Development of a standardized classification system for the translation of Patient-Reported Outcome (PRO) measures

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INTRODUCTION AND OBJECTIVES

- In its draft guidance on the use of PRO measures in the evaluation of medicinal products, the FDA recommends that *"sponsors provide evidence that the methods and results of the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.
- The development of a standardized classification system indicating the methods used to establish the translations of PRO measures could therefore be helpful for users and developers of PRO instruments as well as for the regulatory agencies.
- In this poster we share the results of a preliminary search for existing classification systems for translations of PRO measures.

METHODS OF THE LITERATURE SEARCH

Medline and Embase

Key words: "translations", "questionnaires", "linguistic validation", "translating", "classification", "cultural adaptation", "category", "rank ", "graduation", and "grading".

Database of MAPI Research Trust

Key words: "linguistic validation", "classification of translations".

Operational Guideline of one Pharmaceutical Company regarding the levels of translations being requested for different phases of clinical trials.

RESULTS

Medline and Embase searches

105 articles retrieved. Only ONE met our search criteria: Maneesriwongul and Dixon's article [2] in which:

- 47 papers about translations were reviewed.
- The classification system introduced a hierarchy of 6 categories.
- The 6 categories were based on two criteria:
  - · "method of translation" (forward with and without back translation)
  - · "method of testing" (monolingual subjects and/or bilingual subjects)
- Category 1: minimal level of effort to ensure validity of translation to Category 6: substantial level of effort (Table 1).

Table 1: 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*

MAPI Research Trust database

The search retrieved one document:

- Abstract presented at the European Respiratory Society (ERS) congress of 2006 [3].
- It outlines the classification developed by MAPI Research Institute and the developer (see Table 2):
  - · A grading system of 64 translations of the St George's Respiratory Questionnaire (SGRQ);
  - · The system used 4 categories to indicate the acceptability of the translations as evaluated against the process recommended by the MAPI Research Institute:
    - Grade A: use of the full linguistic validation process, recommended by MAPI Research Institute - official version;
    - Grade D: total lack of information about the process used and the absence of documentation - not acceptable version due to its low standard.
  - · Recommendations regarding additional work required to achieve a higher grade.

Table 2: SGRQ Translation Classification System

Linguistic Validation Method	Grade A	Grade B	Grade C	Grade D
Documentation of all steps	+	+	+	-
Forward Translation (FT)[1]	+	+	+	?
Back Translation (BT)[2]	+	+	+	?
Comprehension Test (CT)[3]	+	+	-	?
International Harmonization (IH)[4]	+	-	-	?.
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

[1] (FT) Two forward translations and their reconciliation. [2] (BT) Translation of reconciled version back to source language, comparison with original. [3] (CT) Test of reconciled version on monolingual subjects. [4] (IH) International Comparison of translations.

Operational Guideline for a Pharmaceutical Company

The system of grading of translations was developed:

- To facilitate the planning of translations for clinical trials.
- To ensure that lower grade translations developed for early trials could be used as building blocks towards higher grade translations for later trials.

This system includes four grades (Table 3): Grade A - all the steps recommended by this system, to grade D - only two documented forward translations and a consensus version. All the grades required a report of the methods and a translation certificate.

Table 3: Grading of translations for Clinical Trial Planning

	Grades			
	Grade A	Grade B	Grade C	Grade D
Consultation with developer	+	+	+	+
Report / Certificate	+	+	+	+
Forward (2) and 1 consensus version[5]	+	+	+	+
Backward[6]	+	+	+	
Reconciled version[7]	+	+	+	
Pilot test / cognitive debriefing[8]	+	+		
International harmonisation[9]	+			

[5] Two independent forward translations and reconciliation to obtain a consensus version. [6] One Translation of the forward translation version into the source language. [7] Comparison of the source questionnaire with the "back" translation to result in revised target language version. [8] Test in patients/users to assess comprehensibility and cognitive equivalence. [9] Harmonization of all new translations with each other and the source version to ensure consistency of translation decisions.

DISCUSSION

Three classification systems for translations of PRO measures were retrieved and reviewed.

The system proposed by Maneesriwongul and Dixon:

- Implies that back translation adds value to the translation process;
- Implies that testing on patients is a plus to both translation methods proposed (forward only, forward + backward);
- Does not include an International Harmonization step as none of the studies reviewed mentioned this step.

In the classification system for the SGRQ:

- Comprehension tests are ranked higher than international harmonization and lower than the back translation step;
- Grade D discards the translation on the basis of no documentation available without further discussing the intrinsic quality of the translation;
- Forward translation with a comprehension test is not considered as a possible grade: This may be explained by the fact that the classification of the translations of the SGRQ was based on the process recommended by MAPI Research Institute where such a combination does not exist.
- Two criteria were not explicitly mentioned in the SGRQ classification because in the translations reviewed, the developer was involved and the concepts clearly defined:
  - · The developer's involvement;
  - · The definition of concepts.

The classification system proposed in the operational guideline for the pharmaceutical company was specific about:

- The individualization of the reconciliation step (i.e. the modification of the consensus version in the light of the comparison between the original and the back translation)
- The categorization of Grade D (two forward with one consensus version with documentation for the classification of the pharmaceutical company versus one forward and no documentation for the classification of the SGRQ), and
- The explicit mention of the consultation with the developer.

<u>In summary, the three classifications:</u>

- **Do not provide formal evidence of the added value of any one of these steps:** for example, of the back translation over the comprehension test and of the comprehension test over the international harmonization. One way of supporting the added value of one step over another might be the investigation into the number of errors that can be avoided by each step. The research being proposed by the Translation and Cultural Adaptation Special Interest Group (TCA SIG) might be helpful in providing this evidence. (See www.isoqol.org, SIG section).
- **Do 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), which have to be taken into consideration.
- **Infer that the use of the optimal methodology leads to a translation of optimal quality without providing direct methods of translation quality assessment (TQA).** The classifications provide an assessment of the quality of the methodology used but do not give a formal assurance of the intrinsic quality of the translations.

CONCLUSION

- There is a need to develop a standardized classification system for the translations of PRO measures.
- This system could:
  - · Be based on a the review of existing classifications;
  - · Include input from the key stakeholders - developers, users and regulatory agencies as well as documentation specialists;
  - · Include a multi-step process where each step can be used as a building block to which an additional step can be added.
- This could provide an increasing level of confidence about the validity of a translation for the context in which the PRO measure and its translation will be used. For example, different levels of confidence may be expected if the PRO measure is being used as an exploratory, primary or secondary endpoint in a research programme.
- The new, standardized classification system might then be extended to all translations in the PRO field.

References

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