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## Danish translation and linguistic validation of new body-Q scales measuring expectations, eating behavior, distress, symptoms and work life

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### ABSTRACT

The aim of this study was to translate and achieve a linguistic and cultural adaptation of the newly developed BODY-Q Obesity Module for use in Danish patients. The BODY-Q Eating Module consists of five new modules aiming to measure expectations of weight-loss, eating behavior, eating-related distress, eating-related symptoms and work life. Translation and linguistic validation were performed using a combination of the recommendations developed by the World Health Organization and the International Society for Pharmacoeconomics and Outcomes Research. The translation was performed in five steps consisting of a forward translation, backward translation, expert panel meeting, cognitive debriefing and final proofreading. Each step aimed for a conceptual and cultural equal translation that was easily understood by patients. The discrepancies encountered in the forward translation included the use of layperson versus medical terminology, different tense and sentence structure. The harmonized version was then backwards translated which led to no conceptual differences. The expert panel reviewed the instrument in full and found two items needing correction in the instrument. Cognitive debriefing did not lead to any revisions and the instrument was well received by the participant group. Proofreading of the instrument led to few corrections in grammar and punctuation but no conceptual corrections. The translation of the BODY-Q Eating Module led to a conceptual and cultural equal version of the instrument for use in Danish patients. The instrument can be used in clinical care and research to inform advancements in the field of bariatric and body contouring surgery.

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BODY-Q; patient-reported outcome measure; health-related quality of life; cultural adaptation; linguistic validation; translation; bariatric surgery; body contouring surgery

### Introduction

Obesity is a complex disease with a rapidly increasing prevalence globally [1]. In 2017, 16.8% of the Danish adult-aged ( $\geq 18$  years) population was diagnosed with obesity, with a continuous increase in prevalence seen throughout the last decade [2]. Obesity is associated with secondary disease such as cardiovascular and pulmonary disease, diabetes, arthritis and cancer [3–6]. Bariatric surgery is the most efficient long-term treatment of obesity [7]. However, the rapid weight loss achieved through bariatric surgery often leaves patients with large amounts of excess skin [8], which in turn leads to reduced physical and psychosocial well-being [8–13]. Body contouring surgery after massive weight loss aims to improve a patient's quality of life and is specifically targeted to enhance one's body image and physical function [10,14,15].

Outcome assessments in bariatric and body contouring surgery have widely focused on conventional clinical outcomes such as mortality, weight reduction and complication rates. However, there is a growing need to measure outcomes from the patient perspective using well-developed and validated patient-reported outcome measures (PROMs). The BODY-Q is an internationally recommended condition-specific PROM developed for use in bariatric and body contouring surgery patients [16–18]. The BODY-Q is composed of independently functioning scales measuring

appearance, health-related quality of life (HRQOL) and experience of care.

Recently, five new scales were developed to form the BODY-Q Eating Module. These new scales provide a mean to evaluate weight management treatments. The scales measure expectations of weight-loss, eating behavior, eating-related distress, eating-related symptoms and work life [19]. Our team previously translated the original BODY-Q scales into Danish [20–22]. The aim of the present study was to translate and culturally adapt the new BODY-Q Eating Module for use in Danish patients undergoing bariatric and body contouring surgery.

### Materials and methods

The study was reported to the health research list within the Region of Southern Denmark in lieu of Health Research Ethics Board approval, since studies utilizing questionnaires are exempt from full review.

Translation and linguistic validation of the BODY-Q Eating Module was performed using the World Health Organization (WHO) and International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommendations [20,21]. Table 1 describes the recommended steps by the WHO and ISPOR as well as the steps taken to translate and linguistically validate the

**Table 1.** Comparison of the international guidelines and the adopted steps.

Step	ISPOR guidelines	WHO guidelines	Our study
1	<b>Preparation:</b> Project manager asks for approval of translation and invites developers and key in-country persons to participate in the study if interested.		<b>Preparation:</b> Project manager obtained permission to translate the BODY-Q Eating Module and invited developers, translators, and key in-country persons.
2	<b>Forward translation:</b> Two or more individuals translate the PROM into the target language. The primary translator must be a native speaker of the target language, and the second translator is <i>preferably</i> a native speaker. When translating the PROM, translators should maintain the conceptual meaning of the items.	<b>Forward translation:</b> Performed, <i>preferably</i> , by a healthcare professional who is knowledgeable in the terminology and with interview skills should perform the translation. The translator should be knowledgeable in English language and speaking culture and the primary language of the target culture. Translation should be aimed at a conceptual equivalent rather than literal translation with an aim for the most common audience.	<b>Forward translation:</b> The forward translation was performed by two translators: 1. Native Danish professional translator who is fluent in English 2. Native Danish clinician who is fluent in English. Translators were asked to prepare a conceptually equivalent and culturally relevant translation of the BODY-Q Eating Module.
3	<b>Reconciliation:</b> Reconciliation is achieved through a meeting with the translators and project manager.	<b>Expert panel:</b> Designated meeting by the project manager aiming at a bilingual identification and resolving of inadequate expressions, concepts and discrepancies. The number of participants vary, but should include the original translator, experts in the field as well as experts with experience in translation and development of instruments. Participants should be given materials helping with consistency compared to previous translations.	<b>Reconciliation:</b> Reconciliation consisted of a meeting between the forward translators reaching a consensual forward translation.
4	<b>Back translation:</b> Back translation is performed after reconciliation of the forward translation. The nature of the back translation (conceptual or literal) is to be determined by the project manager prior to commencement.	<b>Back translation:</b> The translation should be performed using the same approach as the first step. The translation is to be performed by a translator whose mother tongue is English and who has no previous knowledge of the instrument. Emphasis of the backtranslation should be on conceptual and cultural equivalence as the first translation. Discrepancies from the backtranslation should be discussed with the project manager and drawing experience from the previous steps until an equivalent version is achieved.	<b>Back translation:</b> The back translation was performed by an experienced native English translator fluent in Danish. The nature of the translation was stressed to be conceptual rather than literal.
5	<b>Back translation review:</b> The project manager should review the back translation against the source instrument.		<b>Back translation review:</b> The back translation was compared to the original instrument and presented to the developers of the instrument. Discrepancies were marked for discussion and revision at the expert panel.
6	<b>Harmonization:</b> Items problematic in terms of conceptual understanding is identified by the project manager and harmonization is performed by including the translator participating in the project.		<b>Expert panel:</b> A designated meeting including the participating translators, the project manager and a bariatric specialist was held. All participants were native Danish speakers fluent in English except the back translator who were a native English speaker fluent in Danish. The meeting was held in Danish. All participants were provided with significant materials prior to the meeting, and each item of the instrument was discussed in plenum.
7	<b>Cognitive debriefing:</b> The translated instrument should be tested on a group of 5–8 participants in the target country.	<b>Pre-testing and cognitive interviewing:</b> Pre-test respondents should include participants of the target group and should preferably include 10 participants. The instrument is administered, and participants is systematically debriefed regarding the instrument and its scope and interpretation.	<b>Cognitive debriefing interviews:</b> 15 participants were included and briefed regarding the purpose of the instrument. In total three participants prior to bariatric surgery, four participants post bariatric surgery, four participants prior to body contouring surgery and four participants post body contouring surgery were included. Each participant was thoroughly debriefed.
8	<b>Review of cognitive debriefing results and finalization:</b> The project manager reviews the results and changes should be agreed on by the project manager and the key in-country participants.		<b>Post-interview reconciliation:</b> Discrepancies and/or feedback regarding items were noted and evaluated for edition of the instrument.

(continued)

Table 1. Continued.

Step	ISPOR guidelines	WHO guidelines	Our study
9	<b>Proofreading:</b> The instrument is proofread for spelling, diacritical, grammatical or other errors in the final version.	<b>Final version:</b> A serial number is to be added to each edited version throughout the process. The final version should be the result of all completed steps.	<b>Proofreading:</b> Proofreading were performed by two clinicians experienced in the field.
10	<b>Final report:</b> A final report is written by the project manager including an item-by-item based process.	<b>Documentation:</b> The process should be described systematically and retracable through the steps performed.	<b>Documentation:</b> The process was described throughout each step of the process. An item-by-item approach was taken regarding all edited items.

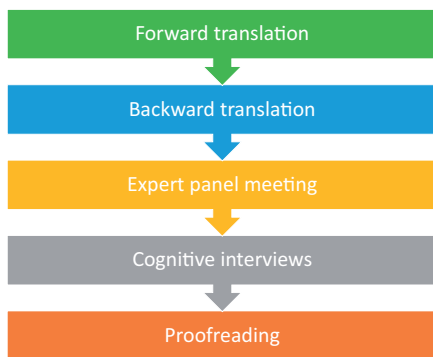


Figure 1. Steps in the process of translation.

BODY-Q Eating Module. Figure 1 shows the five steps in the translation process. The steps followed are described in detail below:

Step 1: Forward translations were independently prepared by two translators who were native Danish speakers and fluent in English. A reconciliation meeting was held between the two forward translators to compare their translations and develop Danish version one of the BODY-Q Eating Module.

Step 2: A back translation was prepared by one translator who was a native English speaker and fluent in Danish. The back translation was sent to the BODY-Q development team to review the items, instructions, or response options for conceptual equivalence relative to the original English version.

Step 3: An expert panel meeting was held to systematically review the Danish version of the BODY-Q scales and to appraise the cultural meaning and chosen wording for the items, instructions and response options. The comments provided by the BODY-Q development team after reviewing the back translation were also discussed and resolved. Any changes made to the Danish version after completion of the expert panel were back translated and sent to the BODY-Q development team for review and approval.

Step 4: Cognitive debriefing interviews with Danish patient representatives receiving bariatric and body contouring surgery were performed. Participants were included if they were aged 18 years or older, were of any gender, could read and communicate in Danish, and had bariatric or body contouring surgery. Participants, recruited from the departments of endocrinology and plastic surgery, were chosen to ensure representation of the different treatment stages (i.e. pre/post bariatric or body contouring surgery). Potential participants were approached in-person by the project manager to explain the purpose and outcomes of the study and their participation. Those who agreed to participate were interviewed in-person during their visit or were scheduled for a phone interview later. During the interview participants were asked to review the BODY-Q Eating module using the 'think aloud' approach to identify any words or phrases that were difficult to understand, and to further

assess the content and cultural equivalence of the Danish translation [23]. Any items, instructions or response options that were expressed as difficult to understand or ambiguous were re-translated and tested with additional patients. Interviews continued until no new problems with the comprehensibility of the items, instructions or response options were raised. Changes made after the cognitive debriefing interviews were back translated and sent to the BODY-Q development team for review and approval.

Step 5: The final Danish BODY-Q Eating Module was proofread by two independent clinicians for spelling or grammatical errors.

## Results

The forward translations included a clinician translator, who was a resident in the field of plastic surgery, and a paid professional translator. Review of the two forward translations resulted in several discrepancies including the use of lay versus medical terminology, different tense, or sentence structure. For example, the instructions of the Expectation scale ask patients to 'Imagine that 2 years have passed since you had bariatric surgery...'. Bariatric surgery was translated as 'fedmekirurgi' by the professional translator and as 'bariatrisk kirurgi' by the clinician translator. Through the reconciliation meeting the term 'fedmekirurgi' was kept as it was found to be more neutral and easily understandable due to it being a lay person's term. Furthermore, the translators used different conjugations when translating several items, instructions, and response options.

For example, item three in the Eating-related Distress scale, the word 'Unhappy' was translated as 'Ulykkelig' by the professional translator and 'Ulykkelighed' by the clinician translator. Through the reconciliation meeting the laymans terms 'Ulykkelig' was preserved since the conjugation was thought to be the simpler translation.

Comparison of the back translation to the original English version revealed some literal discrepancies in the wording or phrasing although conceptual equivalence was maintained for all items, instructions, and response options. Since the conceptual meaning was maintained, no changes were made these items.

The expert panel meeting involved the two forward translators, the back translator, the project manager and a surgeon specializing in bariatric medicine. Results from the expert panel meeting prompted two items for revision; (1) the item 'Eat the right amount of food' in the Eating Behavior scale was revised to add an example to improve clarity 'Eat the right amount of food (e.g. 'not too much)'; and (2) the item 'discouraged' in the Eating-related Distress scale was translated as 'disheartened' in the Danish version. The expert panel concluded that the translation 'disheartened' maintained the same meaning as 'discouraged' in Danish, and the translation was therefore maintained. The revised version of the BODY-Q Eating Module was reviewed and

approved by the BODY-Q developers prior to the cognitive debriefing interviews with patients.

Fifteen patients participated in the cognitive debriefing interviews: three pre-bariatric surgery, four post-bariatric surgery, four pre-body contouring surgery and four post-body contouring surgery. Two males and 13 females participated with an age range of 24–59 (mean age 41.6 years). Overall, participants found the items, instructions and response options to be relevant, comprehensible and comprehensive. Participants emphasized that they were pleased to see questions regarding eating behavior and emotions as these concepts are often overlooked. Three items were brought forward as specifically relevant to five of the 15 participants including items relating to their weight, workplace and eating food. One participant described that work life was essential to measure since ‘we spend most of our days in the workplace’. Another participant elaborated on the item ‘Chew food thoroughly before swallowing’ stating that ‘this question is very relevant, as you oftentimes have a tendency not to chew thoroughly and swallow food too fast prior to bariatric surgery’.

Proofreading of the Danish BODY-Q Eating Module by two experienced clinicians resulted in few grammatical and punctuation corrections, leading to the final version of the Danish BODY-Q Eating Module.

## Discussion

The translation of the new BODY-Q Eating Module allows for the measurement of important concerns for bariatric surgery patients [24–26]. We applied a combination of the WHO and ISPOR guidelines [27,28] to translate and linguistically validate the new BODY-Q Eating Module. The WHO and ISPOR guidelines share several overlapping steps and are therefore readily combined to enhance the translation and linguistic validation process [20,21]. Differences between the two guidelines include the expert panel meeting that is recommended by the WHO guidelines, and the use of ‘two or more’ translators for the forward translation that are recommended by ISPOR. The expert panel meeting proposed by the WHO promotes a more thorough translation by including input from experts (e.g. medical professionals, linguistics experts, patients).

Discrepancies in the translations are to be expected. In our previous experience translating the original BODY-Q scales into Danish, we found that the forward and back translation steps resulted in the majority of discrepancies. This can in-part be explained by the fact that the English language consists of approximately twice as many words as the Danish language [29,30].

This study has some limitations. The expert panel meeting included only four participants who and did not represent the full range of healthcare professionals, such as nurses and dieticians, who treat bariatric and body contouring patients. Furthermore, patients were not included in the expert panel meeting but solely through cognitive interviewing. Including patients in the expert panel meeting could further promote comprehensibility and content validity. For the cognitive debriefing interviews, we attempted to include an equal number of patients that varied by age, gender, and stage of treatment (Pre- bariatric surgery, post-bariatric surgery, pre-body contouring surgery, post-body contouring surgery). However, in our final cognitive debriefing sample only two males of the 15 participants were included. Since males are generally underrepresented in the bariatric and body contouring patient population [7,31], we do not anticipate that the inclusion of additional males would have altered the results.

## Conclusions

The international field-test study to assess the psychometric properties of the new BODY-Q Eating Module is now complete. The sample included 4004 participants of whom 907 were from Denmark. Analysis to explore Differential Item Functioning by language (English, Danish and Dutch) provided evidence to support the use of a common scoring algorithm for each scale for international use [19]. The Danish version of the BODY-Q Eating Module can be used in clinical care and in research to inform advancements in the field of bariatric and body contouring surgery.

## Disclosure statement

Mike Mikkelsen Lorenzen, Lotte Poulsen, Christoffer Bing Madsen, Elena Tsangaris and Jens Ahm Sørensen declare that they have no conflict of interest. The BODY-Q Eating Module is owned by McMaster University and Memorial Sloan Kettering Cancer Centre. Drs Anne Klassen and Andrea Pusic are co-developers of the BODY-Q and as such, receive a share of any license revenues as royalties based on the inventor sharing policy.

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