

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

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1. BACKGROUND

- A quality PRO translation may be defined as one that is conceptually equivalent to the original and culturally relevant to the context of the target country. Mapi Institute (MI) has increasingly been involved in the assessment of the quality of existing translations of PRO instruments to be used in the context of international clinical trials to facilitate pooling and comparison of data. To date no comprehensive tool for the evaluation of such translations exists.

2. OBJECTIVE

- Previous research for classification systems for translations of PRO instruments have shown that existing classifications¹:
 - do not give formal evidence of the added value of any one step of the translation process;
 - do not address the importance of the number of translators, their qualification or where they are located; and
 - do not provide information about how the intrinsic quality of the translations of PRO measures may be evaluated to meet the quality criterion defined above.
- In the absence of an appropriate existing system to evaluate the quality of translations of PRO instruments, there is a need to develop such a tool. The objective of our study is to fill this gap and to develop this tool in form of a checklist based on the translation methodology employed by MI.

3. METHODS

- We conducted:
 - A literature search in Mapi Research Trust database with the following key words: translation, quality, assessment, control and evaluation;
 - A review of the process MI used to translate more than 500 instruments in some 145 languages since 1995; and
 - Interviews with project leaders of MI involved in the translation of PRO instruments to obtain their reactions to the process they conduct and which is described in the MI Manual on linguistic validation² to ultimately confirm the key elements guaranteeing quality translations for the context of clinical trials.

4. RESULTS

Literature Search

Ten articles were retrieved³⁻¹². The review of these confirmed that **Translation Quality Assessment (TQA)** is not a new field of inquiry and that **no generally accepted objective criteria currently exist for evaluating the quality of translations**. The search for translation quality standards and measurement tools modeled on ISO quality standards and methods of industrial quality control is worthwhile because it responds to the need for objectivity. However a translation is an intellectual product and, as such, is a complex, heterogeneous one, not a physical unit that can be replicated exactly by a machine. This is why TQA has proven to be so difficult and why TQA models have so many detractors. No TQA model has so far been developed to address the particular quality level a translation of a PRO measure has to meet.

Review of MI Linguistic Validation Process

To produce conceptually equivalent and culturally relevant language versions to facilitate pooling of data in international clinical trials, a PRO instrument is translated according to the following 7-step methodology: Conceptual Definition with the developer, Forward Translation, Backward Translation, Cognitive Debriefing, International Harmonization, Proofreading and Report. Experience has shown that a rigorous application of the methodology produces translated versions that: 1) Are faithful to the intent of the author(s) of the original questionnaire; 2) Use forms of expression acceptable and familiar to respondents; 3) Make the decision-making process transparent and retraceable.

Interviews

The MI project managers stated that **2 elements were key to the production of conceptually equivalent and culturally relevant language versions: (1) the method used to translate, and (2) the team involved in the process. Quality evaluation should be based on the availability of evidence backing each step.** For instance, evidence of the conceptual definition of the different items as defined by the developer should be retraceable as well as evidence that forward translations were conducted within the target countries to ensure cultural relevance.

- Based on these reviews and interviews, the MI checklist to assess the quality of the translations of PRO instruments was designed:

- concentrating on the methodology and the team involved in the process,
- based on the evidence available,
- based on MI internal criteria described in the LV manual².

The 3 examples in the tables (excerpts from the checklist) contain the 3 most important factors to produce conceptually equivalent and culturally relevant language versions and detail the required evidence to satisfactorily conclude that the requirement have been met: the development of a list of concepts and developer involvement, the fact that forward translators should live in the target country, and the need for documenting each step.

5. CONCLUSION

- The use of the MI checklist will facilitate the evaluation of the quality of existing PRO measures and the basis of evidence about how the translation process was conducted. This will help to decide if a translation of a PRO measure can be considered conceptually equivalent to the original and culturally relevant to the context of the target country, 2 pre-requisites to facilitate pooling and comparison of data in an international clinical trial. Results of the quality evaluation will need to be confronted with the psychometric evaluation of each translation.
- This 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.

Tables extracted from the checklist

Written evidence of collaboration with the developer This indicates that the developer of the PRO instrument is aware of the translation and that it is authorized.	Availability			Comments
	Yes	No	Step not done	
Evidence of written contact with the developer - Permission from developer to translate: e-mail <input type="checkbox"/> fax <input type="checkbox"/> mailed letter <input type="checkbox"/>				
List of definitions of concepts to be measured: concepts defined by developer or MI and agreed upon by developer				
List of translation alternatives on the basis of the concepts list (if questionnaire already translated in other languages)				

Tables extracted from the checklist

1 Evidence of establishment of forward translation (FT)	Availability			Comments
	Yes	No	Step not done	
a Team				
Translator 1				
Evidence of background information: CV - Mother tongue should be target language - Translator should live in target country - Should specify diploma or experience in translation				
Evidence of briefing (e.g. what are the objectives of a linguistic validation and the requirements of a forward translation) - Proof that briefing package was sent: e-mail <input type="checkbox"/> fax <input type="checkbox"/> - Proof that briefing package was received: e-mail <input type="checkbox"/> fax <input type="checkbox"/> - Proof that briefing package was understood: e-mail <input type="checkbox"/> fax <input type="checkbox"/>				

Tables extracted from the checklist

1 Evidence of establishment of forward translation (FT)	Availability			Comments
	Yes	No	Step not done	
b Methodology				
Translation + analysis and reconciliation process				
Evidence of forward translations performed - Copy of FT1 - Copy of FT2				
Evidence of analysis and written report specifying: - Difficulties encountered - Final decisions leading to reconciled version				
c Version 1				
Copy of reconciled version				
Evidence of proofreading				

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