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RESEARCH-ARTICLE



Danish translation and linguistic validation of the BODY-Q Chest Module

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ABSTRACT

The aim of this study was to translate and linguistically validate the patient-reported outcome (PRO) instrument body-q chest module, designed to measure outcomes following chest contouring surgery. The BODY-Q Chest Module includes two scales that measure appearance of chest and nipples. The translation and validation were performed according to the guidelines from the world health organization (who) and the international society for pharmacoeconomics and outcomes research (ISPOR). This approach involved two independent forward translations, a backwards translation, an expert panel meeting and cognitive debriefing interviews with patients. Each step was undertaken with the aim of achieving a conceptual and culturally equal instrument. This process led to a linguistically validated and conceptually equivalent danish version of the body-q chest module. The forward translation resulted in several discrepant translations of items that were harmonized to form the backward translation. This translation included three items with conceptual differences that required further revision. The revised version presented at the expert panel meeting had six items that needed to be revised due to conceptual discrepancies. The cognitive debriefing interviews led to revision of one item. The practices from the who and ispor guidelines were essential to developing a translation that preserved the meaning of the content of the body-q chest module from the original development study. The translation and linguistic validation methods used in our study could be used for further translations and validation of pro instruments. These new scales have since been field-tested as part of an international psychometric study.

Abbreviations: MWL: Massive weight loss; HR-QOL: Health-related quality of life; PRO: patient-reported outcome; WHO: World Health Organization; ISPOR: International society of Pharmacoeconomics and Outcomes Research; MAQQL: Moorehead-Ardelt Quality of Life Questionnaire

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Introduction

Patients with gynecomastia [1–3], excessive loose skin following massive weight loss (MWL) [4–6] and those seeking gender confirming chest surgery [7,8] often experience a negative impact on psychological health due to chest abnormalities. These chest conditions can have a negative impact on body image and health-related quality of life (HR-QOL) [2,9]. One of the goals of chest surgery is to improve the physical appearance of the chest and thereby improve body image and HR-QOL.

Generic patient-reported outcome (PRO) instruments have been used in plastic surgery but fall short in terms of specificity to the cause, rendering them ineffective in measuring change. Content validity is crucial in a PRO instrument that aims to measure change. The BODY-Q is a PRO instrument developed to assess outcomes that matter to patients undergoing weight loss and/or body contouring surgery. Research using the BODY-Q showed that HR-QOL and appearance could be reliably assessed in a reproducible manner following MWL surgery [10–12].

The BODY-Q Chest Module is a supplementary scale to the BODY-Q that measures chest and nipple appearance for men and trans men. Since the original language of the Chest Module is English, this module needed to be translated and validated prior to its application in Denmark. We followed the steps taken

previously to translate the BODY-Q into Danish, which are published in detail elsewhere [13]. The steps adhered to the World Health Organization (WHO) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines for linguistic validation and cultural adaption of PRO instruments [11,14].

The aim of this study was to achieve a validated Danish version of the BODY-Q Chest Module for use with patients by health-care professionals and researchers.

Material and methods

Original BODY-Q Chest Module

The original BODY-Q Chest Module was developed by re-examining the 63 interviews from the development of the BODY-Q. Due to the limited number of male participants further cognitive interviews were performed with ten post-bariatric patients, ten gynecomastia patients and five female-to-male gender confirming patients. The version was later field-tested on 689 patients from Canada, USA, Denmark, and the Netherlands. The sample included 224 post-bariatric patients, 174 gynecomastia patients and 291 trans men. The field-test found the BODY-Q Chest Module to be reliable and valid.

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

Step	ISPOR guidelines	WHO guidelines	Our study
1	Preparation: The project manager should obtain permission and send out invitations to authors and key persons prior to beginning. Development of explanations of concepts in the instrument.		Authors granted permission and agreed to participate in the study. The translators were recruited at this stage.
2	Forward translation: More than one forward translation should be produced from independent translators' native in the target language. Provision of explanation of the concepts in the instrument to the key in-country persons and forward translators.	Forward translation: One health professional familiar with the terminology of the instrument should convey the task. The translator's mother tongue should be the target language, and the translator should be knowledgeable of the English-speaking culture. A conceptual rather than literal translation should be emphasized, and language should be as natural and acceptable as possible.	Two forward translations were done by a native Danish translator and an experienced clinician. Conceptual and cultural translation rather than literal was emphasized.
3	Reconciliation: The forward translations are reconciled into one single forward translation		Consensus was achieved at a reconciliation meeting between the two forward translators.
4	Back translation: The reconciled version is translated back into the target language.	Back translation: The translation should be performed by an independent translator whose mother tongue is English and who has no knowledge of the questionnaire. Cultural and conceptual equivalence should be emphasized. Discrepancies should be discussed with the editor-in-chief and should be iterated as many times as needed until a satisfactory version is reached.	Back translation was performed by a professional translator whose mother tongue was English. Conceptual and cultural translation rather than literal was emphasized.
5	Back translation review: Review of the back translations against the source language.		Comparison of the backwards translation to the original BODY-Q Chest Module was performed by the original authors (Dr. Klassen and Dr. Pusic). Differences were discussed, and prompted to be discussed further at the expert panel meeting. This led to the Danish version two.
6	Harmonization: Comparison of all new translations with each other and the source version.	Expert panel: A bilingual expert panel is recommended. Experts should be given any materials that can help them to be consistent with previous translations. The goal is to identify and resolve the inadequate expressions/concepts of the translation, as well as any discrepancies between the forward translation and the existing previous versions. The panel should include the original translator, experts in the fields, as well as experts in instrument development and translation.	The expert panel consisted of a bariatric surgeon, two plastic surgeons, three translators and a coordinator, all being fluent in Danish and English. All documents and guidelines were sent to the participants prior to the meeting. Every translation was discussed openly in the panel. The consensus resulted in Danish version three.
7	Cognitive debriefing: Cognitive debriefing usually with patients drawn from the target population.	Pre-testing and cognitive interviewing: Included individuals should be representative of the patient group. It is recommended to include 10 participants that represent the target population. The respondents should be systematically debriefed and asked regarding the understandability of the instrument.	We performed 8 cognitive interviews with two pre-bariatric, two post-bariatric, two male pre-body contouring patients and two gynecomastia patients. Patients were thoroughly briefed and debriefed.
8	Review of cognitive debriefing results and finalization: Results of the cognitive debriefing are reviewed and the translation finalized.		Reconciliation and harmonization led to the Danish version four.
9	Proofreading: The finalized translation is proofread.	Final version: The final version of the instrument should be the result of all iterations described.	Proofreading by two independent clinicians led to the final version of the Danish BODY-Q Chest Module.
10	Final report: Report is written on the development of the translation.	Documentation: All the cultural adaptation procedures should be traceable through the appropriate documents. The samples used in this process (i.e. the composition of the expert panel and the pre-test respondent samples) should be described.	All changes throughout the process were documented (Supplementary Appendix 1)

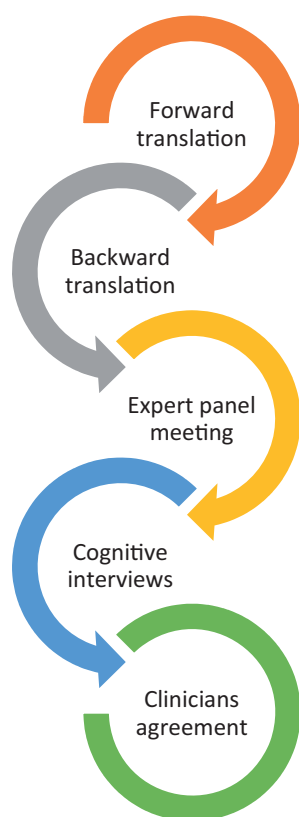


Figure 1. Steps in the adopted approach.

Translational procedure

The study was approved by the Danish Data Protection Agency. The field-test version of the BODY-Q Chest Module included two scales to measure appearance of the chest and nipples.

An overview of the translation process can be seen in Table 1. The translation from the English to the final Danish version was carried out in five steps (Figure 1):

1. The Danish Chest Module version 1 was developed from two independent forward translations by a native Danish professional translator and an experienced clinician. Consensus was achieved in a meeting between the two translators.
2. The Danish Chest Module version 2 was obtained from a backward translation by a professional translator in collaboration with the Chest Module developers.
3. The Danish Chest Module version 3, aiming to be both clinically relevant and easily understandable, was obtained from a consensus of an expert panel evaluating all the material used in steps 1 and 2 and recommendations from two consultant plastic surgeons and a bariatric surgeon. The participants of the meeting included the translation coordinator and the three translators. Three of the participants were Danish native speakers and fluent in the English language and one (the backward translator) was an English native speaker fluent in Danish.
4. The Danish BODY-Q Chest Module version 4 was finalized following thorough reading and interpretation of version 3 by eight patients in different phases of their treatment.
5. The final version of the Danish Chest Module was obtained following proofreading of version 4 by two independent clinicians.

Results

The stepwise process led to a linguistically validated and conceptually equivalent Danish version of the BODY-Q Chest Module.

Supplementary Appendix 1 provides an overview of the changes made in each step of the translational process.

Step 1. The first translation was prone to synonymous translations resulting in literal discrepancies rather than conceptual. An example of a literal discrepancy was the translation for the item 'How your CHEST (breast area) looks in a snug T-shirt'. Here the two forward translators translated the word snug to 'tight' and 'tight-fitting', respectively. The words snug, tight and tight-fitting were ruled conceptually equal. The translation resulted in four items that conflicted conceptually with the meaning in English. The items were revised in a reconciliation meeting between the two translators.

Step 2. The backward translation of the Danish version 1 and the original Chest Module included three conceptual discrepancies that were subsequently retranslated and reviewed by the developers. An example of a discrepancy between the back translation and the original version was related to the item 'How toned your CHEST (breast area) looks without a shirt on', which was back translated into 'How trim your CHEST (chest area) looks without a shirt?' Toned and trim were ruled to be conceptually different and thus required retranslation. Consensus of a conceptual translation was reached through ongoing discussion and revision with the developers.

Step 3. The expert panel meeting resulted in six items that required major revision to the translation. An example of a major revision from the expert panel was regarding the word 'chest'. In Danish version 2 the word for 'chest' originally translated to a word with a feminine origin 'bryst'. The word was retranslated to a synonym that was more equivalent to 'chest' and was changed.

Step 4. The eight patients who reviewed the scales included two male pre-bariatric patients, two male pre-body contouring patients, two male post-body contouring patients and two patients with gynecomastia, with one of the gynecomastia patients being a trans man. All patients were Danish with a median age of 44 years (22–70). This sample confirmed that the Danish version of the Chest Module was easily understandable and comprehensive in terms of items. The interviews confirmed that the changes suggested by the expert panelists were appropriate. Patient input resulted in preserving the term 'i.e. symmetric' in item 6 of the chest scale, 'How similar (i.e., symmetric) both sides of your CHEST (breast area) look?' No other changes were made during this step. The tested version was labeled Danish version 4.

Step 5. Proofreading by clinicians led to no changes.

Discussion

We combined the recommendations by the World Health Organization (WHO) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines to achieve a high quality, conceptually equal, linguistic validated and cultural adapted Danish translation of the English BODY-Q Chest Module [11,14]. Until recently no validated PRO instrument has been available for measuring outcomes following chest surgery. The BODY-Q Chest Module was created and validated through internationally accepted guidelines. The development followed the same method our team previously used in their similar development studies [10,15,16]. Previously, generic questionnaires like the Short Form 36 (SF-36), the Moorehead-Ardelt Quality of Life Questionnaire (MAQOL) and adhoc questionnaires have been used in weight loss and body contouring research, however, such scales lack content validity for evaluating surgical interventions as they do not ask about the specific outcome targeted by surgery,

i.e., chest appearance. Furthermore, these scales were not developed through qualitative interviews in the target population of patients seeking chest contouring [17–20]. Generic questionnaires rarely address appearance, even though appearance is often a key outcome in plastic and reconstructive surgery [13,21].

Application of a combination of the two guidelines proved to be straightforward and thorough, however, there are discrepancies. The WHO guideline recommends using one healthcare professional familiar with the terminology, whereas the ISPOR guideline recommends ‘more than one’ forward translator. WHO also recommend an expert panel meeting, which added value in our study as it led to important major revisions. Both guidelines rely on cognitive interviewing and debriefing, which ensures sufficient patient involvement. The two guidelines complement each other, as each adds unique steps, which made the process more rigorous than use of either guideline on its own.

Our interview sample of eight patients adhered to the ISPOR guideline recommendations of 5–8 patients. While the size of the sample needed in a translation study can always be debated, we found that eight participants provided sufficient evidence that the translation was easy to understand and required no further changes [11]. The participants in our patient group did not follow the exact proportions of the development study due to two limiting factors: (1) most patients scheduled for surgery had been already involved in PROM data collection and (2) all female-to-male gender confirming surgeries in Denmark take place at a single center in a separate town. Our patient group did however represent a broad range of patients for whom the scales were designed (e.g., pre- and post-bariatric, gynecomastia and trans men). In our experience the combination of the two guidelines facilitates the best possible translation from English into Danish [13].

Conclusions

In this study, we translated and linguistically validated the English version of the BODY-Q Chest Module PRO instrument to create a Danish version. This Danish translation can be used to measure outcomes of chest conditions in Danish men and trans men from the patient perspective. The method used throughout our study could be used in other translations and linguistic validations of PRO instruments. The approach we followed would ensure that new translations of the PRO instruments maintain the same meaning as the original version and make it possible for international comparisons of results. The BODY-Q Chest Module has since been field-tested in an international psychometric study that includes 689 men and trans men from Canada, USA, Denmark, and the Netherlands.

Disclosure of interest

No potential conflict of interest was reported by the authors.

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