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ICF CORE SETS FOR DIABETES MELLITUS

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Objective: **To report on the results of the consensus process integrating evidence from preliminary studies to develop the first version of a Comprehensive ICF Core Set and a Brief ICF Core Set for diabetes mellitus.**

Methods: **A formal decision-making and consensus process integrating evidence gathered from preliminary studies was followed. Preliminary studies included a Delphi exercise, a systematic review, and an empirical data collection. After training in the ICF and based on these preliminary studies relevant ICF categories were identified in a formal consensus process by international experts from different backgrounds.**

Results: **The preliminary studies identified a set of 253 ICF categories at the second, third, and fourth ICF levels with 99 categories on *body functions*, 40 on *body structures*, 55 on *activities and participation*, and 59 on *environmental factors*. Fifteen experts attended the consensus conference on diabetes mellitus (8 physicians with various sub-specializations; 5 physical therapists, one epidemiologist and one social worker). Altogether 99 categories (85 second-level and 14 third-level categories) were included in the Comprehensive ICF Core Set with 36 categories from the component *body functions*, 16 from *body structures*, 18 from *activities and participation*, and 29 from *environmental factors*. The Brief ICF Core Set included a total of 33 second-level categories with 12 on *body functions*, 6 on *body structures*, 5 on *activities and participation*, and 10 on *environmental factors*.**

Conclusion: **A formal consensus process integrating evidence and expert opinion based on the ICF framework and classification led to the definition of ICF Core Sets for diabetes mellitus. Both the Comprehensive ICF Core Set and the Brief ICF Core Set were defined.**

Key words: diabetes mellitus, function, disability, outcome assessment, quality of life, ICF

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INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease caused by a relative or absolute deficiency of insulin (1). The consecutive hyperglycaemia and the deranged balance of carbohydrates, fats and proteins can lead to states of metabolic and circulative decompensation (comata) and, in the long course, damages the arterial blood vessels (the small ones first) and the peripheral neurones of all organs, pathognomonically of the retina, the kidney and the sensomotor and autonomous nervous system.

The prevalence of DM in industrial countries lies between 5.9% and 8.1% and has been increasing dramatically due to increasing obesity and lack of exercise (2–4). Of all deaths in the USA, 3.6–5.1% of all deaths are attributable to DM, which makes it the seventh leading cause of death (5). In the UK, a 20% increase in the prevalence of DM II is projected from 2000 to 2030 (6). For individual and public health, DM is responsible for 1.9% of all disability-adjusted life years (DALYs) lost in developed countries (7) and is the third most costly physical health condition in the USA (8). The direct (mainly due to dialysis) and indirect costs of DM in the USA have exceeded $100 billion (9).

Diabetic symptoms that may be seen at time of diagnosis are thirst, polyuria, fatigue, general malaise, infections, and blurred vision. Over time patients with DM also develop symptoms related to major microvascular (i.e. retinopathy, nephropathy, neuropathy, diabetic foot problems) and macrovascular (i.e. cardiovascular disease, cerebrovascular disease and peripheral vascular disease) complications (10, 11).

Current recommendations for the medical treatment of DM focus primarily on the close measurement and regulation of blood sugar. In addition, symptoms related to diabetic complications should be monitored closely (12). A recently published review of health-related quality of life measurements in DM shows the wide variety of generic, diabetes-specific and psychological measures that have been used in patients with diabetes (13). However, no systematic framework that covers the spectrum of diabetic symptoms and problems in functioning has been established thus far.

With the approval of the new International Classification of Functioning, Disability and Health (ICF, formerly ICIDH-2 http://www.who.int/classification/icf) (14) we can now rely on a

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globally agreed framework and classification to define the typical spectrum of problems in functioning of patients with DM. For practical purposes and in line with the concept of condition-specific health status measures it would thus seem most helpful to link specific conditions or diseases to salient ICF categories of functioning (15). Such generally-agreed-on lists of ICF categories can serve as Brief ICF Core Set to be rated in all patients included in a clinical study with DM or as Comprehensive ICF Core Set to guide multidisciplinary assessments in patients with DM. The objective of this paper is to report on the results of the consensus process integrating evidence from preliminary studies to develop the first version of the Comprehensive ICF Core Set and the Brief ICF Core Set.

METHODS

The development of the ICF Core Sets for DM involved a formal decision-making and consensus process integrating evidence gathered from preliminary studies including a Delphi exercise (16), a systematic review (17), and an empirical data collection using the ICF checklist (18). After training in the ICF and based on these preliminary studies relevant ICF categories were identified in a formal consensus process by international experts from different backgrounds.

Fifteen experts from 9 different countries attended the consensus process for diabetes. The professional background of the experts (8 physicians with various sub-specializations; 5 physical therapists, 1 epidemiologist and 1 social worker) covered the wide spectrum of problems in functioning that occurs in diabetic patients. The decision-making process for DM involved 3 working groups with 5 experts each. The process was facilitated by the condition co-ordinator for DM (JR) and the 3 working-group leaders (ZO, DE, FA).

RESULTS

The tables on the pre-conference studies (16–18) presented to the participants included 253 ICF categories at the second, third, and fourth levels (99 on *body functions*, 40 on *body structures*, 55 on *activities and participations*, and 59 on *environmental factors*).

Tables I–IV show the second and third level of ICF categories included in the Comprehensive ICF Core Set. Table V shows the second-level ICF categories that were selected for the Brief ICF Core Set, as well as the percentage of experts willing to include the respective category in the Brief ICF Core Set.

Comprehensive ICF Core Set

The number of second and third level categories in the Comprehensive ICF Core Set is 99, with 85 categories on the second level and 14 categories on the third level. The 14 third level categories are a further specification of 6 categories on the second level. The total number of second level categories included in the Brief ICF Core Set is 33. No third level category was selected for the Brief ICF Core Set.

The 99 categories of the Comprehensive ICF Core Set are made up of 36 (36%) categories from the component *body functions*, 16 (16%) from the component *body structures*, 18 (18%) from the component *activities and participation*, and 29 (29%) from the component *environmental factors*.

Thirty-one of the 36 categories of the component *body functions* are at the second and 5 at the third level of the classification. The 31 categories at the second level represent 22% of the total number of ICF categories at the second level in this component. With exception of chapter b3 *voice and speech functions*, all *body-functions* chapters are represented in the Comprehensive ICF Core Set. Most of the *body-functions* categories belong to chapter 4 *functions of the cardiovascular, haematological, immunological and respiratory systems* (9 categories), whereas 3 categories are specifications at the third level of the included second-level category b455 *exercise tolerance functions*. Chapter 1 *mental functions* is represented by 7 categories, 2 of which, b1300 *energy level* and b1302 *appetite*, are also specifications at the third level of the included second-level category b130 *energy and drive functions*. Chapter 2 *sensory functions and pain*, chapter 5 *functions of the digestive, metabolic and endocrine systems*, and chapter 6 *genitourinary and reproductive functions* are each represented

Table I. *International Classification of Functioning, Disability and Health (ICF) – categories of the component body functions included in the Comprehensive ICF Core Set for diabetes mellitus*

ICF code		ICF category title
2nd level	3rd 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
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

Table II. *International Classification of Functioning, Disability and Health (ICF) – categories of the component body structures included in the Comprehensive ICF Core Set for diabetes mellitus*

ICF code		ICF category title
2nd level	3rd 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

by 5 categories at the second level. Chapter 8 *functions of the skin and related structures* and chapter 7 *neuromusculoskeletal and movement-related functions* are represented by 3 and 2 categories at the second level, respectively.

Ten of the 16 categories of the component *body structures* are at the second and 6 at the third level of the classification. The 10 categories at the second level represent 18% of the total number of ICF categories at the second level in this component. Similar to the *body-functions* component, all chapters of the *body-structures* component with exception of chapter 3 *structures involved in voice and speech* are represented in the Comprehensive ICF Core Set. Chapter 4 *structures of the cardiovascular, immunological and respiratory systems* is represented by 5 categories, whereas only s410 *structure of cardiovascular system* is at the second level, and the remaining 4 categories are its specifications at the third level. Chapter 6 *structures related to the genitourinary and reproductive systems* is represented by 2 categories at the second level and by the third-level category s610 *structure of urinary system*. Chapter 1 *structures of the nervous system* and chapter 8 *skin and related structures* are each represented by 2 categories at the second level. Chapter 7 *structures related to movement* is represented by 1 category at the second and another category at the third level of the classification. Chapter 2 *the eye, ear and related structures* and chapter 5 *structures related to the digestive, metabolic and endocrine systems* are represented by 1 category at the second level, respectively.

Table III. *International Classification of Functioning, Disability and Health (ICF) – categories of the component activities and participation included in the Comprehensive ICF Core Set for diabetes mellitus*

ICF code		ICF category title
2nd level	3rd 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

Fifteen of the 18 categories of the component *activities and participation* are at the second and 3 categories at the third level of the classification. The 15 categories at the second level represent 13% of the total number of ICF categories at the second level in this component. Chapter 4 *mobility* is represented by 4 categories at the second level. Chapter 9 *community, social and civic life* is also represented by

Table IV. *International Classification of Functioning, Disability and Health (ICF) – categories of the component environmental factors included in the Comprehensive ICF Core Set for diabetes mellitus*

ICF code	ICF category title
e110	Products and 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
e510	Services, systems and policies 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

Table V. *International Classification of Functioning, Disability and Health (ICF) – categories included in the Brief ICF Core Set for diabetes mellitus and percentage of experts willing to include the named category in the Brief ICF Core Set. 50% represent a preliminary cut-off. (>50% in bold typeface)*

ICF component	%	ICF code	ICF category title
Body functions*	**100**	**b540**	**General metabolic functions**
	100	**b210**	**Seeing functions**
	100	**b530**	**Weight maintenance functions**
	100	**b130**	**Energy and drive functions**
	100	**b270**	**Sensory functions related to temperature and other stimuli**
	92	**b420**	**Blood pressure functions**
	92	**b415**	**Blood vessel functions**
	92	**b455**	**Exercise tolerance functions**
	69	**b410**	**Heart functions**
	69	**b545**	**Water, mineral and electrolyte balance functions**
	61	**b610**	**Urinary excretory functions**
	23	b730	Muscle power functions
Body structures	**84**	**s550**	**Structure of pancreas**
	84	**s410**	**Structure of cardiovascular system**
	84	**s220**	**Structure of eyeball**
	76	**s610**	**Structure of urinary system**
	76	**s750**	**Structure of lower extremity**
	15	s150	Structure of parasympathetic nervous system
Activities and participation	**100**	**d570**	**Looking after one's health**
	100	**d450**	**Walking**
	100	**d520**	**Caring for body parts**
	100	**d240**	**Handling stress and other psychological demands**
	15	d630	Preparing meals
Environmental factors	**100**	**e310**	**Immediate family**
	100	**e355**	**Health professionals**
	100	**e580**	**Health services, systems and policies**
	100	**e110**	**Products and substances for personal consumption**
	92	**e115**	**Products and technology for personal use in daily living**
	84	**e570**	**Social security services, systems and policies**
	84	**e465**	**Social norms, practices and ideologies**
	84	**e585**	**Education and training services, systems and policies**
	23	e320	Friends
	7	e555	Associations and organizational services, systems and policies

* Category b430: the participants agreed that measurement of, e.g. HbA1C or blood glucose, is an important element in the Brief ICF Core Set. However, there was disagreement whether category b430 (*haematological system functions*) covers those parameters (see discussion section).

4 categories, whereas only d920 *recreation and leisure* is at the second level, and the remaining 3 categories are its specifications at the third level. Chapter 7 *interpersonal interactions and relationships* is represented by 3 categories and chapter 5 *self care*, chapter 6 *domestic life*, and chapter 8 *major life areas* by 2 categories, respectively. Chapter 2 *general tasks and demands* is exclusively represented by 1 category.

The 29 categories of the component *environmental factors* are all at the second level of the ICF hierarchy. They represent 39% of the total number of ICF categories at the second level of this component. Most of the *environmental-factors* categories belong to chapter 5 *services, systems and policies* (10 categories), chapter 4 *attitudes* (9 categories) and chapter 3 *support and relationships* (8 categories). Chapter 1 *products and technology* is represented by 2 categories.

Brief ICF Core Set

The Brief ICF Core Set includes a total of 33 second-level categories, which represent 39% of all second level categories that were chosen in the Comprehensive ICF Core Set. Twelve categories were chosen from the component *body functions* (representing 39% of selected second level categories in the Comprehensive ICF Core Set), 6 from *body structures* (representing 60% of selected second level categories in the Comprehensive ICF Core Set), 5 from *activities and participation* (representing 33% of selected second level categories in the Comprehensive ICF Core Set) and 10 from *environmental factors* (representing 34% of selected second level categories in the Comprehensive ICF Core Set).

All ICF categories taken into account in the final decision process are presented in Table V. However, a preliminary cut-off was established at 50% to reflect majority opinion.

DISCUSSION

The formal consensus process integrating evidence from preliminary studies and expert knowledge at the third ICF Core Sets conference led to the definition of the Brief ICF Core Set and the Comprehensive ICF Core Set for multidisciplinary assessment.

Table VI. *International Classification of Functioning, Disability and Health (ICF) – categories that were discussed controversially but not included in the ICF Core Sets*

ICF component	ICF code	ICF category title	Arguments that were exchanged
Body functions	b117	Intellectual functions	Category is critical for successful diabetes education, however intellect is not primarily affected by diabetes
	b122	Global psychosocial functions	Same argument as for b117
	b525	Defecation functions	Frequently constipation and diarrhoea are related to therapy rather than to diabetes itself
	b535	Sensations associated with the digestive system	Prevalence of those symptoms considered to be low
	b750	Motor reflex functions	Category was not considered to lead diabetic neuropathy symptoms; However, data by Eastman, 1995 (20) underline importance of category
Body structures	s580	Structure of endocrine glands	Evidence suggests a link between type 1 diabetes and extrapancreatic autoimmune disease (22)
	s820	Structure of skin glands	The reason for anhydrosis was considered to be due to autonomous neuropathy rather than to structural changes of skin glands
Activities and participation	d910	Community life	Uncertainty whether associations for diabetic patients are linked to this category or to category e585
Environmental factors	e125	Products and technology for communication	As an example the consequences of loss of vision were mentioned (25)

A main challenge during the development of ICF Core Sets for DM was comprehensively to cover the wide spectrum of diabetes-related changes in *body functions* and *structures*, as well as of *activity limitations* and *restrictions in participation*, while constantly keeping the focus on DM itself without shifting attention to related co-morbidities, such as stroke, which are the subjects of separate ICF Core Sets. The 99 categories (85 second-level categories) that were included in the Comprehensive ICF Core Set reflect the complex functional changes that occur in diabetic patients. As diabetes is a systemic disease, multiple *body functions* and *structures* may be affected.

A general point that was raised on multiple occasions during the consensus process was the time sequence of problems in functioning in DM. As supported by the high rates of undiagnosed diabetic patients (19), diabetes might be present with very few symptoms at disease onset. In later stages of disease, patients experience a variety of changes in *body functions and structures*, as well as diabetes-related limitations in activities and restrictions in participation. While the Comprehensive ICF Core Set aims to cover the wide spectrum of problems in functioning in DM, many of the selected categories might not be altered in early stages of the disease.

With respect to the 4 main components of the ICF the following issues were raised: the variety of *body-functions* categories included in the Comprehensive ICF Core Set and the Brief ICF Core Set reflect the complexity of functional alterations in diabetic patients. As diabetes is a metabolic disease that affects the organism as a whole, a focus of the ICF Core Sets was on complex *body functions*, such as *general metabolic functions*, *weight maintenance*, *energy and drive functions*, and *water balance functions*. Some selected functions are related to specific organs: *seeing functions*, *sensory functions*, *cardiovascular functions*, and *urinary functions* such as polyuria were also included. Some additional categories were discussed, but not included in the Comprehensive ICF Core Set (Table VI). While *intellectual and global psychosocial functions* were considered critical for appropriate education of patients, these functions are not primarily affected by diabetes and were, therefore, not included. There was a discussion about *motor reflex functions*. While some participants considered that category as highly relevant (20), others focussed on different expressions of polyneuropathy such as sensory and proprioceptive functions.

Expressions of autonomous polyneuropathy are manifold, since every organ is affected. Analogously to the *urination functions* (b620), the *defecation functions* (b525) and *the sensations associated with the digestive system* (b535) can be impaired, but the first 2 categories were not included because urination and defecation symptoms are rarely reported by the patients. However, textbooks emphasize these symptoms for sensitive monitoring of the disease's course (1, 20).

The category *haematological system functions* (b430) is defined by the ICF as *functions of blood production, oxygen and metabolic carriage, and clotting*. Many participants felt that an elevated blood-glucose level is not covered by this category and therefore b430 should not be included. This was controversial, as it was unclear which other category would then cover core primary endpoints in DM trials such as HbA1C. There was agreement among the experts that if category b430 covers parameters such as HbA1C, fasting plasma glucose, it should be included in the Brief ICF Core Set.

The selection of *body structures* included those structures that are mainly affected by DM, such as pancreas (islets), eyeball, nervous system, cardiovascular system, urinary system and the lower extremity (11). The Comprehensive ICF Core Set also includes structural changes of the skin, nails and reproductive system. Regarding the reproductive system, reference was made to structural changes causing erectile dysfunction, which occurs

frequently in diabetic patients (21). One expert suggested also including category s580 (*structure of endocrine glands*, Table VI). The respective evidence was reviewed (22). The majority of the consensus group considered the pathological changes of other endocrine glands, such as the thyroid gland, that occur in autoimmune type-1 DM to be separate conditions that should not be covered in the ICF Core Sets for DM. There was a discussion about category s820 (*structure of skin glands*). However, the category was not included as anhydrosis was considered to be related to autonomous neuropathy rather than to structural changes of the skin glands.

Category d570 *looking after one's health*, which includes managing diet and fitness was a key category in the discussion of *activities and participation* categories. Considering the close link between obesity and diabetes (23), this item received highest ranks from the majority of experts during the Brief ICF Core Set voting procedure. There was uncertainty whether *community life* (category d910, Table VI) included patient-initiated DM groups. The experts decided to vote for category e585 instead. However, some experts felt that category e585 is not specific enough.

The discussions regarding *environmental factors* reflected the wide scope of the internationally selected experts. Cultural differences exert a considerable impact on the applicability of individual categories in various countries. There was general agreement that DM has an enormous impact on the immediate family, both in developed and developing countries. However, as the developing countries account for the majority of the expected increase in the prevalence of DM globally (24), initiatives on the improvement of their DM-related health services (category e580) are disparately required. Category e125 (*products and technology for communication*) was discussed controversially. Some group members cited as an example assistive devices that are used to manage retinopathy, cataracts and glaucoma, the major 3 vision disorders in diabetes (25).

The breadth of ICF chapters contained in the Comprehensive ICF Core Set reflects the important and complex *impairments*, *limitations in activity*, and *restrictions in participation* involved, as well as the numerous interactions with *environmental factors*. The selection of categories for the Brief ICF Core Set does not result in a loss of relevant information, as the Brief ICF Core Set still contains most of the chapters represented in the Comprehensive ICF Core Set. This is especially true for the components *body functions*, *body structures*, and *environmental factors*.

Regarding the comprehensiveness of the ICF, it is most interesting to note that in general the panel of experts did not identify problems of patients not contained in the ICF. However, it has to be clarified to what extent "composition of blood" (blood glucose level, but also level of lipids, level of minerals and level proteins) is addressed by the category b430 *haematological system functions*. Also, it is unclear whether participation in patient-initiated groups is covered by the category d910 *community life*. Either an amendment in the definitions of these 2 categories or the addition of 2 corresponding new categories was suggested.

The organizers of the consensus process took much care in the selection of the experts and were successful in reaching 15 experts with different professional backgrounds and from 9 different countries. However, no nurses, dieticians or chiropodists were participating. In addition, the results of any consensus process may differ with different groups of experts. This emphasizes the importance of the extensive validation of this first version of the ICF Core Sets from the perspective of different professions and in different countries. The first version of the ICF Core Sets will also be tested in the view of patients and in different clinical settings. It is important to note that this first version of the ICF Core Sets is only recommended for validation or pilot studies.

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