

Original Article

Danish translation and linguistic validation of the Melanoma Concerns Questionnaire

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ABSTRACT

INTRODUCTION. Increased focus on monitoring health-related quality of life (HRQoL) in melanoma patients has highlighted the need for validated instruments such as patient-reported outcome measures (PROMs). Rather than developing new measures, it is generally recommended to translate and linguistically validate a suitable existing PROM.

METHODS. The Melanoma Concerns Questionnaire (MCQ-28) was adapted from English to Danish following the guidelines by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). A forward-and-backwards translation was conducted, followed by cognitive debriefing interviews based on the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN), focusing on comprehensiveness, comprehensibility and relevance.

RESULTS. The Danish MCQ-28 was tested on 21 patients, including seven in each risk group. Overall responses were positive, though several patients – especially those at a low risk or further in follow-up process – struggled with the timeframe of certain items. The interviews also revealed that some items were interpreted differently depending on individual patient perspectives.

CONCLUSIONS. By following the ISPOR guideline, a culturally relevant, linguistically validated Danish version of the MCQ-28 was developed. It is a candidate for implementation in Danish melanoma follow-up and for use in international HRQoL research on melanoma patients; however, psychometric validation in a Danish context is necessary.

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Rising awareness of health-related quality of life (HRQoL) has led to the development of numerous quality-of-life measures, also termed patient-reported outcome measures (PROMs). Some are generic, suitable regardless of diagnosis, whereas others are disease-specific PROMs. Before selecting a PROM, users should consider the objective and scope of the examination, as well as the quality of the PROM [1, 2].

In Denmark, most melanoma patients enter a national stage-specific, risk-stratified follow-up programme based on recurrence risk, including clinical examinations and PET/CT according to risk category. Clinical follow-up visits focus on a thorough examination of the skin and lymph node regions, leaving little time to address the patient's concerns.

PROMs are effective tools for incorporating the patient's perspective during follow-up visits with limited time [3, 4]. Patients complete the PROM before the consultation, allowing the clinician to ask targeted questions based on

their responses. Furthermore, PROMs are a fast, cost-effective way to collect subjective data on treatment satisfaction, sequelae, fear of recurrence and HRQoL for research or quality assessment [5]. It is advisable to use PROMs that are already in use and ideally psychometrically validated [6] because this enables cross-study comparisons and requires fewer resources than developing new PROMs.

We identified the Melanoma Concerns Questionnaire (MCQ-28) and Functional Assessment of Cancer Therapy – Melanoma (FACT-M) as the most promising PROMs in melanoma; both have undergone psychometric validation in English [7]. The MCQ-28 is a PROM developed to measure “the patient experience following diagnosis and treatment of melanoma” and was published in 2019 by Winstanley et al. ([Supplementary material](#)) [8]. It was originally developed as a supplementary module to the European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire (QLQ-C30). The original measure followed guidelines for PROM development outlined by the EORTC Quality of Life Group [9]. The MCQ-28 is developed as a standalone measure but can also be combined with the QLQ-C30 [8, 10]. To compare the usability of the MCQ-28 with that of the FACT-M, which has already been translated, the MCQ-28 also needs to be translated into Danish.

When translating PROMs, it is important to consider cultural relevance. A linguistic validation consists of a translation process and a cultural adaptation to ensure both the understandability and the conceptual equivalence between the original and the translated measure. Ideally, this occurs in close collaboration with the measure’s developers.

This study is a linguistic validation of the MCQ-28 from English to Danish. The process was based on the guidelines for translation and cultural adaptation of PROMs developed by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) [11]. The MCQ-28 is ideal for this process, as it has already been tested for content validity and psychometrically validated in a cohort of 132 patients, and because it has been found to be a valid instrument [12].

Methods

The translation of MCQ-28 from English to Danish followed the ISPOR guidelines, which describe the stepwise process involved [11]. All ten steps of the process are outlined in **Figure 1**.

FIGURE 1 The linguistic validation (translation) process of the Melanoma Concerns Questionnaire, from English to Danish following the International Society for Pharmacoeconomics and Outcomes Research guidelines [11].

1. Preparation	Permission to translate and test MCQ-28 was obtained from the developers. Clarification of ambiguities and explanation of concepts provided by one of the developers (Winstanley). Registration of the study with the Regional Research and Innovation Register under case ID: P-2023-76
2. Forward translation	Translator 1: Professional translator with experience in PROM translation Translator 2: Medical research student with melanoma experience (JRB) Translator 3: Clinical professor in plastic surgery with extensive melanoma experience (LRH) Translator 3 provided technical explanations All are native Danish speakers and fluent in English. Translators 1 and 2 performed individual translations with focus on conceptual rather than literal translation in a language understandable for a 12-year-old
3. Reconciliation	Merging of the two forward translations. Discrepancies were solved by discussion The draft and a few translational difficulties were presented to a panel consisting of four doctors, two nurses, and one professor (all working with melanoma patients). Changes were made accordingly
4. Back translation	Translator 4: Professional translator with experience in PROM translation. Native English-speaker and fluent in Danish Translator 4 had no prior knowledge of MCQ-28, no medical training, and translated the Danish draft as literally as possible into English
5. Back translation review	Translators 2, 3, and one of the developers (Winstanley) compared the back-translated version of the MCQ-28 to the original version
6. Harmonization	Discrepancies were identified as "identical" "insignificant" or "significant" and were discussed between the forward translators and the developers until all parties were satisfied with the results
7. Cognitive debriefing	21 melanoma patient interviews were performed by AVM and/or JRB using a pilot-tested interview guide
8. Review	All interviews were recorded and transcribed. Relevant replies were compiled and synthesized
9. Proofreading	The finalized draft of the questionnaire, approved by the above-mentioned panel, the developers, and a sample of melanoma patients, was proofread by a linguistic expert, resulting in a finalized Danish version of the MCQ-28
10. Final report	The final report, the focus of this paper, is a summary of all questions and obstacles that arose during the translation process

MCQ-28 = Melanoma Concerns Questionnaire; PROM = patient-reported outcome measure.

Step 7 – cognitive debriefing – consisted of 21 semi-structured interviews with patients at different melanoma stages. Patients were randomly invited and interviewed during scheduled follow-up visits at the Department for Plastic Surgery at Herlev Hospital; however, to secure representation, seven patients from each of the three risk groups were included. Debriefing was conducted as a content validity study, focusing on comprehensibility, comprehensiveness and relevance, and following COSMIN standards [13-15]. The interview guide was developed by two authors (JRB and LRH), pilot-tested on nine patients and revised before use in all interviews. Interviews were conducted by JRB and AVM, and covered item- and questionnaire-level comprehensibility and relevance, as well as clarity of instructions, recall period, response options and overall length. All interviews were recorded, transcribed and qualitatively analysed by both interviewers.

Trial registration: not relevant.

Results

The results are presented according to the ISPOR guideline steps [11]:

Step 1 Preparation: Seven items were considered ambiguously phrased and needed clarification from the

developers before forward translation. They are outlined in **Table 1**.

TABLE 1 Items from the Melanoma Concerns Questionnaire, MCQ-28, which needed clarification from the developers during the linguistic validation process from English to Danish.

Item no.	Subject	Question	Response
1	Have you had swelling near your melanoma site?	Does “swelling” refer to local swelling around the scar or regional lymphoedema?	“Swelling” refers to local swelling, not lymphoedema
2-5	Questions regarding complications due to melanoma surgery	Are complications from a potential lymphadenectomy included in these items?	The patient is asked to focus on complications due to the melanoma excision alone
11	Have you felt confused by information about your diagnosis or treatment from different sources (e.g. the internet)?	Does this item refer to confusion due to conflicting information from different sources or merely confusion due to complicated information?	Conflicting information is correct
28	Have you felt confident that your healthcare team communicate with you in a professional manner?	Does “healthcare team” refer to hospital staff?	No, “healthcare team” refers to any clinical staff involved in the treatment

Step 2 Forward translation: At every point of uncertainty, the translators aimed for a conceptual rather than a literal approach, as per the ISPOR guideline [11]; however, this was not always straightforward. The term “melanoma” is not widely used in Danish. Therefore, “melanoma” was changed to “modermærkekræft” (Danish for mole cancer) to ensure understandability for all patients. This is consistent with most other patient-facing materials on melanoma in Denmark.

Step 3 Reconciliation: The translators proposed two different sets of response options and eventually settled on the version used in similar PROMs (the Q-Portfolio) [16].

Step 4 Back translation: The back translator had no notes on the process.

Steps 5 + 6 Back-translation review and harmonisation: The original MCQ-28 was thoroughly compared with the back-translated version by JRB. A total of 25 items, the introduction and all the instructions were deemed to be “identical” or having only “insignificant” discrepancies. After this initial review, comments were made by two Danish translators (LRH and JRB) to explain the remaining three items, which had discrepancies marked as “significant”. The back-translated version and the translators’ comments were sent to one of the developers for review. Some additional items had discrepancies that were deemed “insignificant” by the translator but “significant” by the developer. This was solved by further explanations. All discrepancies were eventually accepted by both the developers and the translators. See **Table 2** for all “significant” discrepancies and comments.

TABLE 2 Discrepancies between the original Melanoma Concerns Questionnaire, MCQ-28, and the back translation.

	Discrepancy		Discussion			
Item no.	original	back translation	translator's comment (the term in Danish)	developer's comment	translator's comment (the term in Danish)	Solution
	"site of the melanoma" / "melanoma site"	"spot where the melanoma was removed"	Discrepancy is insignificant	Could "spot" be "area"?	Asking a patient to indicate the "area" ("område") of their melanoma site, they will indicate the region whereas asking them to indicate the "site" (sted ") will more likely make them point directly at the scar. In the back translation, "sted" was translated to "spot"	"sted" is accepted
7, 8, 10, 13-15, 23, 24, 28	"Have you"	"Did you"	This is simply an effect of the back translation. The Danish translation uses present perfect as in the original	Accepted	-	-
17	"feel positive"	"think positively"	The Danish understanding of "to feel" was discussed and it was decided that "think" would be easier to interpret correctly for a Danish population while carrying the same meaning	Accepted	-	-
19	"melanoma doctor"	"plastic surgeon/ oncologist"	"Melanoma doctor" cannot be translated into Danish. This was the solution to accommodate the original question	Suggests "clinician in charge of treating your melanoma"	The average Danish patient is unfamiliar with the term "melanoma" ("melanom"), and there is no Danish word equivalent to a melanoma doctor. "Clinician" ("klinikker") is an equally foreign term to many Danes. The clinician in charge of the melanoma treatment will always be either an oncologist or a plastic surgeon in a Danish setting	Accepted
22	"primary care doctor"	"your own doctor"	"own doctor" ("egen læge") is a common Danish term for GP, which is how this item was interpreted	Accepted	-	-

GP = general practitioner.

Steps 7 + 8 Cognitive debriefing and review: The focus was to ensure that the content was true to the original concept and to make only minor adjustments to ensure the questionnaire's fit with the Danish population. We interviewed 21 patients (57% female, 42% over 70 years old), seven patients in each follow-up category (low, intermediate og high risk). We applied an analytical approach consisting of thematisation based on verbatim transcriptions of the audio-recorded interviews to ensure comprehensiveness. See **Table 3** for all patient demographics.

TABLE 3 Patient demographics of the 21 patients who participated in the cognitive debriefing interviews in the linguistic validation process of the Melanoma Concerns Questionnaire, MCQ-28, from Danish to English.

	Total, n (%) (N _{tot} = 21)	Follow-up groups, n		
		low risk (N _l = 7)	intermediate risk (N _i = 7)	high risk (N _h = 7)
<i>Sex</i>				
Male	9 (43)	3	2	4
Female	12 (57)	4	5	3
<i>Age</i>				
48-54 yrs	6 (29)	4	2	0
55-69 yrs	6 (29)	1	2	3
70-80 yrs	9 (42)	2	3	4
<i>Clinical stage</i>				
I	13 (62)	7	6	0
II	3 (14)	0	1	2
III	3 (14)	0	0	3
IV	2 (10)	0	0	2
<i>Point of follow-up</i>				
3 mos.	7 (33)	7	0	0
6 mos. – 1 yr	5 (24)	0	3	2
> 1 yr – 2 yrs	4 (19)	0	2	2
> 2 yrs – 3 yrs	1 (5)	0	1	0
> 3 yrs – 4 yrs	2 (10)	0	0	2
> 4 yrs – 5 yrs	2 (10)	0	1	1
<i>Disease status^a</i>				
Local disease	16 (76)	7	7	2
Spread to regional lymph nodes	2 (10)	0	0	2
Spread to other organs	2 (14)	0	0	2
<i>ASA</i>				
Preoperative:				
Class I	7 (33)	5	1	1
Class II	12 (57)	2	5	5
Class III	2 (10)	0	1	1
Current ^b :				
Class I	6 (29)	5	1	0
Class II	11 (52)	2	5	4
Class III	4 (19)	0	1	3
<i>Social</i>				
Living alone ^c	6 (29)	1	1	4
Married/living with partner	15 (71)	6	6	3
<i>Education</i>				
Primary school	1 (5)	0	0	1
Vocational training	6 (29)	1	1	4
Academic or higher degree	14 (67)	6	6	2
<i>Employment</i>				
Working	11 (52)	4	3	4
Retired	9 (42)	2	4	3
Other	1 (5)	1	0	0

ASA = American Society of Anesthesiologists Physical Status Classifications System.

a) Disease status was inconsistently marked for 1 patient and was omitted.

b) As of the day of the interview.

c) Unmarried, divorced, widowed.

Overall, patients found the MCQ-28 relevant and welcomed the idea of it being an integrated part of their melanoma follow-up.

A recurring theme was that low- and intermediate-risk melanoma patients and patients at later stages in their follow-up programme experienced next to none of the symptoms and concerns described in the questionnaire and thus encountered mild difficulties in answering the questions. This prompted some patients to mark certain items as irrelevant. If asked again, they would say that they still appreciated being asked and could imagine it being relevant to other melanoma patients. Additionally, most patients completed the first section of the PROM (items 1-5 should only be completed if a patient has had surgery for their melanoma within 12 months), even if

more than a year had passed since their melanoma surgery.

In the *SUP* (items 19-24) and *CARE* (items 25, 27, 28) scales, patients are asked to address any distress or dissatisfaction regarding encounters with the healthcare system. As these questions are posed within a four-week timeframe, many of the participants struggled to answer because most follow-ups are scheduled at three- to six-month intervals. A negative reply (“not at all”) to item 19, for example, (“How much has your melanoma doctor supported you?”) could either be interpreted as “I did not receive any support from my melanoma doctor” or, as was most often the case, within this timeframe and especially for low-risk patients with fewer sequelae, “I did not require any support from my melanoma doctor”. Equally, item 22, “How much has your primary care doctor supported you?” was deemed problematic as the primary care doctor/general practitioner in Denmark is responsible only for referring the patient to further specialist diagnostic assessment. Thereafter, follow-up is performed by a plastic surgeon or oncologist at the facility undertaking the patient’s treatment and/or follow-up.

Finally, items 25 and 27 caused confusion for some of the patients. Both items concern treatment options. Several patients reported not having had different options and were instead just informed of the treatment plan.

Step 9 Proofreading: The finalised draft of the translated questionnaire, approved by the developers and a sample of melanoma patients, was proofread by a linguistic expert.

Discussion

To our knowledge, this is the first Danish linguistic validation of the MCQ-28 following the ISPOR guidelines [7]. Contributions from both a professional translator and a medical translator, supported by clinical experts, ensured a balance between conceptual accuracy and fidelity to the original. Patients considered the MCQ-28 relevant and expressed support for its integration into routine melanoma follow-up care.

Even though unambiguity was intended, patient interviews revealed considerable variation in how items were interpreted. This variation appeared to reflect individual perspectives, i.e. the influence of comorbidities, which made it difficult for patients to distinguish melanoma-related concerns from other health conditions. A trained interviewer could potentially mitigate these issues by clarifying item meaning and ensuring that patients focus on melanoma-specific experiences. Additionally, many patients overlooked instructions such as completing items 1-5 *only* if surgery had occurred within the past 12 months, further highlighting the potential value of guidance. However, providing personal support is neither feasible nor cost-effective in large-scale clinical settings, ultimately undermining practicality, consistency and efficiency, and motivation for PROM use. Possible solutions to this issue include highlighting important information or creating hard stops in an electronic version of the PROM.

As noted in the Results section, the general practitioner plays little or no role in the primary treatment of melanoma in Denmark. This, along with the four-week recall period, makes it difficult for Danish patients to answer the items in the *SUP* and *CARE* scales consistently. Individual misinterpretations can be clarified during follow-up, and clinicians might choose to include only the relevant subscales for the patient. For research on larger cohorts or databases, researchers might consider omitting certain subscales and refraining from reporting total scores. In that case, researchers will need to be aware of potential changes to the scoring system's integrity.

Depending on each patient’s personal disease experience, their interpretation of the PROM contents can vary considerably. Similarly, personal experience and severity of symptoms might translate very differently into PROM scores. This is why most PROMs have great potential to measure changes in perceived well-being at the patient level. When conducting research, however, it is important that the PROM, in this case the MCQ-28, is thoroughly validated and that all psychometric properties are accurately characterised in an appropriate sample

group before large-scale implementation [13, 14].

One major limitation of the MCQ-28 is that it contains no items on sentinel lymph node biopsy (SLNB) or complete lymph node dissection (CLND). SLNB is currently performed in about 40% of the Danish melanoma population [17]. Fortunately, the number of patients undergoing CLND in case of positive sentinel node has decreased dramatically since 2018, when the results of two randomised clinical trials found no effect on survival [18, 19]. Sequelae after lymph node surgery can have a considerable impact on function and HRQoL [20]. The interviewers noted that patients who had undergone lymph node surgery, especially those experiencing sequelae, sometimes mistakenly assumed that this was what some of the questions about “swelling” in the first block referred to. Our study group suggested to the developers that they either add items asking about lymphoedema to the first section for patients who have undergone surgery within the past 12 months, or develop a stand-alone lymph-node surgery module.

Strengths and limitations

A strength of this study is that the linguistic validation of the MCQ-28 was conducted in strict accordance with the ISPOR guidelines for translation and cultural adaptation of PROMs. Additionally, the results were strengthened by expanding the patient cohort to 21 interviewees in total rather than the recommended ten to compensate for the heterogeneity of the group [11].

As this is a single-site study, the representativeness of our participants is limited. Additionally, the patients were only presented with the Danish MCQ-28 immediately before the interview. Had they been allowed a few days to read, consider and evaluate the questionnaire before the interview, they might have been able to provide further insight and opinions. However, we aimed to amend this by using a pre-tested interview guide.

Conclusions

Following the ISPOR guidelines, a culturally relevant, linguistically validated Danish version of the MCQ-28 was developed. The MCQ-28 is an interesting candidate for future implementation in Danish and other settings that care for melanoma patients and will potentially enable cross-clinic and international collaborations on studies of melanoma-related HRQoL. Before the measure is put to clinical use, however, it will need to undergo further psychometric validation in the Danish context.

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Supplementary material [a11250963-supplementary.pdf](#)

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