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# A novel method for the translation and cross-cultural adaptation of health-related quality of life patient-reported outcome measurements

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## Abstract

**Objectives:** This paper presents a novel methodology for translation and cross-cultural adaptation of health-related quality-of-life patient-reported outcome measures, incorporating the Delphi method. Specifically, we describe the process of translating the Pelvic Floor Distress Inventory-20 and Pelvic Floor Impact Questionnaire-7 from English to Norwegian using this method.

**Methods:** The multistep translation method combined the European Organization for Research and Treatment of Cancer Quality of Life guidelines, an Expert Panel review, and the Delphi method. It comprised two independent forward and back translations with the addition of the Delphi method (comprising three attributes: anonymity, controlled feedback, and statistical group response) to establish consensus on translated items using a bilingual pelvic floor Expert Panel. The Expert Panel was added to ensure rigorous cross-checking and effective cross-cultural adaptation.

**Outcomes:** Application of the Delphi method in the Expert Panel phase proved adequate in producing comprehensible intermediate Norwegian versions ready for pilot testing. The Expert Panel reviewed participant comments and offered advice to allow final translated versions to be produced and tested for measurement properties. This iterative approach, internal logic and anonymity between rounds improved the evaluations that the panel members provided, which in turn enhanced the final translated PROMs.

**Conclusions:** To our knowledge, this work represents the first demonstration applying this specific set of procedures: an Expert Panel review incorporating a Delphi method to cross-culturally validate and translate health-related quality-of-life instruments. The controlled feedback approach, iterative nature, internal logic and anonymity of the Delphi consensus method appeared to ensure a good cross-cultural adaptation of these PROMs.

## Introduction

Patient-reported outcome measurements (PROMs), including those that assess health-related (HR) quality of life (QoL), are commonly developed within a single specific context, logically carrying with them embedded linguistic and cultural nuances. The goal of effective translation and cross-cultural adaptation is therefore to acknowledge these features and provide a reliable and valid alternative for the target language and/or culture. In other words, ensuring equivalence between the source and the target versions of HRQoL PROMs. The result should increase the chance that the data will be accurate, for example, in identifying an important clinical

change [1].

Ensuring equivalence between the source and target versions of instruments begins with the choice of an appropriate translation methodology [1]. Although a range of translation methods have been documented, including back-translation [2], and cognitive interviewing (pilot testing) [2], no consensus has established a gold standard. Nevertheless, the preference for multistep rather than single-step methods is clear and recommended by both the International Society for Pharmacoeconomics and Outcomes Research and the European Regulatory Issues on Quality of Life Assessment Group [2].

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In most multistep translation procedures, a key component is the Expert Panel [3]. Although methodologies vary in how they incorporate experts, face-to-face group meetings with the researchers are common. These meetings are beneficial for recording opinions concerning equivalence and resolving items perceived as discrepant. However, face-to-face dialogue can be a disadvantage when a dominant personality or personalities are present or if inappropriate group pressure toward conformity becomes evident [4].

One subtle variation on the Expert Panel is the Delphi method which incorporates the concepts of anonymity, controlled feedback, and statistical group response [4]. Anonymity is potentially advantageous in avoiding the influence of dominant personalities and group pressure for conformity. Several studies have employed the Delphi method, relying on interviews in conjunction with an Expert Panel in the development of health-related instruments [5,6]. However, we are aware of no studies that have used a combined Expert Panel and Delphi method in the translation and linguistic validation of instruments.

### The study context

Condition-specific HRQoL PROMs are becoming increasingly useful tools for identifying and assessing patient symptoms and QoL [7,8]. In the Norwegian language, there are currently few measures available for assessing pelvic organ prolapse (POP) and pelvic floor dysfunction. In this group of conditions, pelvic organ prolapse usually coexists with other pelvic floor dysfunction symptoms (e.g. lower urinary tract and bowel) [7].

The options were to develop new instruments or adapt existing instruments validated in another language [3]. If feasible, the latter is preferable because it provides a basis for a cross-cultural comparison of data. The translations allow Norwegian-speaking clinicians to assess their performance [9] and treatment of patients against international benchmarks

Two common PROMs available in English are the 20-item Pelvic Floor Distress Inventory (PFDI-20) and 7-item Pelvic Floor Impact Questionnaire (PFIQ-7) [10]. Both have moderate to excellent reliability, validity, and responsiveness to change both generally and when tested against their respective longer versions [10]. Given these observations and their applicability in both clinical and research settings, the PFDI-20 and PFIQ-7 are ideal condition-specific HRQoL measures for assessing POP and pelvic floor dysfunction in Norwegian samples [10].

### Summary

The method and outcomes to be reported involved the translation, assessment of equivalence, and cross-cultural adaptation of the PFDI-20 and PFIQ-7. The multistep method combined the Delphi method [4], European Organization for Research and Treatment of Cancer (EORTC) QoL guidelines [11], and Expert Panel review [3]. We extended the latter approach by adding iterative interviews and a physical meeting, with the goal of achieving consensus, rigorous cross-checking, and effective cross-cultural adaptation.

### Method

Translation and cross-cultural adaptation of the Norwegian PFDI-20 and PFIQ-7 consisted of seven main steps: forward translations into Norwegian, synthesis of translations, back-translations, back-translation review, expert panel using the Delphi Method, and pilot test of Intermediate Version 1.0 with a sample of 20 women with symptomatic Pelvic organ prolapse

(POP). After pilot testing, the Expert Panel reviewed comments from the participants (Intermediate version 2.0), rendering the final translation Version 3.0. The testing of measurement properties, also referred to as psychometric properties, (test and re-test reliability, internal consistency, content validity, construct validity using hypotheses testing, ceiling and floor effects, responsiveness and interpretability) of Intermediate Version 3.0 were conducted in a sample of 205 women with POP [12].

### Translation and cross-cultural adaptation process

The methodology for this study was informed by EORTC QoL guidelines [11], with the following modifications: (i) a principal researcher responsible for both coordination of EORTC translations and project management; (ii) involvement of a Translational Advisory Group (health and language specialists) at all stages, replacing the role of the EORTC Translation Committee; and (iii) the addition of an Expert Panel review [3] using a modified Delphi method. Figure 1 presents a schematic representation of the expert panel Delphi rounds and meeting.

### Ethics approval

Ethics approval for both this methodology and the collection of quantitative data pertaining to the reliability and validity of data obtained from the resultant Norwegian instruments [12] was granted by [removed for blind review].

### Initial translation

Following permission from the authors of the original PFDI-20 and PFIQ-7, which also involved an inquiry about any known translation difficulties, two native speaking Norwegian translators with high English fluency conducted forward translation independently. The principal researcher compared the resulting translations, which were reconciled by resolving any items of discrepancy to achieve equivalence [11]. For further quality control, a single translated version was then agreed upon and back-translated. This step further verified the equivalence between the English and Norwegian versions. Following consensus that the back-translated instruments were equivalent, Norwegian Version 1.0 of the PFDI-20 and PFIQ-7 were considered ready for the Expert Panel review. The expert panel review is comprised of two phases: an expert panel review (using a Delphi method) of the intermediate version 1.0, followed by the expert panel review of the intermediate version 2.0.

### Expert panel

The Expert Panel comprised gynecologists, colorectal surgeons, a urologist, a physiotherapist, and a nurse [5,13]. All members had a relevant background and expertise in pelvic floor dysfunction [3,13]. They were bilingual, highly skilled in written communication [3], and working within a multidisciplinary hospital-based pelvic floor center. Based on recommendations by Dalkey and Thangaratinam [4,14], eight people were invited to join the Expert Panel.

Version 1.0 of the translated scales was sent, by mail or electronically, to each member of the Expert Panel who responded either by email and/or telephone. The role of the panel was to verify semantic, idiomatic, experiential, and conceptual equivalence between the source and Norwegian versions of the PFDI-20 and PFIQ-7 [3,12]. Members also were asked to assess comprehensibility, readability, and specific domain terminology, identify discrepancies within any items, and modify or reject items. The feedback obtained (during Rounds 1-4) allowed for production of a cross-culturally appropriate Version 2.0 for pilot testing.

There were no drop-outs in this study. Measures to reduce the dropout rate among the 8 panelists included using the expert panel's preferred form of communication (i.e. e-mail or telephone) and continually working around the panelists busy schedule.

### Delphi method

As illustrated in Figure 1, the Delphi method allowed for several rounds (rounds 1 to 3) and if required, a final meeting of the Expert Panel. The aim was to establish the extent of agreement across the panel and reach consensus if possible. After Round 3, if substantial disagreement remained on any items, a face-to-face meeting became the format of Round 4 [5]. Furthermore, as noted above, the Delphi method embodies the attributes of anonymity, controlled feedback, and statistical group response [4]. For anonymity, the panelists did not know which panelists had provided which responses. This anonymity was maintained through independent communication between panel members and the principal researcher. Controlled feedback involved the use of iterative feedback, and summaries of results from previous rounds were communicated to all Expert Panel members.

Statistical group response pertains to the use of a quantitative measure of panel members' opinions for each item [5,14-16]. In Round 2 and subsequently, the experts were asked to rank the 'appropriateness' of each item using a 5-point scale ('strongly disagree', 'disagree', 'undecided', 'agree', 'strongly agree') and provide qualitative comments. In Round 2 or 3, the panelists could assess the views of other experts, allowing determination of the extent of group agreement (consensus if possible). Data were collected using an assessment form designed to capture responses to any specific problems noted and enable experts to refine their views as the rounds progressed. Consensus for a given item was considered achieved if response of 'agree' or 'strongly agree' was achieved by more than 75% of the expert panelists. The threshold for consensus was decided a priori. This threshold was deemed to reflect a general agreement among the substantial majority [15]. Based on previous Delphi studies, items that were rated as median  $\geq 4$  and by at least 75% of the panelists were included in the Norwegian language versions of the PFDI-20 and PFIQ-7 [5].

### Pilot test

The pilot test was modelled after the EORTC QoL Group translation patient face-to-face interview guide[11] and aimed to identify problem items within the translated questionnaire (e.g. wording that caused confusion or words that were difficult to understand; to check equivalence and hesitations [3]. No hesitations in filling out the questionnaires indicated adequate linguistic validation or, as Guillemin et al asserted, face validity [3].

### Outcomes

Application of the Delphi method in the Expert Panel phase proved adequate in producing a comprehensible Norwegian Intermediate Version 2.0 with few items of discrepancy and showed semantic, conceptual, idiomatic, and experiential equivalence with the original versions, The Norwegian Intermediate Version 2.0 was then ready for pilot testing. The pilot testing undertaken during this study provided evidence that the Norwegian Intermediate Version 2.0 had a clear set of items with few discrepancies and no hesitations. After pilot testing, the Expert Panel reviewed comments from the participants, rendering the final translation Version 3.0 ready for testing of measurements properties.

The Expert Panel review phase led to identification of several discussion topics and themes. During the Expert Panel phase, the panelists received information about their answers and the anonymous answers of the other panelists, as well as a statistical collective opinion (using medians). This iterative process and information gave the panelists the opportunity to re-evaluate their previous response to see if they wanted to reassess and change their rating. Furthermore, throughout the rounds, several alternatives were reviewed, and the task of iteration resulted in the expert panel becoming more focused on problem solving.

Although the overall agreement was that the inclusion of qualitative data improved cross-cultural adaptation quality, participants also agreed that the procedure was time-consuming. However, no panelists suggested that the Delphi method should not have been used. Participants further noted the value of the opportunity for controlled feedback, which gave panel members time to assess and evaluate the group judgment. Finally, internal logic was evident because, for many items, panel agreement increased as the process evolved.

Aspects of professional asymmetry were evident during the Expert Panel review phase. During rounds 2 and 3, two panelists commented several times that their opinions were perhaps not as valuable. However, these panelists were among the most active members of the group, contributing several suggestions that were incorporated into the result. After the final meeting, one of the panelists expressed surprise that other members supported their proposal. These comments indicated that health professionals often feel a degree of professional asymmetry and different levels of hierarchy [17]. The principal researcher also observed that during the meeting, two Expert Panel members dominated the group in the decision-making process. The dynamics of health professions are challenging, and the Delphi method in the Expert Panel situation can be beneficial when dealing with a dominant panelist. Anonymity was useful in this situation to avoid domination of the communication process by particular panel members based on their profession, age, or personality [4,14]. This factor facilitated a situation in which all panelists felt that they could express their opinions freely and share their extensive field of knowledge.

Of interest, the Expert Panel almost unanimously voted for or against suggested phrasing of an item on many questions. Analysis of the PROM subscales containing these items also revealed that the panel was extremely efficient in evaluating the results of the initial translation stages for items involving clinical domain terminology. Furthermore, different panelists pointed out that a layperson would seldom use Latin words to describe anatomical structures in Norwegian and that this could result in misunderstandings and ambiguities [18]. For example, several panelists pointed out that the Norwegian layman term 'skjeden' was a better term than the Latin based 'vagina'. The importance of a multidisciplinary Expert Panel was evident throughout the rounds. Each domain specialist contributed to the various subscales in the questionnaires.

### Discussion

Efforts to ensure a good translation and cross-cultural adaptation of the PFIQ-20 and PFIQ-7 from English to Norwegian led to the development of a new study methodology, using a Delphi approach with a bilingual pelvic floor Expert Panel. The method was effective in producing a Norwegian PFDI-20 and PFIQ-7 Intermediate Version 3.0 with a clear set of items that showed semantic, conceptual, idiomatic, and experiential

equivalence with the original versions thus providing an adequate translation and cross-cultural adaptation.

Of note, incorporating controlled feedback into the Expert Panel in the form of a quantitative statistical representation provided a far more precise and accurate measure of the panel's collective opinion and degree of consensus. In addition, the modified Delphi method proved to be a highly structured, systematic communication technique with a rigorous documentation process. This systematic communication technique and documentation process can help elicit an even more rigorous procedure, which is often recommended by international translation task forces, within translation and cross-cultural adaptation.

To our knowledge, this study was the first to use novel translation methodology, including EORTC QoL guidelines, Expert Panel review, and a Delphi approach to cross-cultural validation and translation of such instruments. Significantly, the translation and cross-cultural adaptation of the PFIQ-20 and PFIQ-7 will provide improved assessment tools in this overlooked field of clinical practice in Norway. This iterative approach enabled the panel time to assess the group judgment, revise and improve ideas and by doing so, improve cross-cultural adaptation. Anonymity and statistical group response also improved the cross-cultural adaptation between rounds and ensured that input from every member of the panel was considered during the process and final response. Hence, anonymity, the iterative nature and internal logic of the Delphi method seemed to improve cross-cultural adaptation because it identified and addressed limitations within the translation and cross-cultural adaptation method, namely back-translation and back-translation review. Task Force for Translation and Cultural Adaptation (ISPOR task force TCA) [21] and other authors acknowledge the importance of a back-translation review for cross-cultural adaptation [1,11,21]. However, Swaine-Verdier et al. [22] and other authors assert that back-translation is merely another way of checking, and clearly a scientific basis for back-translation is lacking [19, 23]. This study also demonstrated the limitations of the back-translation and review phases. A situation arose in which the single forward translation seemed too literal and appeared too close to formal aspects of the original version in terms of syntax. The back-translations should have revealed this issue but instead indicated that the single forward translation was adequate.

Nevertheless, the expert panel through iterative nature and internal logic of the Delphi method identified these shortcomings of the back-translation and more importantly, demonstrated a need for a more comprehensive multistep (i.e. Delphi consensus method with an expert panel, expert panel review and pilot testing after cross-cultural adaptation) for rechecking and identifying poor specific domain terminology and semantic, idiomatic, conceptual, and experiential equivalence.

Several other translation and cross-cultural adaptation methods exist [2], however still no gold standard has been established [22]. With no gold standard, the Delphi consensus method with an expert panel, expert panel review and pilot testing can be used and applied to most translation and cross-cultural adaptation methods to help identify poor specific domain terminology and equivalence from original versions.

The Norwegian PFDI-20 and PFIQ-7 Intermediate Version 3.0 were ready for further extensive evaluation of measurement properties including reliability, validity and responsiveness at baseline and after surgical treatment. Norwegian translations of

the PFDI-20 and PFIQ-7 were demonstrated to have adequate reliability, content and construct validity, responsiveness to change and interpretability [12]. However, cross-cultural validation was not performed on the Norwegian PFDI-20 and PFIQ-7 Intermediate Version 3.0. This type of validation process determines whether the items have the same meaning after the translation [19, 20].

Finally, more studies are evidently needed in this area of research to examine whether this method is suitable, viable, and reliable for translation and cross-cultural adaptation.

### Strengths and limitations

The strengths of this study included the use of a mixed methodology in the translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 to produce a data-rich evidence base (i.e., forward- and back-translations), reinforced with qualitative and quantitative evaluations (i.e., the Delphi consensus method with an expert panel).

Study limitations included that members of the Expert Panel considered the study to be time consuming. This perception could lead to drop-out or at least loss of interest [13], with the consequence of 'agreement' without full evaluation. Second, it was difficult to assess and measure whether the Delphi method employed during the Expert Panel phase did, in fact, improve the quality of the cross-cultural adaptation. Third, the response option 'undecided' could be interpreted as being unable to answer the question. The option 'neutral' might have reduced participant misunderstanding [1]. Last, the criteria changed between rounds, which could have created bias in the analysis of data. Round 1 was designed to collect options from the panelists and encourage them to suggest alternative wordings [14,15]. Rounds 2, 3, and 4 were aimed at achieving consensus [14,15] by voting using a 5-point scale. This scale could have been used in all rounds but carried the risk of not drawing several new suggestions for alternatives [14,15].

A multistep procedure was important in improving equivalence and ensuring good cross-cultural adaptation during the translation of the PFDI-20 and PDIQ-7 [3]. This method ensured a rigorous cross-checking system during the whole process particularly prior and after back translation; back-translation review and pilot testing. Second, discrepant items may have been difficult to resolve without domain-level expertise. This difficulty was alleviated by using a multidisciplinary Expert Panel. Finally, the overall translation procedure might have been improved by giving the Expert Panel more information around the problem items identified during the early steps of the process. However, in the current study, the consequence of withholding information on problem items yielded a verification effect that helped to confirm which persistently difficult items should be included in pilot testing.

### Future research

We recommend further evaluation of the applicability and viability of the multi-step method described. Several alternatives to the Delphi method with an Expert Panel exist, including the nominal group technique and multi-voting. Future research could reasonably include comparisons with other such methods, with the aim of developing a gold standard process for translation, cross-cultural adaptation, and validation of HRQoL and similar measures. The proposed study would aid in further assessment of the iterative nature and internal logic of the Delphi consensus method, in particular, the system of anonymity, in improving cross-cultural adaptation results.

Furthermore, after translation of HRQoL measures using a Delphi method, cross-cultural validation would be recommended to ensure conceptual equivalence [19, 20]. Cross-cultural validation is an integral part of testing measurement properties and is normally performed using confirmatory factor analysis, DIF analysis or IRT techniques [19, 20].

## Conclusion

This study presents a new methodology for translation and cross-cultural adaptation on of two PROMs, the PFDI-20 and PFIQ-7, by using a Delphi method with a bilingual pelvic floor Expert Panel. To our knowledge, this study was the first to use this novel translation methodology. The thorough method resulted in a Norwegian PFDI-20 and PFIQ-7 Intermediate version .0, that wastested for measurement properties, and demonstrated adequate reliability, content and construct validity, responsiveness and interpretability.

The rigorous documentation process, controlled feedback approach (in the form of a quantitative statistical representation), iterative nature, and internal logic of the Delphi consensus method appeared to ensure a good cross-cultural adaptation of these questionnaires. Finally, anonymity improved the cross-cultural adaptation between rounds and ensured that input from every member of the panel was considered throughout the process and in the final response. However, further studies are needed to determine whether this approach is a feasible and reliable translation method more generally.

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## Precis

A novel methodology for the translation and cross-cultural adaptation of health-related patient-reported outcome measurements that incorporates the Delphi method is described and illustrated by example.

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