Objective: 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 for obesity.

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 219 ICF categories at the second, third and fourth ICF levels with 87 categories on body functions, 34 on body structures, 53 on activities and participation and 45 on environmental factors. Twenty-one experts attended the consensus conference on obesity (18 physicians with various sub-specializations and 3 physical therapists). Altogether 109 categories (108 second-level and one third-level categories) were included in the Comprehensive ICF Core Set with 30 categories from the component body functions, 18 from body structures, 28 from activities and participation and 33 from environmental factors. The Brief ICF Core Set included a total of 9 second-level categories with 3 on body functions, 4 on activities and participation and 2 on environmental factors. No body-structures categories were included in the Brief ICF Core Set.

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 obesity. Both the Comprehensive ICF Core Set and the Brief ICF Core Set were defined.

Key words: obesity, consensus development conferences, outcome assessment, quality of life, ICF.

INTRODUCTION

The prevalence of obesity is currently estimated at about 300 million people worldwide (1, 2) and is continuing to rise (3, 4). Therefore, obesity is increasingly becoming a significant cause of disability (5, 6) and appears to lessen life expectancy markedly (7). In developed and low-mortality developing countries obesity is already considered to be the fifth most serious risk factor for disease burdens measured in disability-adjusted life years (DALYS) (8). The major dangers of obesity on a person’s functioning and health include among other things the increased risk of hypertension, dyslipidaemia, type-2 diabetes mellitus, coronary artery disease, stroke, gall-bladder disease, osteoarthritis, sleep apnoea and respiratory problems, as well as certain types of cancer (9, 10). From a societal perspective, obesity is associated with a decreased quality of life (11, 12) and increased healthcare costs (13, 14).

Based on our current understanding of obesity as a complex, multifactor condition with interactions between genetic, metabolic, environmental and personal factors (10), a patient-centred approach is critical for effective treatment (15–17). Accordingly, patient-centred outcomes are necessary both to measure the burden of disease and to evaluate treatment outcomes. The most frequently applied measures focus on surrogates for body fat and its distribution, such as body weight, body mass index (BMI), waist circumference and others. However, condition-specific health-status measures have only recently been developed (18, 19). Several research groups recently reviewed the outcome measures applied in obese patients (20–22). They underline the importance of measurement of health status and suggest the application of both, generic and condition-specific measures. In addition, a number of organizations such as the American Obesity Association (AOA) and “Shape Up America” (www.shapeup.org) consider quality of life a major goal in the treatment of adult obesity (23). Quality of life is also an important dimension in the task force on developing obesity outcomes and learning standards by the North American Association for the Study of Obesity (NAASO) (24). However, no systematic framework that covers the spectrum of symptoms and limitations in functioning of patients with obesity has been established so far.
With the approval of the new International Classification of Functioning, Disability and Health (ICF, formerly ICIDH-2 http://www.who.int/classification/icf) (25) we can now rely on a globally agreed framework and classification to define the typical spectrum of problems in functioning of patients with obesity. It would be therefore most helpful to determine the most relevant ICF categories in patients with obesity. Such a generally-agreed-upon list of ICF categories can serve as Brief ICF Core Set to be rated in all patients included in a clinical study with obesity or as Comprehensive ICF Core Set to guide multidisciplinary assessments in patients with obesity. 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 for obesity.

METHODS

The development of the ICF Core Sets for obesity involved a formal decision-making and consensus process integrating evidence gathered from preliminary studies including a Delphi exercise (26), a systematic review (27) and an empirical data collection using the ICF checklist (28). 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.

Twenty-one experts (18 physicians with various sub-specializations and 3 physical therapists) from 8 different countries attended the consensus process for obesity. The decision-making process for obesity involved 3 working groups with 7 experts each. The process was facilitated by the condition co-ordinator for obesity (JR) and the 3 working-group leaders (PD, RA, EH).

The tables on the pre-conference studies (26–28) presented to the participants included 219 ICF categories at the second, third and fourth levels (87 on body functions, 34 on body structures, 53 on activities and participations and 45 on environmental factors).

RESULTS

Tables I–IV show the second- and third-level 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. In addition, Table VI shows categories that were discussed controversially but not included in the ICF Core Sets and Table VII represents categories that were not pre-selected by the pre-conference studies but which were considered to be important.

Comprehensive ICF Core Set

The number of second-level categories in the Comprehensive ICF Core Set is 108, only one category was on the third level. Those 108 categories are made up of 30 (28%) categories from the component body functions, 18 (16%) from the component body structures, 28 (26%) from the component activities and participation and 33 (30%) from the component environmental factors.

Twenty-nine of the 30 categories of the component body functions are at the second and one is at the third level of the classification. The 29 categories at the second level represent...
19% 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 5 functions of the digestive, metabolic and endocrine systems (8 categories) and to chapter 4 functions of the cardiovascular, haematological, immunological and respiratory systems (7 categories). Chapter 1 mental functions is represented by 6 categories, b1801 body image is a specification at the third level of the included second-level category b180 experience of self and time functions. Chapter 6 genitourinary and reproductive functions is represented by 5 categories and chapter 8 functions of the skin and related structures by 2 categories. Chapter 2 sensory functions and pain as well as chapter 7 neuromusculoskeletal and movement-related functions are represented by one category, respectively. Five categories were discussed controversially but not included in the Comprehensive ICF Core Set and 4 categories considered by the condition group as important could not be included as they were not pre-selected. The categories are listed in Table VI and VII, respectively.

The 18 categories of the component body structures represent 32% of the total number of ICF categories at the second level in this component. Most of the body-structures categories belong to chapter 5 structures related to the digestive, metabolic and endocrine systems (6 categories). Chapter 7 structures related to movement is represented by 4 categories and chapter 1 structures of the nervous system as well as chapter 4 structures of the cardiovascular, immunological and respiratory systems by 3 categories, respectively. Chapter 6 structures related to the genitourinary and reproductive systems as well as chapter 8 skin and related structures are represented by one category, respectively.

The 28 categories of the component activities and participation represent 24% of the total number of ICF categories at the second level in this component. Most of the activities and participation categories belong to chapter 4 mobility (8 categories). Chapter 5 self-care as well as chapter 8 major life areas are represented by 5 categories, respectively, chapter 7 interpersonal interactions and relationships by 4 categories, chapter 6 domestic life by 3 categories, chapter 9 community, social and civic life by 2 categories and chapter 2 general tasks and demands by one category.
The 33 categories of the component environmental factors represent 45% of the total number of ICF categories at the second level in this component. Most of the environmental-factors categories belong to chapter 5 services, systems and policies (10 categories). However, all 5 chapters of this component are represented in the Comprehensive ICF Core Set. Chapter 4 attitudes is represented by 8 categories, chapter 1 products and technology as well as chapter 3 support and relationships by 7 categories, respectively, and chapter 2 natural environment and human-made changes to the environment by the category e225 climate.

**Brief ICF Core Set**

The total number of second-level categories included in the Brief ICF Core Set is 9. No third-level category was selected for the Brief ICF Core Set. Three categories (10%) were chosen from the component body functions, 4 (14%) from activities and participation, and 2 (6%) from environmental factors. No body-structures categories were included in the Brief ICF Core Set. Exclusively categories at the second-level were included.

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 second ICF Core Sets conference led to the definition of the Brief ICF Core

### Table V. International Classification of Functioning, Disability and Health (ICF) categories included in the Brief ICF Core Set for obesity. Percentage of experts willing to include the named category in the Brief ICF Core Set. 50% represent a preliminary cut-off. >50% is bold

<table>
<thead>
<tr>
<th>ICF component</th>
<th>%</th>
<th>ICF code</th>
<th>ICF category title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body functions</td>
<td>100</td>
<td>b130</td>
<td>Energy and drive functions</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>b530</td>
<td>Weight maintenance functions</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>b540</td>
<td>General metabolic functions</td>
</tr>
<tr>
<td>Activities and participation</td>
<td>100</td>
<td>d240</td>
<td>Handling stress and other psychological demands</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>d450</td>
<td>Walking</td>
</tr>
<tr>
<td></td>
<td>89</td>
<td>d455</td>
<td>Moving around</td>
</tr>
<tr>
<td></td>
<td>89</td>
<td>d570</td>
<td>Looking after one’s health</td>
</tr>
<tr>
<td>Environmental factors</td>
<td>100</td>
<td>e110</td>
<td>Products or substances for personal consumption</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>e310</td>
<td>Immediate family</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>ICF component</th>
<th>ICF code</th>
<th>ICF category title</th>
<th>Arguments that were discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Functions</td>
<td>b160</td>
<td>Thought functions</td>
<td>Obsessive and compulsive disorders are usually considered common in obesity. Nevertheless, the evidence regarding their prevalence is not clear from the literature.</td>
</tr>
<tr>
<td></td>
<td>b270</td>
<td>Sensory functions related to temperature and other stimuli</td>
<td>Temperature sensitivity may be increased in obese patients. This may be addressed to some extent by “sensation of pain” which includes “unpleasant feelings.”</td>
</tr>
<tr>
<td></td>
<td>b525</td>
<td>Defecation functions</td>
<td>Increased flatulence in obese patients. Prevalence of this symptom considered to be low.</td>
</tr>
<tr>
<td></td>
<td>b730</td>
<td>Muscle power functions</td>
<td>Not considered to be affected by obesity per se.</td>
</tr>
<tr>
<td></td>
<td>b780</td>
<td>Sensations related to muscles and movement functions</td>
<td>Domain related to level of training rather than level of obesity.</td>
</tr>
<tr>
<td>Body structures</td>
<td>s540</td>
<td>Structure of intestine</td>
<td>Unclear whether lipomatosis of the intestine represents an impairment.</td>
</tr>
<tr>
<td></td>
<td>s610</td>
<td>Structure of urinary system</td>
<td>Anatomical impairment due to fat, no structural changes per se.</td>
</tr>
<tr>
<td>Activities and participation</td>
<td>d177</td>
<td>Making decisions</td>
<td>The ability to freely make decisions when and what to eat may be altered in obese persons.</td>
</tr>
<tr>
<td></td>
<td>d220</td>
<td>Undertaking multiple tasks</td>
<td>In obese class III (BMI ≥40) the undertaking of multiple tasks may be a problem.</td>
</tr>
<tr>
<td></td>
<td>d630</td>
<td>Preparing meals</td>
<td>Same argument as d220.</td>
</tr>
<tr>
<td></td>
<td>d730</td>
<td>Relating with strangers</td>
<td>Obese might have issues with contacting.</td>
</tr>
<tr>
<td>Environmental factors</td>
<td>e240</td>
<td>Light</td>
<td>Syndrome of seasonal defective disorder: i.e. increase of weight in winter times and loss of weight under increasing light radiation.</td>
</tr>
</tbody>
</table>
Life in obesity was emphasized (31) in independent contributor to impaired Health Related Quality of Life (32), as it was not clearly presented. Several experts indicated that gut hormones are an area of research and future interest in obesity. As supported by the literature, gut hormones are an area of research and future interest in obesity. Gut hormones are an area of research and future interest in obesity. Gut hormones are an area of research and future interest in obesity.

Table VII. Domains that were not pre-selected but were considered to be important

<table>
<thead>
<tr>
<th>ICF component</th>
<th>ICF code</th>
<th>ICF category title</th>
<th>Arguments that were discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Functions</td>
<td>b445</td>
<td>Respiratory muscle functions</td>
<td>There are known respiratory muscle dysfunctions in obesity.</td>
</tr>
<tr>
<td></td>
<td>b460</td>
<td>Sensations associated with cardiovascular and respiratory functions</td>
<td>Respiratory symptoms like dyspnoea, sensations of tightness of chest, feelings of irregular beat are common in obesity.</td>
</tr>
<tr>
<td></td>
<td>b559</td>
<td>Functions related to metabolism and the endocrine system, other specified and unspecified</td>
<td>Gut hormones are an area of research and future interest in obesity.</td>
</tr>
<tr>
<td></td>
<td>b740</td>
<td>Muscle endurance functions</td>
<td>Considered to be affected by obesity.</td>
</tr>
</tbody>
</table>

Set and the Comprehensive ICF Core Set for multidisciplinary assessment.

A crucial point during the development of the ICF Core Sets for obesity was to cover the typical symptoms and experiences that are most likely to occur in obese patients – changes in body functions and structures, as well as restrictions of activity and participation – and not to pay too much attention to its serious health consequences, such as cardiovascular events, obstructive sleep apnoea and diabetes. The co-morbidities are moreover in part subject to separate ICF Core Sets.

As has been shown by Fontaine et al. (29) and Fine et al. (30), there is an association between BMI and health status. Patients with higher BMI classes experience greater limitations in function. Therefore, the Comprehensive ICF Core Set may contain functioning and disability categories related to the health condition obesity not necessarily relevant to all obesity patients.

The consensus group felt that some individual clinical and aetiological factors are difficult to capture by the ICF: (i) genetic factors are not explicitly included; (ii) it is not clear how important surrogate parameters (e.g. Hba1c) that are frequently used in clinical trial settings are represented; (iii) another important outcome parameter in obesity, waist circumference, is not clearly presented.

The selection of body functions included in the Comprehensive ICF Core Set showed results consistent with the organ functions usually involved in obesity and in agreement with the evidence from the preliminary studies. As obesity is a systemic disease almost all body organ functions are mentioned in the Comprehensive ICF Core Set. Concurrent to its prominence in the preliminary studies the important role of pain (b280) as an independent contributor to impaired Health Related Quality of Life in obesity was emphasized (31).

Some categories were discussed controversially but not included in the ICF Core Sets (Table VI), for example concerning thought functions (b160) there is no clear evidence in the literature that obsessive and compulsive disorders are more prevalent in obese people.

Additionally, there was a discussion regarding the category b559 (functions related to metabolism and the endocrine system, other specified and unspecified). As supported by the literature (32), several experts indicated that gut hormones are an important area in obesity research. However, as it was not pre-selected in the pre-conference studies this category (b559) was not included in the ICF Core Sets. The same applied to limitations in respiratory functions (b445 and b460). More details are given in Table VII.

According to the large number of body organs involved in obesity, the selection of body structures included almost all chapters of this component. Congruent with body functions, the body structures related to the digestive, metabolic and endocrine system were captured in great depth.

The important criteria waist circumference was allocated to the category structure of trunk (s760) but the condition group considered this category to be too general and suggested a specification of this domain.

After discussion, the recommendation by some group members to include the structure of intestine (s540) was rejected.

Limitations and restrictions in activities and participation are, indeed, of great relevance to patients with obesity. This is reflected by the fact that this component is represented in almost as many categories (28 categories) as the body-functions (30 categories) component. The areas that are covered represent key issues for patients with obesity, including mobility, self care and major life areas such as education, work and employment. Especially the 2 categories walking (d450) and moving around (d455), including climbing, were ranked highest by both the condition group and the preliminary empirical patient data collection (26–28). Similarly the category d570 (looking after one’s health) comprising managing diet and fitness received highest ranks. These categories were included in the Brief ICF Core Set.

Handling stress and other psychological demands (d240) is included in both ICF Core Sets. This is in line with the characteristics that seem to be typical in patients with obesity. They are frequently described as a treatment seeking population with emotional problems (15, 33). Although there is little evidence to support the view that obesity is associated with mental problems, this picture is mostly derived by case studies (34). Nevertheless, obese persons suffer from psychological problems specific to their obesity, including disparagement of the body and body image and binge eating (35). Of the clinically obese, nearly 35% have a binge eating disorder (36), which causes severe psychological impairment.
Several additional categories were discussed but not included in the ICF Core Sets mainly because they may be relevant only in severely obese patients, i.e. patients that, according to one definition mentioned by experts, can be classified in the category “obese class III” with a BMI ≥ 40 (37). For more details see Table VI.

It is significant that 33 categories representing 30% of the categories of the Comprehensive ICF Core Set belong to the component environmental factors. This responds to the current understanding of obesity as a complex condition with many interactions, especially between genetics and environment. Compared with health outcome measures for obesity (38–44) this proportion clearly seems to be higher.

Services, systems and policies but also products and technology, support and relationships and attitudes are highly important to patients with obesity because they can serve as either a barrier or a facilitator. There was general agreement about the essential role of food and that obesity has an enormous impact on the immediate family (e310).

The aim to create a mandatory Brief ICF Core Set short enough to be practical in clinical studies resulted in a noticeable reduction in only 9 categories. Nevertheless the condition group encountered difficulties in determining cut-offs. Different from the Comprehensive ICF Core Set, which is intended for multidisciplinary assessments for example in the context of rehabilitation and teaching, the Brief ICF Core Set, which is primarily intended as a standard for reporting of clinical studies, may well serve as a more practical tool for clinical practice.

The ICF does not currently have categories for genetic factors, and for body composition. The category structure of trunk (s760) was considered too general to cover the item waist circumference which also was the case for, the category of haematological system functions (b430) for the important marker HbA1C. The experts recommended the specification of the mentioned domains.

Although the participants were provided with the option to define the categories not only on the second, but possibly also on the third or fourth levels of the classification, it was decided to keep the definition, except of one category – body image (b 1801), on the second level.

The organizers of the consensus process took great care in the selection of the experts and were successful in reaching 21 experts with different professional backgrounds and from 8 different countries. However, no dieticians or psychologists 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 perspectives of different professions and in different countries. The first version of the ICF Core Sets will also be tested from the patients’ points of view and in different clinical settings. Validation studies are also needed to explore the problems of functioning in subsets of patients. For example, it is not clear whether patients with severe obesity (BMI > 40) may simply have more severe problems or whether the profile of problems differs. Similarly, age and gender, as well as a number of other socioeconomic factors, may influence the spectrum of problems and the severity of these problems. It is important to note that this first version of the ICF Core Sets is recommended only for validation or pilot studies.

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