 2003 Apr; 26(4): 1016–21.

122. Stucki G, Cieza A, Ewert T, et al. Application of the International Classification of Functioning, Disability and Health (ICF) in clinical practice. *Disabil Rehabil*. 2002 Mar 20; 24(5): 281-2.

123. Stucki G, Grimby G. Applying the ICF Medicine. *J Rehabil Med*. 2004 Jul; (44 Suppl): 5-6.

124. Thomas PK. Classification, differential diagnosis, and staging of diabetic peripheral neuropathy. *Diabetes*. 1997 Sep; 46 (Suppl 2): 54-7.

125. Thrailkill KM, Lumpkin CK, JR., Bunn RC, et al. Is insulin an anabolic agent in bone? Dissecting the diabetic bone for clues. *Am J Physiol Endocrinol Metab*. 2005 Nov; 289(5): E735-745.

126. Tongco MDC. Purposive sampling as a tool for informant selection. *Ethnobotany Research & Application*. 2007; 5: 147-158. Available at: http://hdl.handle.net/10125/227.

127. Torbenson M, Chen YY, Brunt E, et al. Glycogenic Hepatopathy: An underrecognized hepatic complication of diabetes mellitus. *Am J Surg Pathol.* 2006 Apr; 30(4): 508-13.

128. Tuomilehto J, Rastenyte D, Jousilahti P, et al. Diabetes mellitus as a risk factor for death from stroke. Prospective study of the middle-aged Finnish population. *Stroke*. 1996 Feb; 27(2): 210-5.

129. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998 Sep 12; 352(9131): 837-53.

130. Unoki H, Takahashi A, Kawaguchi T, et al. SNPs in KCNQ1 are associated with susceptibility to type 2 diabetes in East Asian and European populations. *Nat Genet*. 2008 Sep; 40(9): 1098-102. doi:10.1038/ng.208.

131. Üstün B, Chatterji S, Kostanjsek N. Comments from WHO for the Journal of Rehabilitation Medicine Special Supplement on ICF Core Sets. *J Rehabil Med* 2004; Suppl. 44: 7–8.

132. Vassy JL, Meigs JB. Is genetic testing useful to predict type 2 diabetes? *Best Pract Res Clin Endocrinol Metab*. 2012 Apr; 26(2): 189-201. doi:10.1016/j.beem.2011.09.002.

133. Vierkant RAA. SAS Macro for Calculating Bootstrappes Confidence Intervals about a Kappa Coefficient. 2004;
Available at:
http://www2.sas.com/proceedings/sugi22/STATS/PAPER295.PDF.
Last accessed 26 January 2013.

134. Vinik AI, Maser RE, Mitchell BD, et al. Diabetic autonomic neuropathy. *Diabetes Care*. 2003 May; 26(5): 1553-79.

135. Wagner EH. The role of patient care teams in chronic disease management. *BMJ*. 2000 Feb 26; 320(7234): 569-72.

136. Weigl M, Cieza A, Andersen C, et al. Identification of relevant ICF categories in patients with chronic health conditions: a Delphi exercise. *J Rehabil Med.* 2004; Suppl 44: 12-21.

137. Wheat LJ. Infection and diabetes mellitus. *Diabetes Care*. 1980 Jan-Feb; 3(1): 187-97.

138. WHO. International Classification of Functioning, Disability and Health: ICF. Geneva: World Health Organization, 2001.

139. WHO. International Statistical Classification of Diseases and Related Health Problems: ICD-10. 10th Revision. 2010 ed. Geneva: World Health Organization, 2011. Available at: http://www.who.int/classifications/icd/en/.

140. Wild S, Roglic G, Green A, Sicree R, King H. Global Prevalence of Diabetes. *Diabetes Care.* 2004 May; 27 (5): 1047–53.

141. Wilkinson-Berka JL, Miller AG. Update on the treatment of diabetic retinopathy*. ScientificWorldJournal*. 2008 Feb 6; 8: 98-120. doi:10.1100/tsw.2008.25.

142. Williams GC, Patrick H, Niemiec CP, et al. Reducing the health risks of diabetes: how self-determination theory may help improve medication adherence and quality of life. *Diabetes Educ*. 2009 May-Jun; 35(3): 484-92. doi:10.1177/0145721709333856. Epub 2009 Mar 26.

143. Wolff B, Cieza A, Parentin A, et al. Identifying the concepts contained in outcome measures of clinical trials on four internal disorders using the International Classification of Functioning, Disability and Health as a reference. *J Rehabil Med.* 2004; Suppl 44: 37-42.

144. World Health Organization. Diabetes - Fact Sheet No. 312, 2013. Available at: http://www.who.int/mediacentre/factsheets/fs312/en/. Last accessed 06 April 2013.

145. World Health Organization. Global data on visual impairments 2010.Geneva: World Health Organization, 2012.

146. Yu AS, Keeffe EB. Nonalkoholic fatty liver disease. *Rev Gastroenterol Disord.* 2002; 2(1): 11-9.

147. Zajac J, Shrestha A, Patel P, Poretsky L. Chapter 1: The Main Events in the History of Diabetes Mellitus. In: Poretsky L, ed. Principles of Diabetes Mellitus. 2nd ed. New York: Springer, 2010: 3-16.

10 Attachements (Anhang)

10.1 Comprehensive ICF Core Set for Diabetes Mellitus

Categories of the component *Body Functions*:

ICF Code				ICF Category
1st level	2nd level	3rd level	4th level	
	b110			Consciousness functions
	b130			Energy and drive functions
		b1300		Energy level
		b1302		Appetite
	b134			Sleep functions
	b140			Attention functions
	b152			Emotional functions
	b210			Seeing functions
	b260			Proprioceptive function
	b265			Touch function
	b270			Sensory functions related to temperature and other stimuli
	b280			Sensation of pain
	b410			Heart functions
	b415			Blood vessel functions
	b420			Blood pressure functions
	b430			Haematological system functions
	b435			Immunological system functions

ICF Code				ICF Category
1st level	2nd level	3rd level	4th level	
	b455			Exercise tolerance functions
		b4550		General physical endurance
		b4551		Aerobic capacity
		b4552		Fatiguability
	b515			Digestive functions
	b530			Weight maintenance functions
	b540			General metabolic functions
	b545			Water, mineral and electrolyte balance functions
	b555			Endocrine gland functions
	b610			Urinary excretory functions
	b620			Urination functions
	b630			Sensations associated with urinary functions
	b640			Sexual functions
	b660			Procreation functions
	b710			Mobility of joint functions
	b730			Muscle power functions
	b810			Protective functions of the skin
	b820			Repair functions of the skin
	b840			Sensation related to the skin

Categories of the component *Body Structures*:

ICF Code				ICF Category
1st level	2nd level	3rd level	4th Level	
	s140			Structure of sympathetic nervous system
	s150			Structure of parasympathetic nervous system
	s220			Structure of eyeball
	s410			Structure of cardiovascular system
		s4100		Heart
		s4101		Arteries
		s4102		Veins
		s4103		Capillaries
	s550			Structure of pancreas
	s610			Structure of urinary system
		s6100		Kidneys
	s630			Structure of reproductive system
	s750			Structure of lower extremity
		s7502		Structure of ankle and foot
	s810			Structure of areas of skin
	s830			Structure of nails

Categories of the component *Activities and Participation*:

ICF Code				ICF Category
1st level	2nd level	3rd level	4th Level	
	d240			Handling stress and other psychological demands
	d440			Fine hand use
	d450			Walking
	d455			Moving around
	d475			Driving
	d520			Caring for body parts
	d570			Looking after one's health
	d620			Acquisition of goods and services
	d630			Preparing meals
	d750			Informal social relationships
	d760			Family relationships
	d770			Intimate relationships
	d845			Acquiring, keeping and terminating a job
	d850			Remunerative employment
	d920			Recreation and leisure
		d9201		Sports
		d9204		Hobbies
		d9205		Socializing

Categories of the component *Environmental Factors*:

ICF Code				ICF Category
1st level	2nd level	3rd level	4th Level	
	e110			Products or substances for personal consumption
	e115			Products and technology for personal use in daily living
	e310			Immediate family
	e315			Extended family
	e320			Friends
	e325			Acquaintances, peers, colleagues, neighbours and community members
	e330			People in positions of authority
	e340			Personal care providers and personal assistants
	e355			Health professionals
	e360			Other professionals
	e410			Individual attitudes of immediate family members
	e415			Individual attitudes of extended family members
	e420			Individual attitudes of friends
	e425			Individual attitudes of acquaintances, peers, colleagues, neighbours and community members
	e430			Individual attitudes of people in positions of authority
	e440			Individual attitudes of personal care providers and personal assistants
	e450			Individual attitudes of health professionals
	e455			Individual attitudes of other professionals
	e465			Social norms, practices and ideologies

ICF Code				ICF Category
1st level	2nd level	3rd level	4th Level	
	e510			Services for the production of consumer goods
	e550			Legal services, systems and policies
	e555			Associations and organizational services, systems and policies
	e560			Media services, systems and policies
	e570			Social security services, systems and policies
	e575			General social support services, systems and policies
	e580			Health services, systems and policies
	e585			Education and training services, systems and policies
	e590			Labour and employment services, systems and policies
	e595			Political services, systems and policies

10.2 Questionnaire of the First Delphi Round

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

What are the patients' problems, patients' resources and aspects of environment treated by physicians in patients with diabetes mellitus ?

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

Some information about yourself:

Age years
Gender

Specialties/Certifications

Current professional activity

Professional experience years

Practical experience with patients with diabetes mellitus years

Do you treat diabetes mellitus patients mainly in the ...

... acute situation ?
... early-postacute situation ?
... chronic situation ?

How would you rate your expertise in the treatment of patients with diabetes mellitus ?

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

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 diabetes mellitus ?

ICF code	ICF category title	ICF category description	YES/NO
b1100	State of consciousness	Mental functions that when altered produce states such as clouding of consciousness, stupor or coma.	
b1301	Motivation	Mental functions that produce the incentive to act; the conscious or unconscious driving force for action.	
b1303	Craving	Mental functions that produce the urge to consume substances, including substances that can be abused.	
b134	Sleep functions	General mental functions of periodic, reversible and selective physical and mental disengagement from one's immediate environment accompanied by characteristic physiological changes.	
b152	Emotional functions	Specific mental functions related to the feeling and affective components of the processes of the mind.	
b1522	Range of emotion	Mental functions that produce the spectrum of experience of arousal of affect or feelings such as love, hate, anxiousness, sorrow, joy, fear and anger.	

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

ICF code	ICF category title	ICF category description	YES/NO
b210	Seeing functions	Sensory functions relating to sensing the presence of light and sensing the form, size, shape and colour of the visual stimuli.	
b2100	Visual acuity functions	Seeing functions of sensing form and contour, both binocular and monocular, for both distant and near vision.	
b2102	Quality of vision	Seeing functions involving light sensitivity, colour vision, contrast sensitivity and the overall quality of the picture.	
b21023	Visual picture quality	Seeing functions involving the quality of the picture.	
b230	Hearing functions	Sensory functions relating to sensing the presence of sounds and discriminating the location, pitch, loudness and quality of sounds.	

10.4 Questionnaire of the Third Delphi Round (first page)

Delphi Exercise Round 3 **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 diabetes mellitus?

ICF code	ICF category title	ICF category description	ID-number	% agreement	YES/NO
b1100	State of consciousness	Mental functions that when altered produce states such as clouding of consciousness, stupor or coma.	1;2;3;4;5;6;7;8;9;10;11;12;13;14;16;17;18;19;20;21;23;24;25;26;27;28;29;30;31;32;33;34;35;36;37;38;40;41;42;43;44;45;46;47;48;49;50;51;52;53;54;55;56;57;58;59;60;61;62;63;65;66;68;70;72;73;74;75;76;77;78	89.9%	
b1301	Motivation	Mental functions that produce the incentive to act; the conscious or unconscious driving force for action.	1;3;5;7;9;12;14;17;18;19;20;21;22;24;25;26;27;28;29;30;31;32;33;34;35;36;37;38;39;40;42;43;44;45;46;47;48;49;50;51;52;53;54;55;56;57;58;60;61;62;63;64;65;67;68;69;70;72;74;75;76;77;78	79,9%	
b1303	Craving	Mental functions that produce the urge to consume substances, including substances that can be abused.	3;4;5;7;9;10;12;14;17;18;20;23;24;25;26;28;29;31;32;33;34;35;36;37;38;39;43;44;45;46;47;48;49;50;51;52;53;54;55;56;57;58;61;63;64;67;68;70;72;73;74;75;76; 77;78	69,6%	
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.	2;3;4;5;6;7;9;12;16;17;19;23;25;26;28;29;30;31;32;33;34;35;36;37;38;40;42;43;44;45;46;47;48;49;50;51;52;53;54;55;56;57;58;59;61;62;63;64;66;68;69;70;72;73;74;75;76;77;78	74,7%	
b152	Emotional functions	Specific mental functions related to the feeling and affective components of the processes of the mind.	1;2;3;4;5;7;8;9;12;13;14;17;19;21;22;24;25;26;27;29;30;31;32;33;34;35;36;37;38;39;40;43;44;45;46;47;48;49;50;51;52;53;54;55;56;57;58;59;60;61;62;63;64;65;67;68;69;70;72;73;75;76;77;78;79	82,3%	
b1522	Range of emotion	Mental functions that produce the spectrum of experience of arousal of affect or feelings such as love, hate, anxiousness, sorrow, joy, fear and anger.	1;2;3;4;5;8;9;14;17;19;20;21;24;25;26;27;29;30;31;32;33;34;35;37;38;39;42;43;44;45;46;47;48;49;50;51;52;53;54;55;56;57;58;60;61;62;63;64;67;68;69;70;72;73;75;76;77;78;79	100,0%	

10.5 Results from the second and third Delphi Round

Body Functions:

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th level			
	b110			**Consciousness functions**		
		b1100		State of consciousness	89.9	98.7
	b130			**Energy and drive functions**		
		b1300		**Energy level**		
		b1301		Motivation	79.7	86.8
		b1302		**Appetite**		
		b1303		Craving	69.6	68.4
	b134			**Sleep functions**	74.7	82.9
	b140			**Attention functions**		
	b152			**Emotional functions**	82.3	88.0
		b1522		Range of emotion	100	88.2
	b210			**Seeing functions**	79.7	86.7
		b2100		Visual acuity functions	93.7	97.4
		b2102		Quality of vision	86.1	94.7
			b21023	Visual picture quality	80.8	85.1
	b230			Hearing functions	62.0	62.7
		b2401		Dizziness	89.9	92.0
	b260			**Proprioceptive function**		

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th level			
	b265			**Touch function**	94.9	97.3
	b270			**Sensory functions related to temperature and other stimuli**	97.5	98.7
		b2702		Sensitivity to pressure	88.6	94.7
		b2703		Sensitivity to a noxious stimulus	94.8	98.7
	b280			**Sensation of pain**	97.5	97.3
			b28011	Pain in chest	89.7	92.0
			b28014	Pain in upper limb	83.5	88.0
			b28015	Pain in lower limb	98.7	100
			b28016	Pain in joints	75.9	73.3
	b410			**Heart functions**	89.7	94.7
		b4101		Heart rhythm	83.5	85.3
		b4103		Blood supply to the heart	88.5	93.3
	b415			**Blood vessel functions**	91.1	97.3
		b4150		Functions of arteries	98.7	100
		b4151		Functions of capillaries	87.3	93.1
		b4152		Functions of veins	69.9	68.0
	b420			**Blood pressure functions**	94.9	96.0
		b4200		Increased blood pressure	97.5	98.7
		b4201		Decreased blood pressure	84.8	88.0
		b4202		Maintenance of blood pressure	94.9	98.7
	b430			**Haematological system functions**	73.4	77.3
		b4300		Production of blood	59.5	58.1

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th level			
		b4302		Metabolite-carrying functions of the blood	67.1	64.0
		b4303		Clotting functions	72.2	73.3
	b435			**Immunological system functions**	91.1	94.7
		b4350		Immune response	88.6	94.7
	b440			Respiration functions	67.1	66.7
	b455			**Exercise tolerance functions**		
		b4550		**General physical endurance**	84.8	92.0
		b4551		**Aerobic capacity**		
		b4552		**Fatiguability**	88.6	90.5
		b5104		Salivation	59.5	65.3
		b5105		Swallowing	65.8	68.9
		b5106		Regurgitation and vomiting	83.5	82.7
	b515			**Digestive functions**	86.1	90.7
		b5150		Transport of food through stomach and intestines	91.0	94.7
		b5151		Breakdown of food	60.8	60.0
		b5153		Tolerance to food	62.0	57.3
	b525			Defecation functions	83.5	89.3
		b5251		Faecal consistency	79.7	76.0
		b5252		Frequency of defecation	83.5	85.3
		b5253		Faecal continence	74.7	77.0
	b530			**Weight maintenance functions**	93.7	93.3
	b535			Sensations associated with the digestive system	75.9	81.3

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th level			
		b5350		Sensation of nausea	79.7	82.7
	b540			**General metabolic functions**	93.7	98.7
		b5401		Carbohydrate metabolism	92.4	97.3
		b5403		Fat metabolism	91.1	95.9
	b545			**Water, mineral and electrolyte balance functions**	97.3	93.3
		b5450		Water balance	80.8	86.7
		b5451		Mineral balance	75.9	81.1
	b555			**Endocrine gland functions**	91.1	95.9
	b610			**Urinary excretory functions**	87.3	92.0
		b6100		Filtration of urine	87.2	96.0
	b620			**Urination functions**	92.4	96.0
		b6201		Frequency of urination	93.6	97.3
		b6202		Urinary continence	83.5	90.7
	b630			**Sensations associated with urinary functions**		
	b640			**Sexual functions**	98.7	97.3
		b6400		Functions of sexual arousal phase	78.2	78.7
		b6401		Functions of sexual preparatory phase	82.1	86.5
	b650			Menstruation functions	74.7	77.0
	b660			**Procreation functions**		
		b6600		Functions related to fertility	73.4	72.6
		b6601		Functions related to pregnancy	89.9	94.7
		b6602		Functions related to childbirth	84.8	89.3

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th level			
		b6700		Discomfort associated with sexual intercourse	79.7	84.0
	b710			**Mobility of joint functions**	73.4	73.3
		b7100		Mobility of a single joint	72.2	73.3
		b7102		Mobility of joints generalized	69.6	62.7
		b7200		Mobility of scapula	50.6	48.0
	b730			**Muscle power functions**	69.6	66.7
	b740			Muscle endurance functions	65.8	65.3
	b770			Gait pattern functions	73.4	72.0
		b7800		Sensation of muscle stiffness	67.1	64.0
		b7801		Sensation of muscle spasm	65.8	58.7
	b810			**Protective functions of the skin**	84.8	88.0
	b820			**Repair functions of the skin**	87.3	93.3
	b830			Other functions of the skin	79.7	81.3
	b840			**Sensation related to the skin**	92.2	96.0
	b850			Functions of hair	48.1	40.0
	b860			Functions of nails	68.4	70.7

Body Structures:

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
	s140			**Structure of sympathetic nervous system**	82.3	89.3
	s150			**Structure of parasympathetic nervous system**	78.5	88.0
	s220			**Structure of eyeball**	64.6	69.9
		s2203		Retina	94.9	97.3
		s2204		Lens of eyeball	93.7	98.7
	s320			Structure of mouth	60.8	64.4
		s3200		Teeth	88.6	94.7
		s3301		Oral pharynx	74.7	76.0
	s410			**Structure of cardiovascular system**	91.1	94.7
		s4100		**Heart**	98.7	98.7
		s4101		**Arteries**	98.7	98.7
		s4102		**Veins**	78.5	85.3
		s4103		**Capillaries**	84.8	93.3
	s430			Structure of respiratory system	73.4	77.3
	s530			Structure of stomach	65.8	67.6
		s5400		Small intestine	73.4	80.0
		s5401		Large intestine	75.9	80.0
	s550			**Structure of pancreas**	77.2	84.0
	s560			Structure of liver	78.5	86.7
		s5801		Thyroid gland	79.7	89.3

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
	s610			**Structure of urinary system**	78.5	88.0
		s6100		**Kidneys**	98.7	97.3
		s6102		Urinary bladder	89.9	94.7
	s630			**Structure of reproductive system**		
			s63033	Vaginal canal	73.4	78.4
		s6306		Prostate	63.3	65.3
	s720			Structure of shoulder region	55.1	58.1
		s7201		Joints of shoulder region	62.8	62.7
	s730			Structure of upper extremity	59.0	58.1
		s7302		Structure of hand	74.4	71.6
			s73021	Joints of hand and fingers	79.5	77.3
	s750			**Structure of lower extremity**	79.5	80.0
		s7500		Structure of thigh	59.0	68.0
		s7501		Structure of lower leg	76.9	82.7
		s7502		**Structure of ankle and foot**	93.6	96.0
		s7700		Bones	75.6	82.7
		s7701		Joints	75.6	80.0
		s7702		Muscles	82.1	86.7
	s810			**Structure of areas of skin**	82.1	92.0
		s8102		Skin of upper extremity	70.5	77.3
		s8104		Skin of lower extremity	94.9	96.0
	s830			**Structure of nails**	88.5	91.8

Activities and Participation:

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
		d1551		Acquiring complex skills	51.9	50.7
	d230			Carrying out daily routine	59.9	56.0
		d2301		Managing daily routine	60.8	56.0
		d2302		Completing the daily routine	65.8	60.0
	d240			**Handling stress and other psychological demands**		
	d440			**Fine hand use**	60.8	59.5
	d450			**Walking**		
	d455			**Moving around**		
	d475			**Driving**	56.4	58.7
		d4751		Driving motorized vehicles	52.6	53.3
	d520			**Caring for body parts**		
	d570			**Looking after one's health**	81.0	85.1
		d5701		Managing diet and fitness	92.3	91.8
		d5702		Maintaining one's health	85.9	88.0
	d620			**Acquisition of goods and services**	46.8	41.3
	d630			**Preparing meals**		
		d6505		Taking care of plants, indoors and outdoors	32.9	23.7
	d660			Assisting others	48.1	36.8
	d750			**Informal social relationships**	48.1	39.5
	d760			**Family relationships**	59.5	59.2
	d770			**Intimate relationships**	62.0	68.4

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
	d820			School education	58.2	56.0
	d840			Apprenticeship (work preparation)	51.9	44.7
	d845			**Acquiring, keeping and terminating a job**	60.8	61.8
		d8450		Seeking employment	51.9	48.7
	d850			**Remunerative employment**	52.6	48.0
	d855			non-remunerative employment	41.8	28.9
		d8700		Personal economic resources	49.4	42.1
	d910			Community life	46.8	40.8
		d9100		Informal associations	48.1	40.8
		d9101		Formal associations	42.3	35.5
	d920			**Recreation and leisure**	64.6	67.1
		d9201		**Sports**	73.4	77.6
		d9204		**Hobbies**		
		d9205		**Socializing**		

Environmental Factors:

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
	e110			**Products or substances for personal consumption**		
		e1100		Food	84.8	90.8
		e1101		Drugs	86.1	90.8
	e115			**Products and technology for personal use in daily living**	58.2	55.3
		e1150		General products and technology for personal use in daily living	55.7	49.3
		e1151		Assistive products and technology for personal use in daily living	68.4	68.9
	e120			Products and technology for personal indoor and outdoor mobility and transportation	56.4	56.0
		e1250		General products and technology for communication	54.4	50.7
	e130			Products and technology for education	53.2	48.7
		e1300		General products and technology for education	59.0	51.3
		e1650		Financial assets	38.0	30.3
		e2151		Population density	30.4	30.3
		e2250		Temperature	51.9	46.1
		e2255		Seasonal variation	50.6	47.4
	e230			natural events	48.1	38.2
	e310			**Immediate family**	67.1	69.7
	e315			**Extended family**	53.2	53.9
	e320			**Friends**		
	e325			**Acquaintances, peers, colleagues, neighbours and community members**	57.0	53.9

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
	e330			**People in positions of authority**	55.7	52.6
	e335			People in subordinate positions	49.4	36.8
	e340			**Personal care providers and personal assistants**	63.3	64.0
	e355			**Health professionals**	84.8	89.3
	e360			**Other professionals**	53.2	51.3
	e410			**Individual attitudes of immediate family members**	71.8	71.1
	e415			**Individual attitudes of extended family members**	56.4	55.3
	e420			**Individual attitudes of friends**	60.3	63.2
	e425			**Individual attitudes of acquaintances, peers, colleagues, neighbours and community members**	60.8	59.2
	e430			**Individual attitudes of people in positions of authority**		
	e440			**Individual attitudes of personal care providers and personal assistants**		
	e450			**Individual attitudes of health professionals**	69.6	73.7
	e455			**Individual attitudes of other professionals**		
	e460			Societal attitudes	62.0	64.5
	e465			**Social norms, practices and ideologies**	59.5	60.5
	e510			**Services for the production of consumer goods**		
	e530			Utilities services, systems and policies	49.4	32.0
		e5350		Communication services	49.4	40.0
	e540			Transportation services, systems and policies	48.1	33.3
		e5401		Transportation systems	51.9	58.7
	e550			**Legal services, systems and policies**		

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
		e5500		Legal services	40.5	32.0
	e555			**Associations and organizational services, systems and policies**	49.4	40.0
		e5550		Associations and organizational services	51.9	49.3
		e5552		Associations and organizational policies	52.6	49.3
	e560			**Media services, systems and policies**	51.9	48.0
		e5600		Media services	58.2	64.0
	e565			Economic services, systems and policies	44.3	38.7
		e5650		Economic services	45.6	40.0
	e570			**Social security services, systems and policies**	62.0	61.3
		e5700		Social security services	68.4	71.6
		e5701		Social security systems	64.5	61.6
	e575			**General social support services, systems and policies**	66.2	65.3
		e5750		General social support services	68.4	67.6
	e580			**Health services, systems and policies**	81.0	92.0
		e5800		Health services	87.3	94.6
		e5801		Health systems	82.9	88.9
		e5802		Health policies	76.0	85.1
	e585			**Education and training services, systems and policies**	65.4	68.5
	e590			**Labour and employment services, systems and policies**		
		e5900		Labour and employment services	57.0	50.0
	e595			**Political services, systems and policies**		

ICF Code				ICF category title	round 2 n= 79 %	round 3 n= 76 %
1st level	2nd level	3rd level	4th Level			
		e5951		Political systems	43.6	39.2

Personal Factors:

Answer Personal factors	round 2 n= 79 %	round 3 n= 76 %
Comorbidities	100	98.7
Compliance	94.9	98.7
Conviction	70.9	82.7
Coping	88.6	93.3
Health literacy	83.5	93.3
Healthy lifestyle	97.5	98.7
Heritability of diabetes	88.6	92.0
Knowledge about disease	98.7	98.7
Lack of self-confidence	89.9	97.3
Patient education about disease	100	98.7
Self empowerment	89.9	93.3
Self management	97.5	98.7
Self-decision making	89.9	94.7
Understanding of therapeutic strategies	98.7	98.7
Loss of liberty	81.0	86.7

Health conditions:

Answer **Health conditions**	**round 2 n= 79 %**	**round 3 n= 76 %**
Abscess	92.4	98.6
Anaemia	84.4	91.9
Arthritis	78.5	80.0
Cardiovascular diseases	100	100
Carpal tunnel syndrome	89.9	94.7
Cataract	94.9	97.3
Cerebrovascular disease	98.7	100
Coeliac disease	75.9	80,0
Depression	97.5	100
Diabetes neuropathy	100	100
Diabetic foot	98.7	100
Diverticulitis	59.5	53.3
Endocrine disorders	94.9	98.7
Gestational diabetes	96.2	98.7
Gout	83.5	87.8
Intercurrent pneumonia	84.8	93.3
Nephropathy	100	100
Obesity	100	100
Osteomyelitis	88.6	93.3
Osteoporosis	84.8	88.0
Peripheral vascular disease	100	100
Pregnancy	88.6	94.7

Answer Health conditions	round 2 n= 79 %	round 3 n= 76 %
Pulmonary TBC infection	81.0	82.7
Renal hypertension	88.6	93.3
Retinopathy	98.7	97.3
Scleroedema of skin	64.6	66.7
Sepsis	91.1	97.3
Sleep apnea	84.8	89.3
Type 1 Diabetes	96.2	100
Type 2 Diabetes	97.5	100

Not classified:

Answer Not classified	round 2 n= 79 %	round 3 n= 76 %
Aggravation of diabetes	91.1	97.3
Antibiotic resistance	75.9	78.4
Dealing with the complex medicines and eating dosage regimen	94.9	98.6
Diabetic research	88.6	93.2
Exercise opportunity	89.9	95.9
Insulin resistance	93.7	97.3
Lack of communication between patient and physician	97.5	97.3
neuropathy problems	100	100
Patients are always on the lookout for the proverbial 'cure'	83.5	97.8
Screening for relatives	91.1	93.2
Swelling in their joints	66.7	70.3

10.6 ICF Definitions

(Extracted from WHO, 2001)

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.

Impairment is a loss or abnormality in body structure or physiological function (including mental functions).

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

Participation is involvement in a life 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 Abbreviations

ADA	American Diabetes Association
BMD	Bone mineral density
CVD	Cardiovascular disease
CAN	Cardiovascular autonomic neuropathy
CTS	Carpal tunnel syndrome
DSME	Diabetes self-management education
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information
DAN	Diabetic autonomic neuropathy
DPN	Diabetic distal sensory polyneuropathy
DKA	Diabetic ketoacidosis
DD	Dupuytren's disease
DM	Diabetes mellitus
ESRD	End-stage renal disease
GDM	Gestational diabetes mellitus
GN	Glycogenic hepatopathy
HHS	Hyperosmolar hyperglycaemic state
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
ICIDH	International Classification of Impairments, Disability and Handicaps
IDF	International Diabetes Federation
IGT	Impaired glucose tolerance
IFG	Impaired fasting glucose
LJM	Limited joint mobility
MODY	Maturity-onset-diabetes of the young
MNT	Medical nutrition therapy
NAFLD	Non-Alcoholic Fatty Liver disease
NASH	Non-Alcoholic Steatohepatitis
PCOS	Polycystic ovary syndrome
SMBG	Self monitoring of blood glucose
WHO	World Health Organization