

# **Linguistic Validation of the Perceived Quality of Life Scale**



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## **1.0 General information**

### **1.1 QUALITY OF LIFE INSTRUMENTS AND CULTURAL ADAPTATION**

As with other instruments, a quality of life “instrument” is composed of instructions, items and corresponding response categories or response choices, scoring methods, and methods of interpretation. The linguistic validation of a quality of life instrument is the first step of a process called cultural adaptation which comprises two phases:

- a linguistic validation;
- a psychometric validation

### **1.2 LINGUISTIC VALIDATION**

The linguistic validation of a questionnaire is not necessarily a literal translation of the original questionnaire, but the production of a translation that is conceptually equivalent to the original and culturally acceptable in the country in which the translation will be used.

In order to work towards the establishment of one recognized translation of an instrument in a given language the following points should be followed:

- The translation methodology should be respected and the different phases of the process summarized in a report;
- The translated version of a questionnaire - obtained in collaboration with its developer - should be recognized as the official version in the country concerned.

As per translation agreement (see Appendix B) with the developers of the PQOL questionnaire, the linguistic validation should consist of at least 3 steps:

- Forward translation, (includes the production of a "reconciled" version)
- Backward translation,
- Confirmation by development team.

Participant testing is also desirable, but not required. Processes for participant testing are included in this manual.

The questionnaire should always be considered as a whole (e.g. the wording of the response choices may influence the translation of the items, and vice-versa).

The “list of concepts” (see Appendix A) defining the underlying concept of each item should be used as a basis throughout the linguistic validation process.

### **1.3 PSYCHOMETRIC VALIDATION**

The Scientific Advisory Committee of the Medical Outcomes Trust (*Medical Outcomes Trust Bulletin* 1995; 3(4): 1-4) uses eight criteria in reviewing the psychometric adequacy of research instruments:


- 1) Conceptual and Measurement Model,
- 2) Reliability,
- 3) Validity,
- 4) Responsiveness,
- 5) Interpretability,
- 6) Respondent and Administrative Burden,
- 7) Alternative Forms, and
- 8) Cultural and Language Adaptations (Translations).

Although it is rarely possible to evaluate all of these criteria in any single study, the goal is to address as many as possible, especially measurement model, reliability, and validity.

This manual is not meant as a resource for psychometric validation of the instrument, but be aware that this type of validation is necessary for complete cultural adaptation.

For more information on psychometric validation, please see these papers on the PQOL instruments:

- (1) Patrick DL, Danis M, Southerland LI, and Hong G (1988) Quality of life following intensive care. J Gen Int Med 3(3): 218-223.

- (2) Patrick DL, Kinne S, Engelberg RA, Pearlman RA. (2000). Functional Status and Perceived Quality of Life in Adults with and without Chronic Conditions. Journal of Clinical Epidemiology 53: 779-785
- 

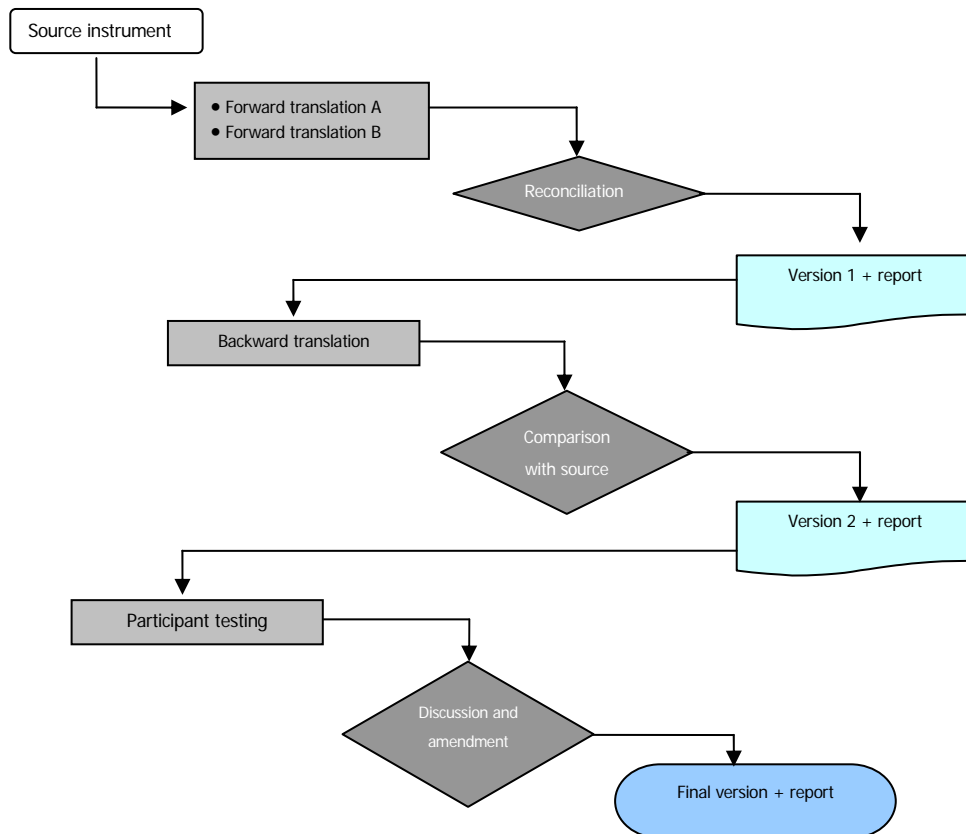
## 2.0 The Linguistic Validation Process

### 2.1 AIM OF LINGUISTIC VALIDATION

The aim of a linguistic validation of a quality of life questionnaire is the production of a version in a language other than the language of the original questionnaire which is **conceptually** equivalent to the original.

### 2.2 THE LINGUISTIC VALIDATION ALGORITHM

After the recruitment of a consultant in each country concerned, and having explained the concepts of a linguistic validation in detail, a quality of life instrument is then ideally translated according to the following algorithm:



## 2.3 Phase 1: Forward translation

### 2.3.1 DEFINITION

The original language in which the questionnaire was developed is called the **source language**. The language into which the questionnaire is translated is called the **target language**. Therefore, the forward translation can be summed up as the passage from the source language to the target language.

### 2.3.2 MEANS

It requires:

- The recruitment of two local professional translators, native **target language** speakers, bilingual in **source language**,
- The involvement of the local project manager.

### 2.3.3 METHODOLOGY

- Production of 2 forward versions: each of the translators will produce an independent forward translation of the original items and instructions and response choices.
- Production of a pooled version, Version 1: both translators and the local project manager must discuss the translations and agree on a reconciled version. The aim should be the production of a conceptually equivalent translation of the original questionnaire and the language used should be colloquial and easy to understand.
- In the case of interpretation problems of the original questionnaire the author can be contacted and according to his explanation of the particular problem the first version in the target language might be modified, leading to the production of a second intermediary forward version.
- Production of a **report** in English outlining the translation issues discussed and how the first version of the items, instructions and the response choices was produced.

### 2.3.4 RESULTS OF PHASE 1

Production of a first version of the questionnaire and a **report** (see Appendix C) on this step.

## 2.4 Phase 2: Backward translation

### 2.4.1 DEFINITION

It is the translation of the first version of the questionnaire into the source language.

### 2.4.2 MEANS

It requires the recruitment of a local professional translator, **native speaker of the source language**, bilingual in target language.

### 2.4.3 METHODOLOGY

- Production of the backward version: the translator will translate the first version of the questionnaire produced in phase 1 back into the source language. He should have no access to the original version of the questionnaire.
- Comparison of the backward version with the original source version:
  - Done by the local project manager during a meeting with the "backward" translator in order to detect any misunderstandings, mistranslations or inaccuracies in the intermediary forward version of the questionnaire.
  - Will result in changes to the first version, giving rise to the second version.
- Production of a **report in English** on the issues which were discussed item-by-item and how the final decisions were made (including English equivalents of items and Target language expressions discussed).
- Sending of the backward translation and report to the PQOL team for review.
- Review of the PQOL team's comments by the local project manager and update of the translation, if needed.

*Remark: Phase 3 should not be launched before the PQOL team's comments are received and integrated in the process.*

### 2.4.4 Results of Phase 2

Production of a second version of the questionnaire and a **report** (see Appendix D) on this step.



## **2.5 Phase 3: Participant testing**

### **2.5.1 AIM**

To test the translated questionnaire on participants to determine whether it is acceptable, whether it is understood in the way it is supposed to, and whether the language used is simple and appropriate.

### **2.5.2 METHODOLOGY**

The second version of the questionnaire (obtained after phase 2) should be tested on a panel of a minimum of 10 participants, 5 with a chronic condition and 5 without. *The participants should all be native speakers of the target language.*

- The comprehension test should be performed through face to face cognitive debriefing interviews during which the interviewer should inquire whether the patient had any difficulty in understanding the questionnaire and check the patient's interpretation of all items. In case of any problem, the interviewer may propose or test alternatives of translations (if this problem had been anticipated), or ask the person to propose alternatives.
- A report on the interviews should be produced in English: it should outline the number of subjects interviewed, their age, the time it took to complete the questionnaire, the difficulties encountered, the solutions suggested and retained and how the third version of the questionnaire was produced.

### **2.5.3 RESULTS OF PHASE 3**

Production of the third version of the questionnaire which should be proof-read to be considered as final, and of a report on this step.

### 3.0 Practical details

A linguistic validation process is much more time-consuming than a single straightforward translation. Sufficient time should be planned at each step for the production of the translations, meetings with the translators, interviews with participants, discussions and production of reports. From our experience you should allow for each step of a linguistic validation process the following timeframe as a minimum:

- Forward translation step: 2 weeks
- Backward translation step: 2 weeks
- Testing on patients: 2 weeks
- Proof-reading and finalisation: 2 weeks

**IMPORTANT:**

In accordance with the developers of the PQOL and in order to keep track of your work, you are kindly requested to:

- Complete the order form and user's agreement for the PQOL and return them to the Seattle Quality of Life Group.

***NB: This should be done before any PQOL materials will be released to you and before your translation and research work can begin.***

- Provide the Seattle Quality of Life Group with a copy of the final version of the questionnaire in your language (both paper and electronic versions) as well as a copy of each report (paper and electronic) you produced in English for each step of the linguistic validation process.
- Please note that your work will be considered for research and evaluation purposes only. Under no circumstances can you use it for commercial or international studies, or dispatch it to any third party for commercial or other use.
- Donald L. Patrick, Ph.D. at the University of Washington, holds the Copyright of the original and all translations of the PQOL.

## **APPENDIX A:**

### **PQOL List of Items**

**Each item is asked on a scale of 0 to 10, 0 being “Extremely dissatisfied” and 10 being “Extremely satisfied.”**

1. Your physical health
2. How well you care for yourself, for example, preparing meals, bathing, or shopping
3. How well you think and remember
4. The amount of walking you do
5. How often you get outside the house, for example, going into town, using public transportation or driving
6. How well you carry on a conversation, for example, speaking clearly, hearing others, or being understood
7. The kind and amount of food you eat
8. How often you see or talk to your family and friends
9. The help you get from your family or friends, for example, helping in an emergency, fixing your house, or doing errands
10. The help you give you family and friends
11. Your contribution to your community, for example, a neighborhood, religious, political or other group
12. Your retirement or current job
13. The kind and amount of recreation or leisure you have
14. Your level of sexual activity or lack of sexual activity
15. The way your income meets your needs
16. How respected your are by others
17. The meaning and purpose of your life
18. The amount of variety in your life
19. The amount and kind of sleep you get

**This item is asked on a scale of 0 to 10, 0 being “Extremely unhappy” and 10 being “Extremely happy.”**

20. How happy are you
-----------------------

**APPENDIX B:**

**TRANSLATION AGREEMENT**

<p><b>Conditions for translation of the Perceived Quality of Life Scale (PQOL)</b></p>
--

Date: \_\_\_\_\_, \_\_\_\_\_  
                    Day           Month           Year

**CONTACT INFORMATION**

Name: \_\_\_\_\_

Agency/University/Company: \_\_\_\_\_

Title: \_\_\_\_\_

Full Address: \_\_\_\_\_

Country: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**SUMMARY OF STUDY**

- **Title:**
- **Disease or disorder:**
- **Type of research**
- **Primary outcome measure or end point:**
- **Design:**
- **Number of expected respondents (total):**
- **Number of expected administrations of the questionnaires per respondent:**
- **Length of the follow-up (if any):**
- **Planned study date:**
- **Name of the funder:**
- **Other questionnaires used in the study:**

- **Number of countries/language versions involved:**

*SPECIFY:*

Norwegian ☐23

USA (Spanish) ☐29,

USA (English) ☒30,

**IMPORTANT REMARK: THE PQOL MAY BE USED IN THE ABOVE MENTIONED INVESTIGATIONS WHEN THE FOLLOWING AGREEMENT IS COMPLETED AND SIGNED BY “USER”.**

« Person, University, Company» referred hereinafter as « User » wishes to use the **PQOL** in the above mentioned versions.

The UNIVERSITY OF WASHINGTON distributes the **PQOL** and its translations available in the following languages: U.S. English, U.S. Spanish, and Norwegian.

**Therefore, User and UNIVERSITY OF WASHINGTON agree as follows:**

**1. UNIVERSITY OF WASHINGTON’s obligations**

UNIVERSITY OF WASHINGTON shall deliver the original **PQOL** and/or the translations requested by “User” subject to the following conditions:

- The translations requested are available, and
- The present agreement is duly completed and signed by “User”

**2. “User”’s obligations**

**2.1 No modification**

“User” shall not modify, abridge, condense, adapt, recast or transform the **PQOL** in any manner or form, including but not limited to any minor or significant change in wordings or organization in **PQOL**, without the prior written agreement of UNIVERSITY OF WASHINGTON, which agreement shall not be unreasonably withheld or delayed.

**2.2 No translation**

“User” shall not translate **PQOL**, without the prior written agreement of **the Authors**.

**2.3 No reproduction**

“User” shall not reproduce the **PQOL** except for the limited purpose of generating sufficient copies for use in investigations stated hereunder and shall in no event distribute copies of the **PQOL** to third parties by sale, rental, lease, lending, or any other profit-making means.

## 2.4. Publication

In case of publication of study results, “User” shall cite (1) “Patrick DL, Danis M, Southerland LI, and Hong G (1988) Quality of life following intensive care. J Gen Int Med 3(3):218-223.” And (2) Patrick DL, Kinne S, Engelberg RA, Pearlman RA. (2000). Functional Status and Perceived Quality of Life in Adults with and without Chronic Conditions. Journal of Clinical Epidemiology 53: 779-785” in reference section of the publication. (New publications may be added and older ones deleted).

## 2.5 Provision of data

All data, results and reports obtained by, or prepared in connection with the **PQOL** shall remain the User’s property. However, UNIVERSITY OF WASHINGTON may request the User to share data, results and reports obtained through the use of the **PQOL**, which request User can accept or reject in its sole and unfettered discretion.

UNIVERSITY OF WASHINGTON shall ensure the anonymisation of such data at three levels, by the removal of: any patient identification, any university or company identification and any therapy name. UNIVERSITY OF WASHINGTON will classify and reorganize such anonymous data and therefore, shall hold all intellectual property rights regarding these data when and if submitted to the data pool.

UNIVERSITY OF WASHINGTON may provide such reorganized data to third parties, for analysis in education, research, consulting, and specifically for the evaluation of cross-cultural equivalence and development of reference values for this **PQOL** or for any other similar project.

## 2.6 Payment

### *2.6.1 Royalty fees (Authors)*

The use of the **PQOL** is free of author’s royalty fees.

### *2.6.2 Distribution fees (UNIVERSITY OF WASHINGTON)*

The use of the **PQOL** in studies is subject to a distribution fee payable to UNIVERSITY OF WASHINGTON, of an amount of 50 dollars for general and administrative expenditures plus 25 dollars per language version requested. This fee includes provision of a user manual and scoring program

The use of the **PQOL** in non-funded academic research in developing countries or by students is subject to a \$25 fee for the instruments and user manual.

### *2.6.3 Invoicement*

For the use of the **PQOL**, at the time of execution of this agreement, “User” shall pay an amount of 50 dollars for general and administrative expenditures plus 25 dollars per language version and “User” shall pay such invoice within thirty (30) days of the date of this agreement.

## **3. Copyright Infringement**

The **PQOL** was developed by Donald L. Patrick, Ph.D. at The University of Washington. Donald L. Patrick holds copyright over the PQOL and all its present and future translations. Each new translation will be made available to third parties once it is available, through UNIVERSITY OF WASHINGTON, under the conditions described in the present document.

If, at any time during the term of this agreement, « User » learns of any infringement by a third party of any Intellectual Property Rights in connection with the **PQOL**, « User » shall promptly notify UNIVERSITY OF WASHINGTON. UNIVERSITY OF WASHINGTON shall notify such infringement to **Authors**. **Authors** will decide to institute or not proceedings against the infringing party.

## **4. Confidentiality**

All and any information related to the **PQOL** including but not limited to the following: information concerning clinical investigations, creations, systems, materials, software, data and know-how, translations, improvements ideas, specifications, documents, records, notebooks, drawings, and any repositories or representation of such information, whether oral or in writing or software stored, are herein referred to as confidential information. Likewise, any information provided by User to **Authors** relating to this Agreement, including information provided in this agreement, shall be treated as confidential information.

In consideration of the disclosure of any such confidential information to the other, each party agrees to hold such confidential information in confidence and not divulge it, in whole or in part, to any third party except for the purpose specified in this agreement.

## **5. Use of name**

It is agreed that UNIVERSITY OF WASHINGTON shall not disclose, whether by the public press or otherwise, the name of “**User’ or institution**”, to any third party to this agreement except to the copyright holder(s) of the **PQOL**.

## **6. Liability**

### **6.1 In case of breach of contract**

In the event of total or partial breach by UNIVERSITY OF WASHINGTON of any of its obligations hereunder, UNIVERSITY OF WASHINGTON's liability shall be limited to the direct loss or damage (excluding loss of profit and operating losses) suffered by “User” as a result of such breach and shall not include any other damages and particular consequential damages.

### **6.2 In the scope of the use of the “Questionnaire”**

Under no circumstances may **Authors** or UNIVERSITY OF WASHINGTON be held liable for direct or consequential damage resulting from the use of the **PQOL**.

### **6.3 In the event of non-renewal of this Agreement**

In the event of non-renewal of this Agreement by UNIVERSITY OF WASHINGTON for any cause or failure by UNIVERSITY OF WASHINGTON to conclude a new agreement with “User” upon the expiry of this Agreement, UNIVERSITY OF WASHINGTON will have no liability for payment of any damages and/or indemnity to “User”.

## **7. Term and termination**

This agreement shall be effective as the date of its signature by “User” and shall continue for a term of 10 (ten) years at least or until the term of the study above mentioned in SUMMARY OF THE STUDY.

Either party may terminate this Agreement immediately upon providing written notice to the other party in the event of: (a) the other party's unexcused failure to fulfill any of its material obligations under this Agreement or (b) upon the insolvency or bankruptcy of, or the filing of a petition in bankruptcy or similar arrangement by the other party. User may terminate this Agreement for any reason upon 90 days written notice.

Upon expiration or termination of this Agreement UNIVERSITY OF WASHINGTON may retain in its possession confidential information it acquired from **PQOL** while under contract. The obligations which by their terms survive termination, include, without



limitation, the applicable ownership, confidentiality and indemnification provisions of this Agreement, shall survive termination.

## **8. Assignment**

This Agreement and any of the rights and obligations of “User” are personal to the “User” and cannot be assigned or transferred by “User” to any third party or by operation of law, except with the written consent of UNIVERSITY OF WASHINGTON notified to “User”.

## **9. Separate Agreement**

This Agreement holds for the above mentioned study only. The use of the **PQOL** in any additional study of the “User” will require a separate agreement **without additional fees, unless significant updates have been added to the user manual (new edition, etc.).**

## **10. Entire Agreement, Modification, Enforceability**

The entire agreement hereto is contained herein and this Agreement cancels and supersedes all prior agreements, oral or written, between the parties hereto with the respect to the subject matter hereto.

This Agreement or any of its terms may not be changed or amended except by written document and the failure by either party hereto to enforce any or all of the provision(s) of this Agreement shall not be deemed a waiver or an amendment of the same and shall not prevent future enforcement thereof.

If any one or more of the provisions or clauses of this Agreement are adjudged by a court to be invalid or unenforceable, this shall in no way prejudice or affect the binding nature of this Agreement as a whole, or the validity or enforceability of each/and every other provision of this Agreement.

## **11. Governing law**

This Agreement shall be governed by and construed in accordance with the laws of the State of Washington. Any disputes will be adjudicated first through the UNIVERSITY OF WASHINGTON and subsequently through courts in the State of Washington.

**IN WITNESS WHEREOF, the parties hereto have caused this agreement to be executed by their duly authorized representatives as of the date first above written.**

User/University/Company:	UNIVERSITY OF WASHINGTON
<b>Name:</b>	<b>Name:</b>
<b>Title:</b>	<b>Title:</b>
<b>Signature:</b>	<b>Signature:</b>
<b>Date:</b>	<b>Date:</b>

## APPENDIX C:

### Sample of Phase 1 Report: Forward Translation of PQOL

The translator will submit a Phase 1: Forward translation report to the Seattle Quality of Life Group for review and approval. The Phase 1 report should include the title and instructions for the instrument as well as all the PQOL items that will be translated.

#### EXAMPLE ONLY

Source Language (U.S. English)	Target Language (e.g. Spanish) – Reconciled Version
<b>Title</b> Perceived Quality of Life Scale	La Calidad percibida de la Vida
21. Your physical health	
22. How well you care for yourself, for example, preparing meals, bathing, or shopping	
23. How well you think and remember	
24. The amount of walking you do	
25. How often you get outside the house, for example, going into town, using public transportation or driving	
26. How well you carry on a conversation, for example, speaking clearly, hearing others, or being understood	
27. The kind and amount of food you eat	
28. How often you see or talk to your family and friends	
29. The help you get from your family or friends, for example, helping in an emergency, fixing your house, or doing errands	
30. The help you give you family and friends	
31. Your contribution to your community, for example, a neighborhood, religious, political or other group	¿Su contribución a la comunidad? Por ejemplo: a un barrio (vecindario), grupos religiosos, políticos u otros grupos.
32. Your retirement or current job	
33. The kind and amount of recreation or leisure you have	
34. Your level of sexual activity or lack of sexual activity	
35. The way your income meets your needs	
36. How respected your are by others	
37. The meaning and purpose of your life	
38. The amount of variety in your life	
39. The amount and kind of sleep you get	
40. How happy are you	

**APPENDIX D:****Sample of Backward Translation – PQOL**

The translator will submit a backward translation document to the Seattle Quality of Life Group for review and approval. The backward translation document should include all PQOL items that will be translated.

**EXAMPLE ONLY**

<b>Source Language (U.S. English)</b>	<b>Reconciled Translated Version</b>	<b>Backward Translation</b>	<b>Comments</b>
<b>Title</b> Perceived Quality of Life Scale	La Calidad percibida de la Vida	The Quality perceived of the Life	
1. Your physical health			
2. How well you care for yourself, for example, preparing meals, bathing, or shopping			
3. How well you think and remember			
4. The amount of walking you do			
5. How often you get outside the house, for example, going into town, using public transportation or driving			
6. How well you carry on a conversation, for example, speaking clearly, hearing others, or being understood			
7. The kind and amount of food you eat			
8. How often you see or talk to your family and friends			
9. The help you get from your family or friends, for example, helping in an emergency, fixing your house, or doing errands			

10. The help you give you family and friends			
11. Your contribution to your community, for example, a neighborhood, religious, political or other group	¿Su contribución a la comunidad? Por ejemplo: a un barrio (vecindario), grupos religiosos, políticos u otros grupos.	Your contribution to the community? For example: to a neighborhood, religious, political or other groups.	Vecindario is more specific than barrio, so both terms were used to mean neighborhood.
12. Your retirement or current job			
13. The kind and amount of recreation or leisure you have			
14. Your level of sexual activity or lack of sexual activity			
15. The way your income meets your needs			
16. How respected you are by others			
17. The meaning and purpose of your life			
18. The amount of variety in your life			
19. The amount and kind of sleep you get			
20. How happy are you			