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Towards the development of a checklist to control the quality of the translations of patient-reported outcomes (PRO) instruments

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(on behalf of Katrin Conway, Managing Director)

Outline

- **Context**
  - Field? Who? What?
  - Translation Guidelines / Classification System

- **Checklist to assess/control the quality of the translation of PRO instruments**

Our Field

Patient-Reported Outcomes Instruments

« A patient-reported outcome (PRO) is a measurement of any aspect of a patient's health status that comes directly from the patient, without the interpretation of the patient's responses by a physician or anyone else. » (FDA)

In the Field of PROs... Who are we?

Mapi Values

- Strategic consulting
- Questionnaire development
- Psychometric validation
- Study design and analysis
- Regulatory submission

Mapi Institute

- Linguistic Validation
- Translatability assessment

Mapi Research Trust

- Information
- Dissemination
- Education

A global team of 185 dedicated staff and a network of 250 experts.

**To allow international pooling and comparison of data,
translations should be established according to a rigorous methodology**

Linguistic Validation

Definitions

Linguistic Validation

Passage of the questionnaire from the "source" language to the "target" language
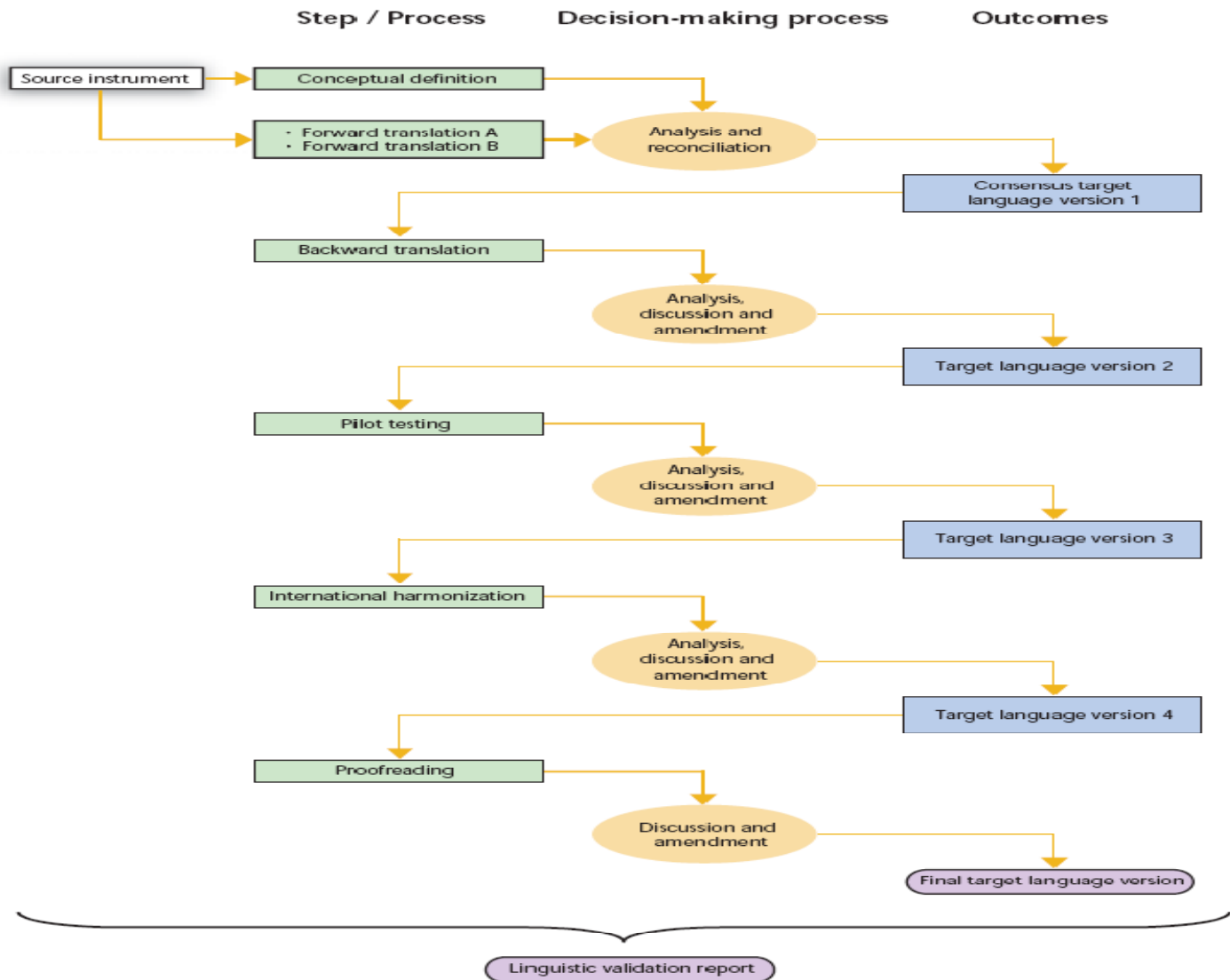
Two requirements

■ Conceptual equivalence between "source" and "target" versions

■ Use of a language accessible to everybody

Five Steps

■ Forward Translation
■ Backward Translation
■ Test
■ International Harmonisation
■ Proof-reading
↓
Certificate

Standard Process

Step / Process — Decision-making process — Outcomes

Source instrument → Conceptual definition

- Forward translation A
- Forward translation B → Analysis and reconciliation → Consensus target language version 1

Backward translation → Analysis, discussion and amendment → Target language version 2

Pilot testing → Analysis, discussion and amendment → Target language version 3

International harmonization → Analysis, discussion and amendment → Target language version 4

Proofreading → Discussion and amendment → Final target language version

Linguistic validation report

Concepts: MOS SF-36

CONCEPTS LIST

|	WORDING OF ORIGINAL	TERM	CONCEPT	TRANSLATION TIPS	POSSIBLE ALTERNATIVES
Item 1	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	moderate activities	Regular physical activities requiring some, but not a lot of effort (requiring less exertion than "vigorous activities").	As far as possible, the translations should refer to 4 activities as in the original.	activities requiring /demanding/involving moderate/average physical effort
		bowling	Example of quite common moderate activity done by women and men in the USA.	Translations must refer to a culturally appropriate activity that would adequately capture the overall energy expenditure	
		playing golf	Example of quite common moderate activity done by women and men in the USA.	Translations must refer to a culturally appropriate activity that would adequately capture the overall energy expenditure	

Methodology: Players

Author

↓

Co-ordinating Center
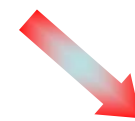
↙ ↓ ↘

Local team

Consultant

« Forward » translators

« Backward » translator

Clinician

Patients

Local team

Consultant

« Forward » translators

« Backward » translator

Clinician

Patients

Local team

Consultant

« Forward » translators

« Backward » translator

Clinician

Patients

15 participants per language version

Network of Experts

Lyon	France	World-wide
■ **100 full time** employees	■ **239** translators	■ **314** consultants (+ their team)
■ Linguists	■ **Native speakers** of 102 languages from:	■ **Native speakers living** in :
■ **Native speakers of** :	• 72 countries	• 92 countries
• French	• North America	• North America
• English	• South America	• South America
• German	• Europe	• Europe
• Spanish	• Asia	• Asia
• Italian	• Middle East	• Middle East
• Croatian	• Africa	• Africa
• South African English	• Oceania	• Oceania
■ Co-ordination	■ International harmonisation meeting	■ Forward translations
■ Quality control	■ Proof-reading	■ Backward translations
	■ Quality control	■ Cognitive debriefing interviews

OVER 500 QUESTIONNAIRES

Translation Guidelines?

Official guideline: FDA Guidance on PROs

« 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. [. . .] Sponsors should consider whether <u>generally accepted standards for translation and cultural adaptation have been used</u> to support the validity of data from a translated/adapted PRO instrument ».

US Food and Drug Administration. Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Available from: http://www.Fda.Gov/Cder/Guidance/5460dft.Pdf [Accessed May 4, 2007]. Federal Register: February 3, 2006, Vol. 71. Number 23) Docket no. 2006D-0044

Translation Guidelines?

Recommendations drafted by ISPOR Task Force, ERIQA (in collaboration with Mapi Institute)

- Use a rigorous and a multistep processed method with centralized review procedures

- Document each step

Translation Guidelines?

Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, Erikson P; **ISPOR** Task Force for Translation and Cultural Adaptation. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health. 2005 Mar-Apr;8(2):94-104.

Wild D, Eremenco S, Mear I, Martin M, Houchin C, Gawlicki M, Hareendran A, Wiklund I, Chong LY, von Maltzahn R, Cohen L, Olsen E. Multinational Trials-Recommendations on the Translations Required, Approaches to Using the Same Language in Different Countries, and the Approaches to Support Pooling the Data: The **ISPOR** Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force Report. Value Health. 2008 Nov 12. [Epub ahead of print]

Acquadro C, Conway K, Hareendran A, Aaronson N; European Regulatory Issues and Quality of Life Assessment (**ERIQA**) Group. Literature review of methods to translate health-related quality of life questionnaires for use in multinational clinical trials. Value Health. 2008 May-Jun;11(3):509-21.

Classification of Translations?

- **Context: Use of PRO instruments in Multinational Clinical Trials**

- **Objective: Give a "value" to translations**

- **Method:**
  1.review of literature to find existing classifications
  2. develop one if needed

Three Classifications retrieved:

- Maneesriwongul W, Dixon JK (2004)

- St George Respiratory Questionnaire Classification System (Mapi Institute – 2006)

- Operational guideline for a Pharmaceutical Company (2006)

Six categories based on two criteria:
- "method of translation" (forward with and without back translation);
- "method of testing" (monolingual subjects and/or bilingual subjects);

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

Maneesriwongul W, Dixon JK. Instrument translation process: a methods review. J Adv Nurs. 2004;48(2):175-86.

St George Respiratory Questionnaire Classification System

■ **Grading system of the 64 translations** of the St George's Respiratory Questionnaire (SGRQ);

■ **4 categories to indicate the acceptability of the translations** as evaluated against the process recommended by the MAPI Institute:

– Grade A: use of the full linguistic validation process, recommended by Mapi Institute ➔ Translation = official version;

– Grade D: total lack of information ➔ Not acceptable version due to its low standard;

Table 2: 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

Operational guideline of a Pharmaceutical Company

■**This system includes four grades:**

- ▫ **Grade A -** all the steps recommended by this system,
- ▫ **Grade D -** only two documented forward translations and a consensus version.

Table 3: Grading of translations for Clinical Trial Planning

	GRADE A	GRADE B	GRADE C	GRADE D
Consultation with developer	+	+	+	+
Report / Certificate	+	+	+	+
Forward (2) and 1 consensus version Two independent forward translations and reconciliation to obtain a consensus version.	+	+	+	+
Backward One Translation of the forward translation version into the source language	+	+	+	
Reconciled version Comparison of the source questionnaire with the "back" translation to result in revised target language version.	+	+	+	
Pilot test / cognitive debriefing Test in patients/users to assess comprehensibility and cognitive equivalence	+	+		
International harmonisation Harmonization of all new translations with each other and the source version to ensure consistency of translation decisions	+			

Conclusion of Review

- **No formal evidence of the added value of any one of the steps**
e.g. 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 (ISOQOL TCA SIG www.isoqol.org, SIG section).

- **Important issues that can contribute to the quality of a translation not addressed**
i.e. the number of translators or their qualification, or the nature of the comprehension test/pilot test (patients/healthy subjects, monolingual/bilingual subjects)

- **Infer that the use of the optimal methodology leads to a translation of optimal quality without providing direct methods of translation quality assessment (TQA)**

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■ **Premature (useless?) to create a grading of translations**
In the absence of a clear consensus of guidelines for translating PRO instruments

■ **Better move towards an internal Quality Control Process**

➔ **Development of a Checklist to control the quality of the translations produced by Mapi Institute**

Checklist / Quality Control

- **This checklist reviews all the steps of the translation of PRO instruments, including the preparatory work with the developer of the instrument**

- **The evaluation is based on the availability (or not) of <u>evidence</u> backing each step**

- **For each step, the evidence concerns the team involved (people), the methodology used (process) and the translation (end product)**

Example

Collaboration with the developer of the PRO Instrument

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.	Availabilty		
	Yes	No	Not done
Evidence of written contact with the developer			
- First contact to request permission to translate: e-mail ☐ fax ☐ mailed letter ☐			
- Permission from developer to translate: e-mail ☐ fax ☐ mailed letter ☐			
List of definitions of concepts to be measured: concepts defined by developer or MI and agreed upon by developer			
List of translation alternatives approved by the developer *(if questionnaire already translated in other languages)*			
Total Yes/No/Not done			

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Forward Translation Step

			Availability		
			Yes	No	Not done
1	**Evidence of establishment of forward translation (FT)**				
a	**Team**				
	Translator 1	**Evidence of background information: CV**			
		o Should specify mother tongue			
		o Should specify that translator lives in target country			
		o Should specify diploma or experience in translation			
		Evidence of briefing (what are the objectives of a linguistic validation and the requirements of a forward translation)			
		- Proof that briefing package has been sent : e-mail ☐ fax ☐			
		- Proof that briefing package has been received: e-mail ☐ fax ☐			
		- Proof that briefing package has been understood: e-mail ☐ fax ☐			

Example

Forward Translation Step (cont')

			Availability		
			Yes	No	Not done
1	Evidence of establishment of forward translation (FT)				
b	Methodology	Translation + analysis and reconciliation process			
		Evidence of forward translations performed			
		- Indication of number of FT: 2 ☐, >2 ☐			
		- Copy of the translations			
		Evidence of analysis and written report specifying:			
		- Difficulties encountered			
		- Final decisions leading to reconciled version			
c	Version 1				
		Copy of reconciled version			
Total Yes/No/Not done					