Assessing comfort in the epilepsy monitoring unit: Development of an instrument

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ABSTRACT

Background/purpose: Some patients perceive the experience of hospitalization in an epilepsy monitoring unit (EMU) to be an uncomfortable one. In order to provide comfort-enhancing measures, nurses need to assess comfort levels. For this purpose, Kolcaba developed the General Comfort Questionnaire (GCQ), which may be modified for usage in specific settings. The objective of this study was to develop an instrument to assess comfort of adult patients during hospitalization in an EMU, namely the Epilepsy Monitoring Unit Comfort Questionnaire (EMUCQ).
Methods: The GCQ was translated from American English into German following the guidelines of the International Society for Pharmacoeconomics and Outcome Research (ISPOR). Three native German speakers with good command of the English language did forward translations. An expert who grew up bilingual did a backtranslation. For use in an EMU, literature-based setting-specific items were added. In a qualitative-descriptive study, cognitive debriefing with 25 patients was conducted using cognitive interviews. Qualitative data analysis was based on the framework method. In a quantitative-descriptive study, nine clinical experts assessed content validity.
Results: For setting-specific modification, 12 items pertaining to surroundings, feeling observed, and feeling afraid of a seizure were added to the translated GCQ. Based on the initial content validity rating, 26 items remained unchanged, 12 items underwent revisions, and 14 items were omitted. Eight items were put aside for a follow-up rating in the context of cognitive debriefing. Cognitive interviewing revealed problems regarding the interpretation of items and missing items. According to the results, 27 items remained unchanged, 11 items were reworded, and six items were added. The final content validity rating showed item-content validity indices (I-CVI) between .33 and 1, and an average CVI on a scale level (S-CVI/ave) of .84.
Conclusions: Enhancing comfort is a fundamental nursing goal in demanding situations. Therefore, the contribution of nurses to the quality of individualized patient care is a substantial one. The EMUCQ is a valuable tool to support the assessment of comfort levels. The ISPOR guidelines proved to be useful to ensure high quality of the translated instrument. Using cognitive interviews enhanced the understandability of items and supported modification of the GCQ. At present, S-CVI/ave value of the EMUCQ is acceptable. Further testing is necessary.

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1. Introduction

There has been an effort to enhance the safety of patients in epilepsy monitoring units (EMUs). Structured information, standardized operation procedures for the treatment of status epilepticus and seizure clusters, alarm seizure buttons, restricted ambulation of patients, and guard rails are compulsory in more than 50% of EMUs in the E-PILEPSY network [1]. The Austrian, German, and Swiss working group on epilepsy surgery demands minimal standards of specific nursing and technician support in EMUs [2]. Research findings confirmed the necessity of personalized safety protocols, specific training of staff, and specially designed bathrooms in order to reduce injuries [3–6]. Despite all the care taken, patients perceive the experience of hospitalization in an EMU to be an uncomfortable one. Apart from worrying about their health condition, patients report distress regarding anxiety, tension, restrictions in privacy and mobility, and feelings of being less than clean [7–9]. When patients undergo stressful healthcare situations, it is important for them to feel strengthened, understood, and safe. These three aspects lead to high levels of experienced comfort [10]. According to Kolcaba, the holistic state of comfort is defined as "*the immediate experience of being strengthened by having needs for relief, ease, and transcendence met in four contexts (physical, psychospiritual, sociocultural,*

and environmental); much more than the absence of pain or other physical discomforts" [11]. Relief is experienced when a specific need is met, ease is defined as a state of contentment, and transcendence refers to the state of rising above problems or pain [12]. Since the time of Florence Nightingale, enhancing patient comfort has been a fundamental nursing goal [13]. This may be achieved by providing targeted measures to deal with comfort-impairing factors. In order to evaluate the effectiveness of comfort-enhancing measures, nurses need to assess comfort levels before and after an intervention. For this purpose, Kolcaba developed the General Comfort Questionnaire (GCQ), which may be modified for usage in specific settings by omitting or adding items [12].

1.1. The GCQ

The GCQ is a self-report scale developed by Kolcaba in 1992 [12]. It consists of 24 positively worded and 24 negatively worded items to reduce any response bias. Kolcaba derived these questions from the 12-cell grid of the taxonomic structure of comfort (Fig. 1, based on [14]). As comfort is defined by situation and moment, all items of the GCQ are worded in the present tense [10]. Originally, there was a 4-point Likert-type scale for answering the questions (decreasing from 4 = strongly agree to 1 = strongly disagree) [15]. Later, Kolcaba recommended a 6-point scale as more choices would enhance the sensitivity of the questionnaire. She also changed the order of the response options (increasing from 1 = strongly disagree to 6 = strongly agree). All scores are summed up to calculate the total comfort level. The total score ranges from 48 to 288 points, whereby a higher score indicates a higher comfort level [10]. The GCQ was tested on patients from medical-surgical, psychiatric, acute care, and oncology departments. Additionally, a community sample was included. A total number of 256 subjects participated in the study [12]. Sample size was calculated based on literature findings, which stated that five participants per item were sufficient for factor analysis. Internal consistency of the GCQ showed a Cronbach's alpha of .88 [10]. Initially, principal component analysis with varimax rotation extracted 13 factors with eigenvalues higher than 1 and accounting for 63.4% of the variance. Since the 13th factor included only one item, it was merged with a similar one. The remaining 12 factors corresponded to the 12 cells of the grid. The scree plot showed a three-factor solution, consistent with the three types of comfort — relief, ease, and transcendence [10,12]. Because of the holistic nature of comfort, all items correlate [12]. Hence, there may be difficulties in separating "relief" and "ease". Therefore, Kolcaba suggested using the four contexts of comfort for analyzing and reporting results [10]. The GCQ was developed in American English. It is also available in Italian, Spanish, and Turkish. Modified versions were translated into Portuguese, Farsi, and Visayan [15]. A translated GCQ can be found in the German edition of Kolcaba's book [16]. However, the publisher's nursing program manager reported that the translation did not follow scientific

criteria (Jürgen Georg, via e-mail, 27 April 2015). Kolcaba and other nurse researchers created setting-specific comfort questionnaires (CQs) by modifying the GCQ [15]. To the best of the authors' knowledge, there are no CQs dedicated to EMU settings. Only one EMU-specific questionnaire was developed by Andrewes, Camp, Cook, and Kilpatrick [17]. They designed the *Concerns about Epilepsy Monitoring Questionnaire* (CAEMQ) to identify anxieties and stressors faced by patients during the monitoring process, leading them to prematurely cancel their stay. The CAEMQ showed a six-factor solution that included concerns and information about surgery, personal concerns (family and pecuniary), information about treatment and monitoring, coping, denial, and support from significant others. Comfort is not covered by the CAEMQ.

1.2. Aim of the study

The aim of this study was to develop an instrument to assess patient comfort during hospitalization in an EMU. Since the GCQ is a valid and reliable instrument and has already undergone translation and modification procedures in former studies, it seemed to be a suitable basis for an EMU-specific CQ.

2. Material and methods

In order to develop and validate the Epilepsy Monitoring Unit Comfort Questionnaire (EMUCQ), a sequential mixed-methods study was conducted as part of the first author's Ph.D. thesis. In this article, the development sequence carried out from June 2016 to November 2017 has been described. The development sequence of the EMUCQ consisted of four parts: (1) creation of the item pool, (2) assessment of content validity by expert rating (described elsewhere) [18], (3) evaluation of items, and (4) second expert rating (see Fig. 2).

2.1. Ethical considerations

This study was submitted to the local ethics commission (reference number 415-EP/73/700-2016). The commission stated that ethical approval was not required as there were no concerns regarding the well-being, safety, and rights of the participants. All participating subjects were fully informed about the study, and patients signed informed consent forms.

2.2. Setting and participants

This study was carried out at the Department of Neurology, Paracelsus Medical University (PMU), Salzburg, Austria. Professional experts as well as EMU patients participated in the study. Participants were recruited with a purposive sampling strategy. Professional experts performed translation and content validity rating. Translation experts had to be either native German speakers with very good command of the English language or vice versa. Clinical experts had to be experienced in the care of EMU patients. Patients were included if they fulfilled the following criteria — 18 years of age or older, being able to read and communicate in German, no mental disability, currently hospitalized at the EMU, and willing to participate in the study.

2.3. Translation and modification

The GCQ was the starting point for creating the item pool. It was downloaded from Kolcaba's website [15], translated into German, and culturally adapted. The translation followed principles of good practice for the translation and cultural adaptation process for patient-reported outcome measures, which were developed by the International Society for Pharmacoeconomics and Outcome Research (ISPOR) task force for translation and cultural adaptation [19]. The aim of the translation was to create an instrument equivalent to the original GCQ to ensure conceptual equivalence (wherein the construct exists in both cultures,
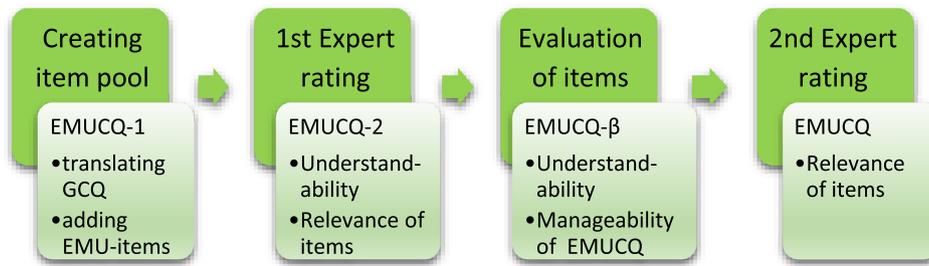
Context in which Comfort occurs	Type of Comfort		
	Relief	Ease	Trans-cendence
Physical			
Psychospiritual			
Sociocultural			
Environmental			

Fig. 1. The taxonomic structure of comfort depicted in a 12-cell grid. Figure based on [14].

Fig. 2. The four steps in developing the EMUCQ.

and the meaning of the construct is similar in the source and the target culture); content equivalence (wherein all individual items are relevant to the target population); and semantic equivalence (wherein the meaning of translated items is equivalent to the original) [19–21]. In order to ensure high quality of the translated instrument, a ten-step procedure was recommended. This procedure was adapted by including a modification step.

2.3.1. Step 1: preparation

In order to respect copyright, Kolcaba was asked for her permission to use, translate, and modify the GCQ.

2.3.2. Step 2: forward translation

Three independent forward translations were undertaken by native German-speaking professional experts with good command of the English language. As comfort is a subjective construct, conceptual (and not literal) translations were carried out. This means that the aim of the translation was not to be a verbatim copy but to render conceptual meanings of the items [19].

2.3.3. Step 3: reconciliation

Reconciliation was based on expert dialogue. Two experts synthesized the three forward translations into a single one. If in doubt, they consulted the German version of the GCQ [16]. This approach is referred to as "Kolcaba (2014)" in Table 1 and Fig. 3.

2.3.4. Step 4: backtranslation

One backtranslation was carried out by a native speaker of American English. This translator was blind about the original version of the GCQ.

2.3.5. Step 5: backtranslation review

The backtranslation was reviewed against the original version. Thus, discrepancies were uncovered between the two versions pertaining to wording and content. Problematic items were discussed between the backtranslator and the first author and refined by consensus. Kolcaba was consulted regarding unsolvable difficulties.

2.3.6. Step 6: harmonization

The backtranslated version of the GCQ was sent to Kolcaba for review and approval.

2.3.7. Step 7: cognitive debriefing

Differing from the ISPOR guidelines, setting-specific modification was undertaken in this step. Typically, general questionnaires include items that are irrelevant to a specific setting while specific items are missing. Hence, modifications were necessary to cover specific aspects that are relevant to the EMU setting. Otherwise, patients would realize the missing face validity of the questionnaire. This could result in their reduced willingness to participate in a study [20]. For this purpose, literature was reviewed and 12 setting-specific items were added, leaving the questionnaire with 60 items (EMUCQ-1). Expert rating was conducted to reduce the item pool and to assess content validity. Content

validity index (CVI) was determined on item level (I-CVI) and on average scale level (S-CVI/ave) [18]. The resultant 48-item EMUCQ-2 underwent cognitive debriefing with EMU patients. In cognitive interviews, comprehensibility and manageability of the questionnaire were assessed [22–24]. Furthermore, eight items that had been put aside after expert assessment underwent a follow-up rating by the patients. Interviews were audio-recorded and transcribed using the free software Express Scribe v 5.75 ©, NCH Software. Qualitative data analysis of cognitive interviews was based on the framework method [25,26]. Data were organized in a matrix created in Excel 2013 (Windows)©, Microsoft Corporation. The matrix was created to classify and organize the data; it consisted of eight columns that included participant details, questionnaire answers, findings from observation and thinking aloud, findings from general probes, findings from comprehension probes, findings from retrieval probes, findings from comfort probes, and other findings [25]. The matrix was formed to identify item-related problems affecting the validity of the questionnaire, issues regarding

Table 1
Items of the GCQ with dissension between translators and/or Kolcaba.

|	
Item 12: The sounds keep me from resting.	
Synthesized item	The noises keep me away from relaxing.
Kolcaba's comment and final item	The sounds keep me from sleeping.
Item 23: I have a favourite person(s) who makes me feel cared for.	
Translator 1	I have a best friend…
Translator 2	I have a special person…
Translator 3	There is at least one person…
Synthesized item	There are special people who make me feel that somebody cares for me.
Kolcaba's comment	I believe I have a special friend who cares for me.
Final item	I believe there is a special person who cares for me.
Item 32: This chair (bed) makes me hurt.	
Translator 1	… is uncomfortable.
Translators 2 and 3	… causes me pain.
Kolcaba (2014)	… is uncomfortable and causes me pain.
Synthesized item	This chair/bed causes me pain.
Kolcaba's comment	This chair/bed causes me discomfort.
Final item	This chair/bed is uncomfortable.
Item 33: This view inspires me.	
Synthesized item	The overview here is inspiring.
Kolcaba's comment and final item	I see things out of my window, which inspire me.
Item 42: This room smells terrible.	
Synthesized item	There is a discomforting smell in this room.
Kolcaba's comment and final item	There is a bad smell in this room.
Item 47: It is easy to get around here.	
Translators 1 and 3	It is easy to find your way around here.
Translator 2	It is easy to get around here.
Kolcaba (2014)	It is easy for me to get along here.
Synthesized item	It is easy to get along here.
Kolcaba's comment	It is easy to walk or ride around in my wheelchair.
Final item	It is easy to walk around here.
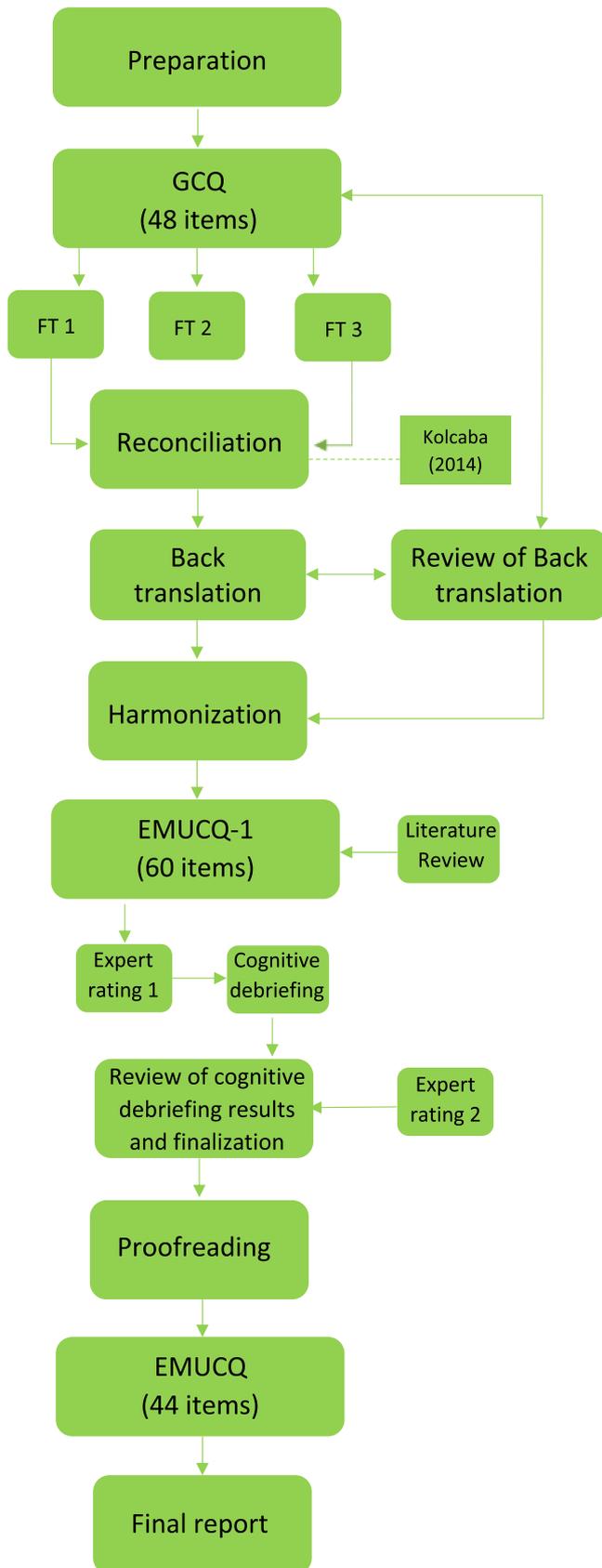
Fig. 3. The process of translation, adaptation, and modification of the GCQ for use in an EMU setting (FT = forward translation).

the reference period, and difficulties that probably led to the occurrence of missing data [27].

2.3.8. Step 8: review of cognitive debriefing results and finalization

Findings of cognitive interviewing were incorporated in the EMUCQ. This questionnaire consisted of 44 items and underwent an additional expert rating.

2.3.9. Step 9: proofreading

Before the EMUCQ could be used in the ongoing quantitative pilot test, proofreading was done as a quality-control step in order to detect spelling and grammatical errors.

2.3.10. Step 10: final report

The procedure and decisions that were made during the translation and modification process are reported in this article.

3. Results

Four experts participated in the translation procedure. Three of them conducted the forward translations and one performed the backtranslation. Please find more details regarding the experts' qualifications in the supplementary material. Nine clinical experts of the Department of Neurology at PMU acted as raters of content validity. The panel consisted of three EMU technicians, two nurses, two physicians, and two psychologists [18]. Finally, 25 patients (13 women and 12 men) aged between 19 and 74 years (mean: 35.2 years) participated in cognitive interviewing.

3.1. Translation

Kolcaba allowed the use and modification of the GCQ (Katharine Kolcaba, via e-mail, 15 May 2015). In 45 out of the 48 items in the GCQ, there were either no differences or only minor differences in the three translations, and a consensus could be found easily. In three items, the translations showed differences that had to be discussed in detail. Kolcaba commented on these three items and also on three additional items. Other than this, she rated the draft as "generally a very accurate back translation" (Katharine Kolcaba, via e-mail, 9 September 2016). For a detailed description, please refer to Table 1.

Special attention was paid to Item 37: *My friends remember me with their cards and phone calls*. Firstly, it was double-barreled [20] by including both "cards" and "phone calls". Furthermore, the GCQ was developed in the 1990s, when the Internet was not in common use. Nowadays, electronic mail and instant messaging are popular forms of communication, but these were not covered in this item. Secondly, this item mentioned "friends" who remember the patient. It was unclear if the term "friends" included solely friends or also relatives and/ or workmates. Therefore, the item was reworded to "Nice people are thinking of me and are in contact with me". In an earlier publication, this item was rated problematically by Kolcaba, too [10].

3.2. Setting-specific modification

Since the GCQ covers the general experience of comfort, literature was reviewed in order to add items that are specific to an EMU setting. Based on the findings of Andrewes et al. [17], Bristol et al. [8], and Egger-Rainer et al. [7], 12 items were created pertaining to feeling observed, feeling clean, feeling bored, feeling tense or afraid of a seizure, physical activity, and surroundings. The resultant EMUCQ-1 consisted of 60 items.

3.3. Cognitive debriefing and expert rating

The EMUCQ-1 underwent an expert rating in order to adjust the item pool. Based on results, 26 items remained unchanged, 12 items

Table 2
Examples of retained items in the EMUCQ with I-CVI <.78.

Item 14: My faith helps me to not be afraid.	
I-CVI 1st/2nd rating	.44/.56
This item was initially omitted because of results of the first content validity rating. However, in the context of cognitive interviewing, patients reported that they missed an item pertaining to God or a higher being. Since psychospiritual comfort includes these aspects, it was decided to retain this item to cover the full concept of comfort.	
Item 16: I am constipated right now.	
I-CVI 1st/2nd rating	1.0/.56
In cognitive interviewing, patients assumed that constipation would become a problem towards the end of their stay at the EMU. As the EMUCQ is dedicated to measure changes in comfort and since this item gained an I-CVI of 1.0 in the first expert rating, it was retained.	
Item 20: I am hungry.	
I-CVI 1st/2nd rating	.56/.33
Primarily male patients missed an item regarding the quality of meals or hunger, which pertains to physical comfort. As item 20 was an original item of the GCQ that was omitted after the first expert rating, it was decided to use it instead of creating a new item regarding quality of meals.	
Item 28: I see things out of my window, which inspire me.	
I-CVI 1st/2nd rating	.78/.44
Because of the way the building was constructed, patients could not look out of the window at the Salzburg EMU. However, the situation may be different in other EMUs. Furthermore, patients reported that an inspiring view was very important for their personal comfort. Therefore, the item was retained.	

underwent revisions, and 14 items were omitted. A comprehensive description of CV rating can be found elsewhere [18]. Eight items were put aside for a follow-up rating in the context of cognitive debriefing of the 38-item EMUCQ-2. For this purpose, 25 patients participated in five rounds of cognitive interviewing. This qualitative approach uncovered problems regarding understandability and manageability of the questionnaire. It took the patients between 5 min 39 s and 11 min 10 s (mean: 7 min 9 s) to complete the EMUCQ-2. According to results, 27 items remained unchanged and six items were added; another 11 items were reworded. Either these items were misunderstood or while answering, patients referred to their general living conditions and not specifically to their situation at the EMU. Negative wording also led to some difficulties. The final content validity rating of the EMUCQ showed I-CVIs between .33 and 1 and an S-CVI/ave of .84. Although Polit, Beck, and Owen [28] recommended the exclusion of items with I-CVI <.78, it was decided to retain all items. For details, see Table 2. At present, the EMUCQ consists of 44 items. The EMUCQ and Table 3, including items which were omitted, are provided as supplementary materials. Key activities of the development process are presented in Fig. 3.

4. Discussion

Because of the lack of a German instrument to measure patient comfort experienced during hospitalization in an EMU, the American GCQ was translated, culturally adapted, and modified for setting-specific use. The process of developing this instrument resulted in a 44-item EMUCQ with an S-CVI/ave level of .84; whereas Polit et al. [28] recommended an S-CVI/ave level of, at least, .90. Therefore, further testing may be advisable.

At present, there is no standardized translation procedure determined by Nursing Science. However, researchers in Nursing and Allied Health Sciences recommend following the ISPOR guidelines [29–31]. In this study, too, the ISPOR guidelines proved to be useful while translating the instrument. The modification of the guidelines in Step 7 for including setting-specific adaptation of the GCQ was helpful. Being in touch with the original author was also useful during the whole procedure, in case any difficulties came up regarding the questionnaire. This was also reported by other translation teams [29,32,33]. The procedure of conceptual forward and backtranslations supported semantic and conceptual equivalence of the items [19,21]. This way, it was possible to detect differences arising out of translations. For example, in Item 33 (*This view inspires me*), if Kolcaba had not reviewed the backtranslation, the item would cover "general things" that patients can see in the room but not the view out of the window. Assessment of content validity by clinical experts was conducted to ensure the relevance of the items regarding the concept of comfort. To reduce burden on patients, it was decided not to include them in the expert rating. However, it was the patients who reported missing items pertaining to psychospiritual comfort (Item 14: *My faith helps me to not be afraid*) and physical comfort (Item 20: *I am hungry*). These two items did not reach the suggested minimum I-CVI of .78 [28] in the expert rating and should have been omitted if only CVI results were taken into account. The low I-CVI of Item 20 (*I am hungry*) was probably because of a women-dominated expert panel. In cognitive interviewing, it was mainly the male participants who supported the inclusion of this item. Although forward and backtranslations were performed accurately, problematic items where the meaning was unclear as well as other problems pertaining to the EMUCQ could be detected in cognitive interviewing with patients. This makes it clear that conducting cognitive interviewing is important to establish face and content validity [17].

At the time of developing the GCQ, the inclusion of positive and negative questions was considered to be state-of-the-art in designing questionnaires. Nowadays, experts suggest avoiding the mix of two types of wording because factor analysis could result in spurious dimensions. Furthermore, participants could be confused and face difficulties, especially while answering negative items [20]. This phenomenon was observed during cognitive interviewing and may be alleviated by rewording the items. In spite of these difficulties, it was decided to maintain the design in order to clarify that this EMUCQ is a part of Kolcaba's CQ family. It can be seen that the initial response options of the GCQ were arranged in descending order [15]. Later versions are organized in an ascending manner [10]. No explanation could be found as to why this decision was made. However, it corresponds to actual suggestions to place the most positive response option at the end of the list [34]. Therefore, it was decided to follow this approach when designing the EMUCQ.

4.1. Limitations

No linguistic expert was included in the translation team. This may be seen as a limitation. It is possible that a linguistic expert and more than one backtranslator would have been helpful in identifying and translating conceptual differences more accurately. Expert rating was done by eight women and one man, which may be seen as being gender-biased. Furthermore, all experts were professionals. Perhaps, it would have been helpful to include patients not only in cognitive interviewing but also in the expert team in order to enhance content validity. Finally, the study was undertaken in a single EMU, and all subjects were free to be included or not at all phases of the study. Therefore, it is not known if only highly motivated persons agreed to take part in the study and whether results would have been different if other people had also participated.

5. Conclusion

As hospitalization in an EMU may be stressful, the experience of high comfort for patients is desirable. Enhancing patient comfort (as compared to previous comfort levels) is a fundamental nursing goal in demanding situations. Hence, the contribution of nurses to the quality of individualized patient care is a substantial one. With the EMUCQ, nurses find a valuable tool to assess comfort levels, identify comfort needs, and conduct comfort-enhancing interventions. The ISPOR guidelines proved to be useful in ensuring high quality of the translated instrument. Using cognitive interviews enhanced the understandability of items and supported modification of the GCQ. At present, its S-CVI/ave value is

acceptable. However, the EMUCQ needs further testing for validity and reliability before it may be used in nursing practice and research.

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