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Validation of the International Classification of Functioning, Disability and Health (ICF) core set for Diabetes Mellitus from nurses' perspective using the Delphi method

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ABSTRACT

Purpose: To explore content validity of the ICF core set for Diabetes Mellitus from nurses' perspective.

Materials and methods: A two-round Delphi study was conducted with nurses specialized in diabetes care, who were recruited by purposive sampling. Level of agreement on relevance of ICF categories was calculated using Item-level Content Validity Index.

Results: Twenty-seven nurses judged 147 second-level ICF categories on relevance for people with Diabetes Mellitus. Agreement was reached on 65 (44.2%) categories, of which 46 were from the ICF core set for Diabetes Mellitus, 17 were from previous validation studies, and two were additional categories that were mentioned as relevant. Forty-six out of the 65 categories were derived from the component body functions and structures. No agreement was reached on 82 (55.8%) categories, of which 33 were derived from the component environmental factors.

Conclusions: Content validity of the ICF core set for Diabetes Mellitus was partially supported by specialized nurses. Agreement was predominantly reached on biomedical categories. Content validity of categories derived from environmental factors received little support.

Relevance: The nursing profession should be aware of a gap between the current biomedical focus and the desired biopsychosocial approach; the latter of which is recommended in chronic care.

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KEYWORDS

International Classification of Functioning; Disability and Health (ICF); nursing; biopsychosocial care; Diabetes Mellitus (DM); Delphi method

► IMPLICATIONS FOR REHABILITATION

- The International Classification of Functioning, Disability and Health (ICF) encourages a biopsychosocial approach in health care, and ICF core sets, such as the core set for Diabetes Mellitus, are useful in identifying the needs of patients.
- Content validity of the ICF core set for Diabetes Mellitus was partially supported by nurses specialized in diabetes care; agreement was predominantly reached on biomedical categories.
- The nursing profession should be aware of a potential gap between the current biomedical focus and a desired biopsychosocial approach, which is particularly recommended in chronic care.
- It is recommended that nurses take part in future revisions of ICF core sets; a multidisciplinary approach enables members to learn from each other's perspectives, including from those of patients.

Introduction



People with a chronic illness face many obstacles in coping with their condition and experience restrictions in daily functioning [1]. To cater to people's personal health-related needs, a biopsychosocial care approach that integrates biomedical, emotional, social, and behavioral dimensions of illness would be most appropriate [2,3]. Although the added value of this holistic and patient-centered care model has been recognized, it proves difficult to apply in practice [4,5].


Background

To support a biopsychosocial care approach, the World Health Organization (WHO) published the International Classification of

Functioning, Disability and Health (ICF) together with the conceptual model of health in 2001 [6]. The ICF, which is complementary to the International Classification of Diseases (ICD) [7], provides a unified and standardized terminology for describing an individual's functioning and the influencing contextual factors. Functioning is an umbrella term that includes the components body functions and body structures and activities and participation. Figure 1 shows how a person's functioning can be influenced by a health condition, environmental factors, and personal factors [8].

The components of the ICF, except for the component personal factors, which awaits classification, comprise approximately 1,500 categories [9]. The ICF categories are denoted by an alphanumeric code starting with a letter that refers to the components

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 Supplemental data for this article can be accessed [here](#).

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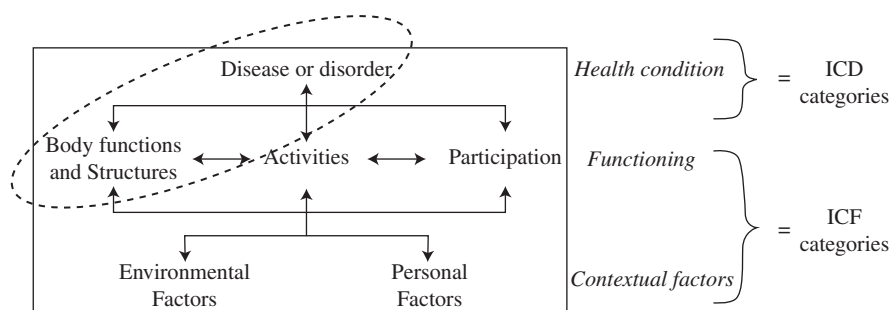


Figure 1. WHO's conceptual model of health representing the interactions between the health condition, components of functioning, and contextual factors. Note the partial perspective of health based on the biomedical model (oval) versus the holistic perspective of health based on the biopsychosocial model (rectangle) [8]. ICD: International Classification of Diseases; ICF: International Classification of Functioning, Disability and Health.

of the classification: body functions (b); body structures (s); activities and participation (d); environmental factors (e). The number of digits following the initial letter indicates the category and its level. For instance, a second-level category has a total of 3 digits, whereas a fourth-level category has 5 digits. The more levels, the more detailed the description of this category. For example, the ICF category d5702 consists of three levels in the domain activities and participation (d). The first level is *self-care* (d5), the second level is *looking after one's health* (d570) and the third level is *maintaining one's health* (d5702).

The ICF can be used by all health professionals involved in people's functioning. It is, however, particularly relevant for nurses because nursing focuses on functioning and human responses to sickness, disability, or limitations instead of a particular pathological condition. Holistic nursing principles were found to be theoretically consistent with the ICF [10].

Considering that it is impractical for health professionals to use the whole ICF in daily practice, specific ICF core sets were developed for different patient populations [11]. These core sets are selections of ICF categories that are considered relevant for the functioning of a specific patient population. Ideally, a broad range of disciplines and patient populations are involved in the development of the core sets [12]. However, nurses did not participate in the development of the comprehensive ICF core set for Diabetes Mellitus (DM), which has a total number of 99 categories (including 85 second-level categories and 14 third/fourth level categories) [13]. In the Netherlands, it is common practice in the care for chronically ill persons that certain (medical) tasks are transferred from physicians to nurses specialized in diabetes care [14] or nurse practitioners [15]. Both types of nursing professionals are distinguished from general nurses by their prescribing authority in this specific field of care.

The importance of the evaluation of ICF core sets from the perspective of nurses has been previously acknowledged [16]. Involvement of nurses in validation studies will contribute to the acceptance and further international implementation of the ICF. This, in turn, is useful for nursing care as it can ensure that potentially relevant aspects of functioning are taken into account [17]. When experts judge the relevance of an item's content, these ratings can be formally documented as a piece of validity evidence, in particular content validity [18]. It is not known how nurses specialized in diabetes care judge the relevance of categories of the ICF core set for DM for people with DM. In other words, it is not known to what extent the content validity of the ICF core set for DM is supported by nurses. Therefore, this study aims to explore the content validity of the ICF core set for DM from the perspective of nurses specialized in diabetes care by using the Delphi method.

Since the ICF core set for DM dates from 2004, first a literature search was performed to identify all ICF categories that have been recognized as meaningful for people with DM in the last 15 years. For this study, a total of 140 ICF categories were identified for judgment of relevance by nurses specialized in diabetes care, hereafter referred to as the expanded ICF core set for DM. In line with an earlier validation study [19], only second-level categories from the ICF core set for DM were included in the expanded ICF core set for DM, resulting in 85 ICF categories. In addition, 55 ICF categories were identified from the literature [1,19–21] and also included in the expanded ICF core set.

The following research questions were answered:

1. How relevant are the 85 categories from the ICF core set for people with DM according to nurses specialized in diabetes care?
2. How relevant are the 55 extracted ICF categories for people with DM according to nurses specialized in diabetes care?
3. Which categories are missing in the ICF core set for DM according to nurses specialized in diabetes care?
4. How relevant are these additional categories for people with DM according to nurses specialized in diabetes care?

Methods

Design

To achieve the research aim, a Delphi study was conducted [22]. The Delphi technique is often used to reach consensus among a panel of experts with knowledge of a specific topic [23]. It is particularly valued for its ability to arrange a geographically dispersed group of participants who are blinded to each other. This anonymity prevents dominance of single individuals in the group. Depending on the aim of the study, 2–4 rounds will usually be conducted until consensus is reached. Assessment of content validity is a two-stage process, consisting of a development stage and a judgment-quantification stage [24]. The aim of the current study was limited to the latter stage, namely judgment of items of an existing ICF core set. Therefore, two Delphi rounds were considered sufficient [25]. The time between rounds was approximately 4 weeks. For both rounds, panel members had 2 weeks to respond.

Definitions of consensus in Delphi studies vary widely. A common definition of consensus is based on "the proportion of participants agreeing in a specific rating range" [26], which was used in this study. Since there are no guidelines for an appropriate level of agreement, many Delphi studies employ levels between 50% [26] and 78% [24]. Based on these recommendations, in Delphi round II categories which reach agreement between 50% and 78%, were presented.

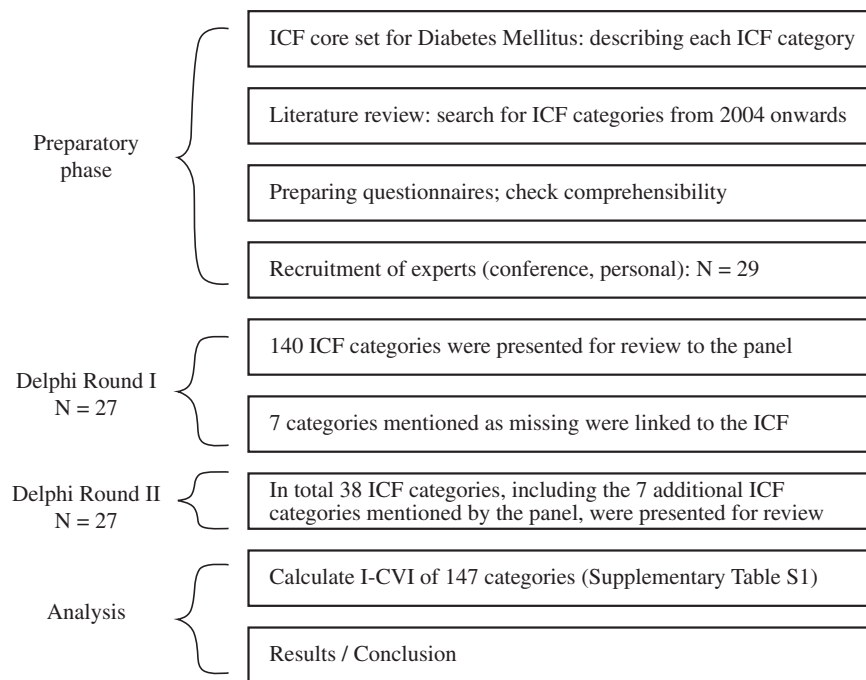


Figure 2. Flowchart to illustrate the stages of the Delphi process. ICF: International Classification of Functioning, Disability and Health; I-CVI: Item-level Content Validity Index.

The study was conducted and reported according to the guidelines of Conducting and REporting DELphi Studies (CREDES) [27]. A flowchart illustrates the stages of the Delphi process (Figure 2).

Participants

To be included in the panel, the participants had to be registered nurses specialized in diabetes care or nurse practitioners working in the field of diabetes. In the Netherlands, nurses specialized in diabetes care work in primary care (e.g., a general practice office, and other settings such as nursing homes or rehabilitation centers), or secondary care (hospital, outpatient). In secondary care, patients with DM generally need more complex medical care due to DM complications or comorbidity. Potential experts for the panel were recruited by purposive sampling, which is suitable for establishing an expert panel that has broad expertise in the field of investigation [28].

Sample size was determined based on the number of experts whose agreement is required to establish content validity that exceeds the significance level of 0.05 [24]. Therefore, an adequate sample size to determine agreement or consensus consists of at least 10 participants. Taking different settings into account, attempts were made to recruit at least 10 experts from primary care and 10 experts from secondary care.

Registered nurses specialized in diabetes care and nurse practitioners were informed about the study during a national nursing conference on diabetes. Interested nurses who met the inclusion criteria were subsequently personally invited to participate. Respondents received additional written information about the goal of the study, estimated time investment, and Delphi procedures.

Data collection

Data were collected between December 2018 and February 2019. All questionnaires were administered using the Encrypting File

System (EFS) version 9.1. A questionnaire about characteristics including gender, age, education level, professional expertise, and current position and setting was sent together with Delphi round I to gain insight into the background of the panel.

Prior to the study, the introduction, questionnaires, and instructions were sent to 2 nurses working in diabetes care for pilot testing of comprehensibility and applicability. Minor adjustments to the instructions were made accordingly. The final draft was reviewed by an external research group.

Delphi round I

The panel was asked to rank a total of 140 second-level ICF categories (85 from the ICF core set DM and 55 extracted categories from the literature) on relevance for people with DM. A category was ranked as relevant if the panel member believed this category could have an impact on the health status of a person with DM, regardless of how often the impact occurs. Impact means that this category influences the health status positively or negatively.

To rank the ICF categories, the panel used a 5-point Likert scale (not relevant, hardly relevant, somewhat relevant, relevant, highly relevant). The panel was also invited to name categories that could influence the health status of people with DM but are currently missing from the ICF core set for DM. When these so-called additional categories were reported by one or more panel members, they were linked to the ICF by means of the linking rules [29]. Linking took place in close collaboration with the senior researcher, who is an ICF expert (H.A.S.).

Delphi round II

ICF categories that were ranked in Delphi round I as relevant by 50%–78% of the total panel were presented to the panel for review in Delphi round II. The panel was asked to indicate these ICF categories as relevant or not relevant. ICF categories ranked as relevant by less than 50% or more than 78% of the panel were not presented for a second review. Finally, the panel was asked to rank the additional categories as relevant or not relevant.

Data analysis

Data were analyzed using IBM SPSS Statistics version 25 (SPSS Inc., Chicago). Descriptive statistics were used to characterize the sample and to calculate frequencies and percentages of ranked categories.

To provide evidence for content validity in this study, the method of computing Item-level Content Validity Index (I-CVI) was applied by using experts' ratings of item relevance. An I-CVI is a formula for calculating agreement among experts on the relevance of individual items divided by the total number of experts [30]. To compute the I-CVI, the ordinal scale (ranging from not relevant to highly relevant) has to be dichotomized. Therefore, all categories from the expanded ICF core set for DM that were ranked as not relevant, hardly relevant, or somewhat relevant by the experts were recoded as not relevant. ICF categories ranked as relevant and highly relevant by the experts were recoded as relevant. Based on the cut-off value of 0.78, categories with an I-CVI ≥ 0.78 were classified as relevant categories. Categories with an I-CVI < 0.78 were classified as not relevant. For example, an I-CVI of 0.40 means that there is no agreement on the relevance of this ICF category because only 40% of the total panel found this ICF category relevant for people with DM.

If 10 or more respondents did not rate a particular category, this category was excluded from the analysis.

Ethical consideration

The study was reviewed and approved by the Medical Ethical Committee of the University Medical Center Groningen (Reference M19.223141). The committee concluded that the study did not fall within the scope of the Medical Research Involving Human Subjects Act (WMO).

Results

In total, 29 Dutch nurses and nurse practitioners specialized in diabetes care were invited to participate in the expert panel. The response rate in both Delphi rounds was 93% ($n = 27$). Secondary care was the predominant work setting ($n = 16$; 59.3%). However, with more than 10 experts in both settings, the sample size was adequate to establish content validity [24]. Most participants were female, aged between 51–65 years old, and had more than 10 years of experience in diabetes care. With 23 panel members (85.2%), a majority of the panel was authorized to prescribe medication to people with DM without consulting a physician (Table 1).

In Delphi round I, the panel reviewed 140 second-level ICF categories, of which 85 categories were derived from the ICF core set for DM and 55 categories were extracted from previous validation studies in patients with DM. In this round, seven topics were mentioned as missing by the panel in the ICF core set for DM. These topics were linked to the ICF as additional categories for this study. The percentage of missing values was 0.03% in Delphi round I.

In Delphi round II, thirty-one categories with an I-CVI ranging between 0.50 and 0.78, were presented to the panel for review in Delphi round II. Moreover, the 7 additional categories were also presented to the panel in this round. The total percentage of missing values was 0.12% in Delphi round II. Therefore, no categories were excluded from the analysis.

The expanded ICF core set for DM consisted of a total of 147 ICF second-level categories. The panel reviewed 70 categories from the component body functions and body structures, 36

Table 1. Characteristics of participants ($n = 27$).

Gender n (%)	
Female	25 (92.6)
Male	2 (7.4)
Age in years n (%)	
31–50	10 (37.0)
51–65	17 (63.0)
Highest education level in diabetes care n (%)	
Secondary vocational without prescribing authority	4 (14.8)
Bachelor including prescribing authority	19 (70.4)
Master including prescribing authority	4 (14.8)
Experience in nursing diabetes care in years n (%)	
≤ 10	8 (29.6)
> 10	19 (70.4)
Setting of work n (%)	
Primary care	
general practitioner office	8 (29.6)
rehabilitation center	2 (7.4)
nursing home	1 (3.7)
Secondary care	
hospital or outpatient	16 (59.3)

categories from activities and participation, and 41 categories from environmental factors (Figure 3). Considering the cut-off point of 0.78, the panel reached agreement on the relevance of 65 (44.2%) ICF categories from the expanded core set for DM. Forty-four (29.9%) categories came from the component body functions and body structures; thirteen (8.8%) came from the component activities and participation; and 8 (5.4%) came from the component environmental factors (Figure 4). An overview of all individual categories from the expanded ICF core set for DM and their corresponding components with an I-CVI ≥ 0.78 is shown in Table 2.

The panel found 82 (55.8%) categories from the expanded ICF core set not relevant. Of these categories, twenty-six (17.7%) came from the component body functions and body structures, twenty-three (15.7%) came from the component activities and participation, and 33 came (22.4%) from the component environmental factors. Supplementary Table S1 shows an overview of all categories from the ICF expanded core set for DM and their corresponding components with an I-CVI < 0.78 . Results are given in detail below.

Initial categories

In total, 46 (54.1%) categories from the initial ICF core set for DM were found to be relevant. Full agreement (I-CVI 1.00) was reached on 5 categories: *energy and drive functions* (b130), *blood vessel functions* (b415), *digestive functions* (b515), *structure of cardio vascular system* (s410), and *handling stress and other psychological demands* (d240).

Agreement was not reached on 39 (45.9%) categories from the initial ICF core set for DM. Categories with the lowest I-CVI scores of 0.07; 0.15 and 0.15 were: *the attitude of extended family members that influence individual behavior and actions* (e415), *the amount of physical and emotional support from extended family* (e315), and *structure of urinary system* (s610).

Extracted categories

In total, 17 ICF categories (30.9%) extracted from previous studies were found to be relevant. Full agreement (I-CVI 1.00) was reached on two extracted categories: *ingestion functions* (b510) and *carrying out daily routine* (d230).

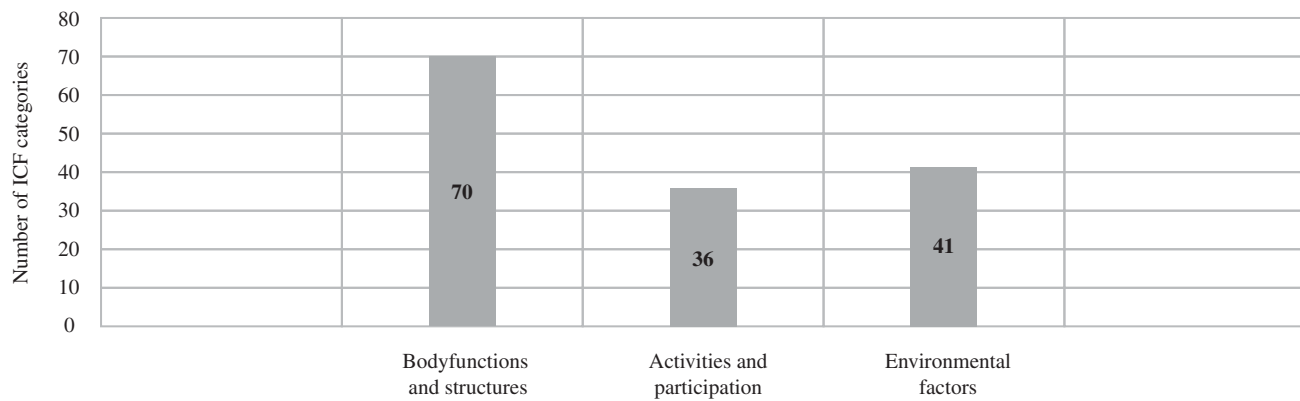


Figure 3. Distribution of 147 second-level ICF categories from the expanded ICF core set for Diabetes Mellitus over the components that were reviewed by an expert panel of nurses specialized in diabetes care. ICF: International Classification of Functioning, Disability and Health.

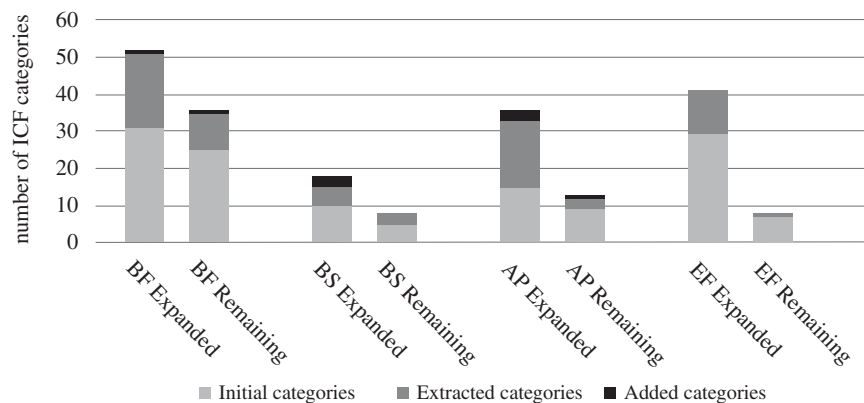


Figure 4. Comparison of the distribution of ICF categories between the expanded core set for Diabetes Mellitus and the remaining core set for DM after two Delphi rounds. Expanded core set for DM: A total of 147 second-level ICF categories consisting of 85 categories from the initial ICF core set for DM; 55 extracted categories from validation studies from 2004 onwards in which they were identified as meaningful categories for patients with DM, and 7 additional categories mentioned by the panel in Delphi round I as missing items in the ICF core set for DM. ICF: International Classification of Functioning, Disability and Health; BF: body functions; BS: body structures; AP: activities and participation; EF: environmental factors.

Agreement was not reached on 38 (69.1%) categories. Extracted categories with the lowest I-CVI scores of 0.00; 0.07; and 0.07, respectively, were *the amount of physical and emotional support of an unrelated individual provides* (e345), *functions of hair* (b850), and *transferring oneself* (d420).

Additional categories

Two categories (28,6%) that were mentioned by the panel as missing in the ICF core set for DM were found to be relevant (I-CVI \geq 0.78). These were: *sensations related to muscles and movement functions* (b780) and *communicating with-receiving-spoken messages* (d310). Agreement was not reached on 5 other added ICF categories (71.4%).

Discussion

The panel of nurses specialized in diabetes care supported content validity of just over half of the second-level categories (46 categories; 54.1%) of the initial ICF core set for DM. The majority of the supported categories were derived from the component body functions and structures. The high level of agreement on these categories can be explained by the fact that Dutch healthcare providers strictly adhere to guidelines from the Organization for General Practitioners [31]. These guidelines are primarily focused on medical outcomes and associated with the component body functions and structures. Since the last 2 decades,

Dutch nurses can formally carry out delegated standardized medical tasks in chronic care. These tasks are similar to the care provided by physicians [32]. A validation study from the perspective of physical therapists [21] found 19 second-level ICF categories from the component body functions and structures relevant for people with DM. In the current study, the panel of nurses found more than half (63.2%) of these 19 ICF categories to be relevant as well. No agreement was reached on 39 (49.1%) categories from the initial ICF core set for DM. A majority of these categories were derived from the component environmental factors and included services, systems and policy for the production of consumer goods, education and training services, legal services, individual attitudes, and practical, physical or emotional support from other people in all domains of life. Previous research found that nurse practitioners predominantly focus on cure rather than on the intersection of cure and care [33]. Nevertheless, this is a remarkable finding, given that a number of innovative devices (e.g., flash glucose monitoring) that aid in the functioning of people with DM have come on the market in recent years. It is likely that nurses specialized in diabetes care have come across flash glucose monitoring and the issues surrounding the funding of this innovation. Low levels of agreement have been recognized before [34]. It could be that although each category was extensively described, the panel may not have recognized the categories as environmental factors.

Extracted ICF categories that were identified as meaningful categories for people with DM in previous studies from 2004

Table 2. Second-level ICF categories with an I-CVI ≥ 0.78 .

ICF code	Component Body functions	Source	I-CVI
b130	energy and drive functions	initial	1.00
b415	blood vessel functions	initial	1.00
b510	ingestion functions	extracted	1.00
b515	digestive functions	initial	1.00
b110	consciousness functions	Initial	0.96
b140	attention functions	initial	0.96
b144	memory functions	extracted	0.96
b420	blood pressure functions	initial	0.96
b134	sleep functions	initial	0.93
b410	heart functions	initial	0.93
b530	weight maintenance functions	initial	0.93
b540	general metabolic functions	initial	0.93
b152	emotional functions	initial	0.89
b265	touch function	initial	0.89
b280	sensation of pain	initial	0.89
b455	exercise tolerance functions	initial	0.89
b555	endocrine gland functions	initial	0.89
b640	sexual functions	initial	0.89
b820	repair functions of the skin	initial	0.89
b160	thought functions	extracted	0.85
b210	seeing functions	initial	0.85
b545	water, mineral and electrolyte balance functions	initial	0.85
b260	proprioceptive function	initial	0.85
b240	sensation associated with hearing and vestibular function	extracted	0.85
b460	sensations of cardiovascular and respiratory functions	extracted	0.82
b620	urination functions	initial	0.82
b760	control of voluntary movement functions	extracted	0.82
b167	mental functions	extracted	0.78
b270	sensory function related to temperature and other stimuli	initial	0.78
b435	immunological system functions	initial	0.78
b710	mobility of joint functions	initial	0.78
b765	involuntary movement functions	extracted	0.78
b740	muscle endurance functions	extracted	0.78
b770	gait pattern functions	extracted	0.78
b780	sensations related to muscles and movement functions	additional	0.78
b810	protective functions of the skin	initial	0.78
Component Body structures			
s410	structure of cardiovascular system	initial	1.00
s550	structure of pancreas	initial	0.96
s580	structure of endocrine glands	extracted	0.96
s110	structure of brain	extracted	0.93
s320	structure of mouth	extracted	0.93
s220	structure of eyeball	initial	0.89
s140	structure of sympathetic nervous system	initial	0.85
s150	structure of parasympathetic nervous system	initial	0.85
Component Activities and Participation			
d230	carrying out daily routine	extracted	1.00
d240	handling stress and other psychological demands	initial	1.00
d570	looking after one's health	initial	0.96
d450	walking	initial	0.93
d630	preparing meals	initial	0.89
d920	recreation and leisure	initial	0.89
d166	reading	extracted	0.85
d440	fine hand use	initial	0.85
d520	caring for bodyparts	initial	0.85
d910	community life	extracted	0.85
d310	communicating with—receiving—spoken messages	additional	0.82
d620	acquisition of goods and services	initial	0.82
d750	informal social relationships	initial	0.82
Component Environmental factors			
e110	products of substances for personal consumption	initial	0.96
e310	immediate family	initial	0.96
e580	health services, systems, and policies	initial	0.96
e320	friends	initial	0.89
e355	health professionals	initial	0.89
e115	products and technology for personal use in daily living	initial	0.82
e125	products and technology for communication	extracted	0.82
e575	general social support services, systems and policies	initial	0.82

After two Delphi rounds, the expert panel of nurses specialized in diabetes care reached agreement (I-CVI ≥ 0.78) on 65 ICF categories (44.2%) from the expanded ICF core set for DM. The first column refers to the ICF code, denoted by an alpha-numeric code starting with a letter that refers to the components of the classification (b: 'body functions'; s: 'body structures'; d: 'activities and participation'; e: 'environmental factors'). The number of digits following the initial letter indicates the category and its level. A total of 3 digits refers to a second-level category. The second column refers to a description of the ICF code. The third column refers to where the ICF code came from: initial (ICF category derived from the ICF core set for DM), extracted (ICF category derived from the literature) or additional (ICF category was mentioned as a relevant category by the panel). The fourth column refers to I-CVI: Item-level Content Validity Index, in descending order.

onwards were also presented to the panel. Most of these extracted ICF categories were found in a validation study from the perspective of people with DM [19]. These extracted categories represent a biopsychosocial spectrum, including categories from all ICF components (body functions and structures, activities and participation, and environmental factors). This seems logical because all categories are related to people's functioning in daily life. In the current study, however, the expert panel judged a majority of these extracted ICF categories as not relevant for people with DM. Categories on which no agreement was reached can be classified as environmental factors. Examples of these categories are societal attitudes, assets, civil protection, transportation services and technology, climate, economic services, and domestic animals. The findings of this study suggest that specialized nurses are mainly biomedically oriented; whereas their professional profile is based on a holistic, biopsychosocial perspective [35]. However, this finding is in line with a previous study, which found that nurses tended to overlook the social and emotional tasks of living with a chronic condition [36]. Another explanation for this finding could be that the dominant setting of the panel was secondary hospital care, which tends to be more biomedically oriented compared with primary ambulatory care or community care. Moreover, patients' expectations of the role of the healthcare provider must also be taken into account. Although patients believe that certain categories are meaningful to them, it is likely that they expect a biomedical focus of healthcare providers during clinical encounters [37,38]. Patients are presumably unaware of the biopsychosocial perspective of nursing care [39].

The panel mentioned 7 additional categories as missing in the ICF core set for DM. Three of these categories could be linked to the components activities and participation. One of the categories on which agreement was reached was *communicating with-receiving-spoken messages* (d310) [9]. For those patients with DM who receive education from health care providers, basic health literacy skills, such as understanding information, are a prerequisite to perform self-management tasks [40]. It is worth mentioning that this ICF category, related to health literacy, was neither included in the existing ICF core set for DM nor in any other ICF core sets for chronic conditions [41].

Some limitations should be mentioned. First, the sample representativeness. To be included in the panel, nurses had to be registered as nurses specialized in diabetes care or as nurse practitioners. Although the sample size in total as well as per work setting was adequate to determine validity, the predominant secondary care work setting of these nurses may have contributed to the preference for biomedical categories. Second, the threshold value of 50% that was used for the second review in Delphi round II, could lead to loss of information. The cut-off point of 50% was chosen based on the assumption that if more than half of the respondents judge an item in Delphi round 1 as not relevant or hardly relevant, a change of opinion in Delphi round II can be estimated as unlikely. Third, a lack of understanding of what the component environmental factors entails could have influenced the results.

A strength of this study was the use of the Delphi method. This method can contribute to broadening knowledge on a specific topic within the nursing profession [25]. In the current study, a high response rate was achieved because the method is accessible in terms of location and time. A safe environment was created because the participants remained anonymous. This study was the first to explore the content validity of ICF categories from specialized nurses' perspectives. These nurses judged the ICF category *communicating with-receiving-spoken messages* (d310),

which is related to health literacy, as relevant to the ICF core set for DM. Health literacy, and in particular insufficient health literacy, is widely recognized as a determinant of health [42]. This result, as well as the dominant biomedical focus emerging from this study, justifies a multidisciplinary approach in the next revision of the ICF core set for DM. This approach enables bilateral learning because members not only learn from each other's perspectives, but also from those of patients.

Conclusion

Content validity of the ICF core set for Diabetes Mellitus was partially supported by nurses specialized in diabetes care. Agreement was predominantly reached on biomedical categories. Less support of validity was found for ICF categories derived from environmental factors. This finding demonstrates a biomedical focus of nurses specialized in diabetes care.

Relevance for clinical practice

The nursing profession should be aware of a potential gap between the current biomedical focus in specialized nursing care and a desired biopsychosocial approach, which is particularly recommended in chronic care. To bridge this gap, nurses should be equipped with the tools required for assessing and reporting on patients' functioning [43]. ICF core sets can therefore be useful [44]. It may be worthwhile for specialized nurses to take part in future revisions of the ICF.

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