



Development of a checklist to assess the quality of translations of PRO instruments

Isabelle Méar

Managing Director,
Mapi Institute, Lyon France

Axelle Nadjar

Project Manager
Mapi Institute, Lyon France

Background

- FDA recommends that *“sponsors provide evidence that the methods and results of the translation process were adequate to ensure that the validity of the responses is not affected”*.^[1]
- ➔ **Providing evidence that appropriate methods** have been employed to develop translations has become a **crucial step** to demonstrate their conceptual **equivalence** with respect to the original and hence to contribute to their **validity**.
- ➔ Should we develop a standardized classification system based on the methods used to establish the translations of PRO measures?

[1] Food and Drug Administration. Patient-reported outcome measures: use in medical product development to support labeling claims. Federal Register 2006;71(23):5862-5863.

Background

- Review of existing classifications [2, 3]

→ Three classification systems retrieved:

Maneesriwongul and Dixon's system, St George Respiratory Questionnaire (SGRQ) classification system, Pharmaceutical company classification system

Description of questionnaire translation categories*

Category (N°)	Descriptions
1. Forward-only translation	Translation of questionnaire from source language (SL) into the target language (TL) without using back translation technique
2. Forward translation with testing	Category 1 plus a test of the TL version
3. Back translation after Forward translation	Translation from SL to TL, TL version back translated to SL and comparison of the two source language versions
4. Forward, Back translation and monolingual test	Category 3 plus test of the TL version among monolingual (TL) subjects
5. Forward, Back translation and bilingual test	Category 3 plus test of the SL and TL versions among bilingual subjects
6. Forward, Back translation and monolingual + bilingual tests	Category 3 plus test of the TL version among monolingual subjects, and test of SL and TL versions among bilingual subjects

*According to Maneesriwongul and Dixon

SGRQ Translation Classification System

Linguistic validation Method	Grades			
	Grade A	Grade B	Grade C	Grade D
Documentation of all steps	+	+	+	-
Forward Translation (FT) (Two forward translations and their reconciliation)	+	+	+	?
Back Translation (BT) (Translation of reconciled version back to source language, comparison with original)	+	+	+	?
Comprehension Test (CT) (Test of reconciled version on monolingual subjects)	+	+	-	?
International Harmonization (IH) (International Comparison of translations)	+	-	-	?
Conclusion	Official version	Acceptable Best available version	Acceptable Not optimal	Not acceptable
Recommendations	No further work	Do IH	Do CT + IH	Do BT, CT and IH

- [2] Acquadro C, Conway K, Wolf B, Hareendran A, Mear I, Anfray C, Nadjar A. Development of a Standardized Classification System for the Translation of Patient-Reported Outcome (PRO) Measures. PRO Newsletter 2008;39:5-7.
- [3] Conway K, Mear I. (2008) Rationale for the development of a classification system for the translations of PRO instruments. 2008 International Society for Quality of Life Research meeting abstracts [www.isoqol.org/2008_conference/AbstractsForBooklet_2008v3.pdf]. *Quality of Life Research supplement*, A-45, Abstract #1311

Background

→ The classification approach is flawed:

- **Does not provide formal evidence of the added value of any one of the translation steps:** for example, of the back translation over the comprehension test and of the comprehension test over the international harmonization
- **Does not explicitly address other important issues that can contribute to the quality of a translation,** i.e. the number of translators or their qualification, or the nature of the comprehension test/pilot test (patients/healthy subjects, monolingual/bilingual subjects)
- **Infers that the use of the optimal methodology leads to a translation of optimal quality without providing direct methods of translation quality assessment (TQA)**

Objective

- **To develop a checklist to assess the quality of translations of PRO instruments**
 - In the absence of a satisfactory classification system
 - And using Mapi Institute (MI)'s methodology as the basis for development

Methods

- 1) Literature search in RefPRO: “translation”, “quality”, “assessment”, “control”, “evaluation”;
- 2) Review of the process we used to translate more than 500 instruments in some 130 languages since 1995;
- 3) Interviews with MI project leaders involved in the translation of PRO instruments to define the key elements in our methodology guaranteeing quality PRO translations: n=3

Results

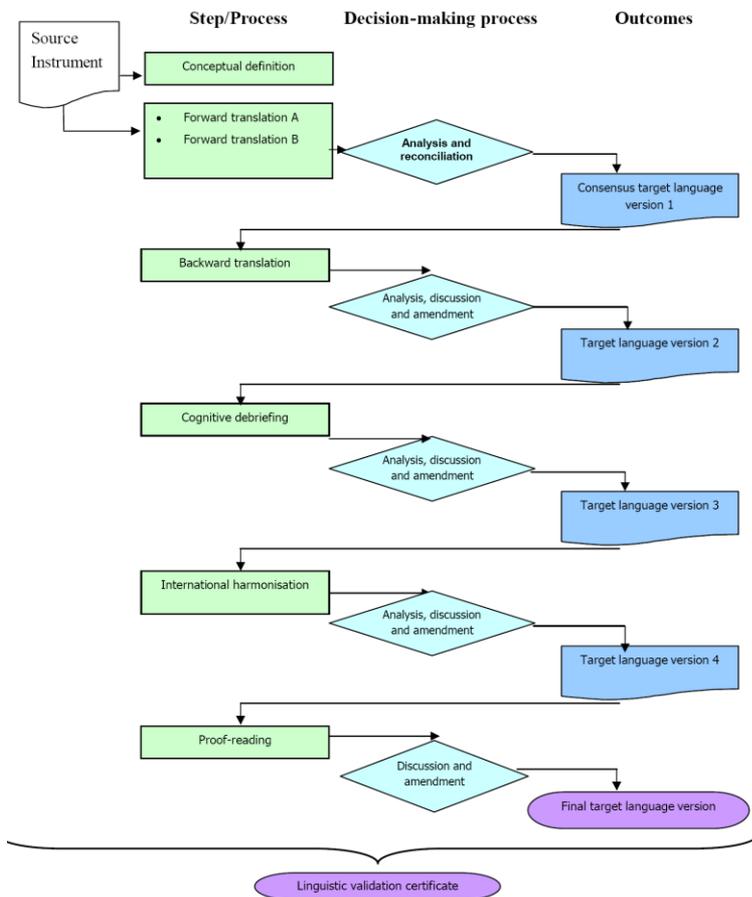
1) 10 papers retrieved in RefPRO

→ no Translation Quality Assessment (TQA) model developed specifically to address the quality of a PRO translation.

→ general TQA models require that, besides the classical quantification of errors, the method used and the team involved be also assessed by providing evidence.

Results

2 & 3) The analysis of our process and the interviews indicates that:



- 6 steps are consistently followed
- 2 key elements are considered important for quality of the “end-product”:
 - a conceptual definition of the different items as defined by the developer
 - forward translations should be conducted within the target countries

MI Checklist Development

- The MI checklist is **meant to evaluate the status of the translation of PRO instruments** by reviewing all the steps of the linguistic validation process and comparing these to the steps required by the MI linguistic validation process.
- The evaluation is based on the **availability of evidence** backing each step:
 - This relates to the team involved (people), the methodology used (process) and the translation (end product).
 - Information about the Consultant (local) and the MI Project Manager (coordination center) is gathered in a single table since each intervenes at every step of the linguistic validation process.

Results: Checklist (extract)

Mapi Institute Quality Checklist for the Evaluation of PRO Instrument Translation

1. Conceptual Definition and collaboration with the instrument's copyright holder and/or developer

This step requires that:

- the copyright holder and/or developer of the PRO instrument is aware of the translation
- the translation is authorized by one of the above, and
- concepts of the instrument are clearly defined

	Step done		Available		Comments (e.g. type of evidence, etc)
	Yes (1)	No (0)	Yes (2)	No (-2)	
Written evidence of conceptual definition and collaboration with copyright holder and/or developer					
Permission asked to translate instrument from copyright holder					
Definitions of concepts to be measured (concepts defined by developer or MI, and agreed upon by developer)					
List of translation options based on the list of concepts					

Results: Checklist (extract)

Mapi Institute Quality Checklist for the Evaluation of PRO Instrument Translation

2. Forward Translation Step

Evidence of forward translation (FT)	Available		Comments (e.g. type of evidence, etc)
	Yes (2)	No (-2)	
Team: Translators			
Translator 1			
Background information: CV			
- Mother tongue is target language and translator is fluent in source language			
- Translator lives in target country			
- Diploma/ degree or experience in translation (specify in comments)			
Evidence of briefing (i.e. general briefing on linguistic validation and PROs, briefing on the instrument and any specific requirements)			
- Proof that briefing package was sent and received			
Translator 2			
Background information: CV			
- Mother tongue is target language and translator is fluent in source language			
- Translator lives in target country			
- Diploma/ degree or experience in translation (specify in comments)			
Evidence of briefing (i.e. general briefing on linguistic validation and PROs, briefing on the instrument and any specific requirements)			
- Proof that briefing package was sent and received			
Methodology			
Evidence of forward translations performed			
- Copy of FT1			
- Copy of FT2			
Evidence of analysis, reconciliation and written report documenting:			
- Issues raised and discussed			
- Review and control by MI Project Manager			
- Final decisions leading to consensus target language version 1 (V1)			
Consensus Target Language Version 1			
Copy of consensus version 1.			
Evidence that final translation decisions have been implemented in the target language version 1.			

Inter-Rater Reliability Test

- Methods
 - 4 raters
 - Different mother tongues (FR, EN), different backgrounds, different professional activities (2 MI, 2 MRT)
 - 20 translations (projects 2008/2009)
 - Stats:
 - Cohen's Kappa coefficients (Cohen, 1960): will be computed for each item of the checklist. IRR will be assessed at 2 levels:
 - answers to the question "Availability of information"
 - answers to the question "Step Done"
 - STATIS approach
- Results: analysis on-going

Conclusion

- The MI checklist:
 - will facilitate **our** evaluation of the quality of existing translations of PRO measures
 - will provide the **basis of evidence** about how the translation process was conducted, and will help us meeting the FDA's requirement
- The MI checklist may be a starting point for:
 - the development of an internationally accepted checklist to assess the quality of translations of PRO measures in the future
 - a **certification process**

TQA References

- Al-Qinai J. Translation Quality Assessment. Strategies, Parametres and Procedures. Meta 2000, vol. 45, n° 3, p. 497-519.
- De Sutter N. Automated translation quality control. Communicator Summer 2005, 22-25.
- Honig, H G. Positions, Power and Practice: Functionalist Approaches and Translation Quality Assessment. Current Issues in Language and Society 1997, 4 (1) :6-34
- House J. Translation Quality Assessment: Linguistic Description versus Social Evaluation. Meta 2001, vol. 46, n° 2, p. 243-257.
- Kingscott G. An Approach to Translation Quality Assessment. <http://www.language-international.net/articles.asp> (26/09/07).
- Larose R. Méthodologie de l'évaluation des traductions. Meta : journal des traducteurs / Meta: Translators' Journal, vol. 43, n° 2, 1998, p. 163-186.
- Rui Rothe-Neves. Translation Quality Assessment for Research Purposes: An Empirical Approach. <http://www.cadernos.ufsc.br/online/cadernos10/rui.pdf>
- Schäffner C. From 'Good' to 'Functionally Appropriate': Assessing Translation Quality. Current Issues in Languages & Society 1997, Vol. 4, No 1.
- Schiaffinao R, Zearo F. Developping and using a translation index. Multilingual July/August 2006; 53-58. (see www.multilingual.com)
- Williams M. Translation Quality Assessment: An Argumentation-Centred Approach. Ottawa, University of Ottawa Press, 2004, 188 p.