The Pressure Ulcer Quality of Life (PU-QOL) Questionnaire

Language translation & cross-cultural adaptation guideline

Recommendations for language translation and cross-cultural adaptation of the PU-QOL questionnaire

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1. Introduction

This is a guideline document to help you through the process of translating and adapting the PU-QOL questionnaire from UK English into other languages and cultures. These translation guidelines are based on International gold standard recommendations including the translation approach of the MAPI institute [1] and methods recommended by the World Health Organisation (WHO) Process of Translation and Adaptation of Instruments guidelines [2].

The PU-QOL questionnaire was developed and evaluated in a national multi-centre study in the United Kingdom (UK) [3]. As such, the validity and reliability of the PU-QOL questionnaire are characteristics of the questionnaire for a specific population (i.e. UK nationals) and should therefore be re-evaluated for a new population. Given the cultural diversity not only in the UK but worldwide, there is a need to be able to judge the effectiveness of pressure ulcer interventions in cross-national and international studies such as multi-country and multi-centre clinical trials. For the PU-QOL to be an effective and useful method for use in international studies, it must be appropriate for each cultural, linguistic and ethnic group under investigation, address the same concepts in other languages, and demonstrate conceptual and item equivalence, cultural relevance, acceptability and psychometric comparability in order to make it possible to pool data and compare results across countries. This requires linguistic validation studies on language translations and cross-cultural adaptation of the PU-QOL questionnaire for use in groups and cultures not represented in the development process.

The linguistic translation and validation process is required to ensure that translated versions of the PU-QOL questionnaire contain conceptual, semantic and pragmatic equivalents to the original UK version and assure that the translated content is culturally appropriate, relevant and meaningful in the target countries. This document outlines the translation and adaptation work that should be undertaken to ensure that the PU-QOL questionnaire is suitable and appropriate for use with other populations.

2. Collaboration – role of the original developer

Producing semantically comparable versions across languages is not an easy task. It requires specific linguistic and translation expertise, knowledge of the disease area and access to the original questionnaire and relevant materials. Therefore, translation and
linguistic validation should ideally be a collaborative effort, with a local multidisciplinary project team assembled.

2.1. Project Team

Members of the project team may include a Principal Investigator (i.e. the person requiring the translated version; this could be an academic researcher, a representative from a private or public company or institution, etc), experts in the health area (e.g. tissue viability specialist), and experts with experience in instrument development and translation (e.g. health outcomes methodologist). The original developer of the PU-QOL questionnaire may be invited onto the project team or consulted regarding the concepts underlying PU-QOL items to enable an accurate reflection of these concepts in translated versions.

2.2. Copyright, conditions of use, existing translations

Before you begin translation work, you are required to ‘Register Use’ of the PUQOL questionnaire (please follow the link http://ctru.leeds.ac.uk/PUQOL), where you will also find information about copyright, conditions of use (see section 1.1 of the PU-QOL questionnaire User manual), and any existing translations (instrument repository).

The role of the original developer of the PU-QOL questionnaire in the translation process should be agreed at the outset. At a minimum, we request that:

- the original developer is contacted to notify them of the intention to undertake translation work and to agree the translation methodology (i.e. approve the research protocol);
- contacted throughout the translation process to check for correct interpretation of conceptual content; and
- provide the original developer with a copy of the linguistic validation report and final translated version to be added to a central repository (see Section 5).

Part of the agreement to use the PU-QOL questionnaire is that any translated versions of the PU-QOL questionnaire be provided to the Clinical Trials Research Unit (CTRU), University of Leeds, where they will be added to an instrument repository and be freely available to use by others. Completion of a ‘Register to use’ will be required and we will notify you of any requests to use the relevant version. Any subsequent validation studies and/or revised versions of the translated questionnaire should also be sent to the CTRU. Copyright of the original PU-QOL questionnaire will remain with the CTRU, University of Leeds and the
Leeds Teaching Hospitals NHS Trust. Copyright of the translated and validated versions will remain with the developers.

This document was developed to help you through the PU-QOL questionnaire translation and adaptation process. It is intended as a useful resource. If you require further help and assistance with any aspects of the translation process or subsequent validation studies, please contact the original developer of the PU-QOL questionnaire as advice is available. A charge may be required for continued detailed advisory, supervisory or consultancy involvement.

3. Cross-cultural adaptation (from English to other language)

The aim of translation is to achieve different language versions of the original PU-QOL questionnaire (UK English version) that are clear and expressed in common language. Specifically, the translation process should ensure conceptual equivalence in each target country/culture (i.e. answers to the same questions in all language versions should reflect the same concepts and concepts should be meaningful and relevant in each culture and language translation has occurred in); item equivalence (i.e. the semantic equivalence of each question survives translation across languages); and each language version should be culturally relevant, acceptable and understandable to the target population. The original PU-QOL English version should be used as the standard from which all other translations are made. Translations should undergo a rigorous process, based on the following iterative forward-backward procedures to ensure that cross-cultural, conceptual and linguistic/literal equivalence is maintained.

3.1. Forward Translation - from English to another language

The standard process should begin with a detailed review of the PU-QOL questionnaire. Two translators, preferably health professionals familiar with pressure ulcer and/or health-related quality of life terminology and with interview skills, should undertake translation. The translators should have knowledge of the English-speaking culture but their primary language should be that of the target culture (i.e. bilingual).

During translation, the following should be considered in this process:

- Aim for conceptual equivalence of a word or phrase rather than a word-for-word (literal) translation. Consider the definition of the original item or question and attempt to translate it in the most relevant way.
• Be clear and concise. Fewer words are better. Long sentences with many clauses should be avoided.
• Use natural and acceptable language for the broadest audience. Consider the typical respondent of the PU-QOL questionnaire and what they will understand when they hear/read the question.
• Avoid jargon, colloquialism, and idioms (e.g. technical terms that may not be easily understood).
• Consider issues of gender and age applicability; avoid any terms that might be considered offensive to the target population.

It is important to note that there may be some variation in the wording as not all English words easily translate into other languages. An example lies in the statement “I feel anxious about my wounds”. In French and German, the word “anxious” does not easily translate. The underlying concept for “anxious” is “worried” therefore French and German translations should reflect this concept rather than seek a literal translation when one is not be possible.

3.2. Review of forward translation
Two independent forward translations are prepared. The two independent translators and a member from the research team should review and compare the two translations and agree a consensus version. At this stage, any problematic items should be discussed and clarified with the original developer if required. The goal here is to identify and resolve any inadequate expressions/concepts and discrepancies between the forward translation and the original PU-QOL questionnaire. Some words or expressions may be questioned and alternatives suggested. Careful inspection of individual items/questions should evaluate face validity and ensure that all relevant outcomes (items) are included in each PU-QOL scale.

This agreed forward translation should then be translated back into English by an independent bilingual translator. This process is known as the backward translation.

3.3. Backward translation into English
Backward translation involves translating the PU-QOL questionnaire back into the original language (UK English) for the purpose of comparing/contrasting the back translation with the original questionnaire. Using the same process as outlined in section 3.1, the PU-QOL should be translated back to English by one independent translator. The translator should be a native English speaker but also proficient in the target language and live in the target
country as it is important for the translator to understand the cultural context but not have prior knowledge of the PU-QOL questionnaire.

As in the initial translation, emphasis in the back-translation should be on conceptual and cultural equivalence rather than linguistic equivalence.

3.4. Review of backward translation

The original PU-QOL questionnaire and backward translations should be reviewed for consistency. Any discrepancies should be discussed and resolved with the main developer and bilingual translators who undertook the forward translation (i.e. problematic words or phrases that do not completely capture the concept addressed by the original item). The goal here is to determine whether equivalent versions across languages and cultures have been created and confirm that satisfactory procedures were followed prior to pre-testing. If equivalent versions have not been created, further work (e.g. additional forward translations, inclusion of additional items/questions to be pre-tested) should be iterated as many times as necessary to achieve a satisfactory translated version.

3.5. Pretesting translated questionnaire

The suitability of PU-QOL questionnaire translations should be pre-tested in each respective language. Translated questionnaires should be administered to a sample (n=15) of individuals representative of the target population (e.g. patients with pressure ulcers) to identify and resolve any problems with translated questionnaires (e.g. determine whether all items and questions are comprehensive and acceptable).

Cognitive interview/debriefing methods are commonly used to understand how respondent’s process and respond to questionnaire items (i.e. the underlying cognitive processes employed in reading, comprehending and interpreting questions and formulating answers [4-8]. Cognitive interviews should be conducted by an experienced interviewer. The cognitive processes may involve respondents completing the translated PU-QOL questionnaire and then asked to feedback on their understanding of individual questions (e.g. what they thought the question was asking; what came to mind when they heard a particular phrase or term; repeat the question in their own words), associated response options, and instructions, and to verbalise how they had gone about producing their answers. These questions should be repeated for each item. If alternative words or expressions exist for an item, the respondent should be asked to select the alternative that best represents their usual
language. If cultural and local differences necessitate the inclusion of 'idiosyncratic' items (e.g. when standard treatment protocols differ or symptom perception is culturally bound), these could be added to PU-QOL scales, provided that the remainder of the scale is equivalent across languages.

Any comments made (i.e. words that were difficult to understand; words or expressions found to be unacceptable or offensive) should be critically reviewed by the project team and decisions about necessary revisions required made. Pre-testing should be iteratively repeated until respondent comments are minimised. This process will produce a final translated version that will need to be psychometrically evaluated.

3.6. Final questionnaire to be field tested

Once linguistic and conceptual equivalence of language versions of the PU-QOL questionnaire are made, subsequent measurement and psychometric properties should be examined through large field-tests [3]. This step is important as one should not simply assume that the validity of the items that are translated from one questionnaire to another remains intact; psychometric properties, such as validity and reliability, should be determined for all translated versions (see Table 1 in Gorecki et al 2013 for examples of required psychometric tests and their criteria; validation work can be undertaken simultaneously as the translated questionnaire is used).

Explicit recommendations for evaluating the measurement and psychometric properties of translated versions are outside the scope of this guideline document. However, the Scientific Advisory Committee of the Medical Outcomes Trust recommends eight key attributes that patient-reported outcome (PRO) instruments should meet [9] and the US Department of Health & Human Services Food & Drug Association (FDA) produced guidance to help ensure that PRO instruments are reliable, interpretable, and valid [10].

For the design and methodology for validation studies, please see Gorecki et al 2013 (field test 2 provides an example of a validation study [3]). Additional examples within the literature may also be useful [11-13], and you can browse our resource page http://ctru.leeds.ac.uk/PUQOL/resources.
4. Use in English speaking Cultures (e.g. Australia, Canada, USA)

The adjusted linguistic validation process (intra-lingual validation) is used for linguistic validation of questionnaires ‘translated’ into varieties of the same language, such as questionnaires originating in UK English, to be used in other English-language countries, such the USA, Australia, Canada, and so on.

The intention here is to determine the suitability of the original PU-QOL questionnaire in terms of clarity and relevance of concepts (based on item wording) and cultural and linguistic specificity of the target country, and adapt if necessary. The forward and backward translation steps (sections 3.1, 3.2 and 3.3) are replaced by a cultural adaptation process.

4.1. Review of the original questionnaire

The original PU-QOL questionnaire is reviewed. The reviewer should be a native English speaker for the target country (e.g. US English). The review process should aim to:

1. Clarify the concepts represented by each PU-QOL item, with consideration of whether the concepts are appropriately reflected in the target language. For example, are the words or phrases appropriate to the target population and phrased in common everyday language? Instructions to “tick one box” in a UK English version may be more appropriate as “mark one box” in US English and “check one box” in Canadian English.

2. Consider the cultural and linguistic context. For example, an everyday word such as ‘block’ used in US English is difficult to translate into UK English. Part of the linguistic process would be to determine the concepts underlying the vocabulary used in each questionnaire item so that the underlying concept can be translated into its cultural equivalent. A UK equivalent for the statement “I can walk a block” that is culturally more appropriate may be “I am able to walk down the street”.

Any potentially problematic items are identified, an interpretation for the item proposed, and a list of alternative words or phrases (translations) made.

4.2. Discussion with developer

Findings from the review of the original PU-QOL questionnaire should be discussed with the developer for confirmation or clarification. Any potentially problematic items identified, interpretations, and alternatives should be discussed and agreed. This process will produce a semantically comparable country-specific version ready for pre-testing.
The remaining process as outlined in sections 3.5 and 3.6 should be completed.

5. Documentation – Translation report

Reports of the translation and cultural adaptation process, and any subsequent pre-testing or psychometric evaluations (e.g. field test to determine validity and reliability of the new translated version), should be sent to the original developer:

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All methods undertaken should be traceable through the report. The report should include:

- the final version of the forward translation;
- a summary of the review process for the forward-translation (e.g. include any difficulties/disagreements encountered);
- the final version of the back-translation;
- a summary of the review process for the back-translation version (e.g. justification for any deviations from the original questionnaire; when a literal translation is not possible, rationale for choosing a particular translation as close to the original should be provided);
- the number and characteristics of the pre-test sample should be described;
- a summary of findings from pre-testing and any modifications made to the translated questionnaire;
- the final version;
- information about the qualifications of the translators; and
- any results from psychometric evaluations pertaining to the validity and reliability of translated versions.

The original developer will review the report to ensure that appropriate methods have been undertaken so that the final translated version can be added to the instrument repository.
The repository will contain both translated PU-QOL questionnaires and those that have been psychometrically evaluated.

6. Requirement for use in future research

The first step to establishing the measurement properties of PU-QOL questionnaires’ scales has been undertaken [3]. Future use of PU-QOL questionnaire scales should include further side-by-side psychometric evaluation to establish the measurement properties in new samples, perform reliability and scaling tests at an International level, and undertake further validation, including sensitivity to change over time and responsiveness.

7. References


Figure 1: Overview for PU-QOL Questionnaire Translation and Validation Process

Has the PU-QOL questionnaire been translated into the language you need and pre-tested in the country you want to use it in? (See CTRU website: http://ctru.leeds.ac.uk/PUQOL/questionnaire)

- **YES** - Use the approved translation
- **NO** - Continue

**Contact original developer**

- Agree role of original developer
- Agree research protocol

**Forward translation into required language**

- Two translations
- Review forward translations
- Agree final forward translations (consensus)

**Backward translation into English**

- One translation
- Review backward translation for consistency with original PU-QOL

**Pre-test with target population**

- Cognitive interviews with small sample (n=15)
- Amendments to the translated version may be required

**Provide the original developer with the final translated version**

Psychometric properties need to be evaluated in a large field test; this may be done simultaneously when the translated version is used

**Provide the original developer with the final validated version**

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